The role of independent pharmacist prescribers in primary care settings in Wales: a mixed-methods evaluation

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SUMMARY

In Wales, the role of independent prescribing pharmacists (IPPs) has developed over time, particularly since 2015, when the Welsh Government implemented its primary care plan and primary care clusters. The aim of this PhD was to explore the development of the role of IPPs within the primary care setting with a focus on the role of IPPs in general practitioner (GP) practices and community pharmacies. The study adopted a mixed-methods approach in which a quantitative stage involved analysis of prescribing data related to IPPs and other nonmedical prescribers, and the qualitative studies utilised semi-structured interviews with IPPs in GP practices and community pharmacies, and community pharmacy leads in different Health Boards (HBs) in Wales. The findings show that the number of non-medical independent prescribers and the volume of prescribing in GP practices in Wales increased over the study period, particularly since the implementation of primary care clusters. Thematic analysis of the interviews revealed that this increase, as perceived by participants, may have helped reduce the pressure on GPs, enhanced IPPs' skill sets across various therapeutic areas, and increased their job satisfaction and motivation. Moreover, the role of IPPs in community pharmacies was more related to acute conditions, whereas their involvement with chronic conditions was more evident in GP practices.

Some challenges to the role of IPPs were identified in this study, such as the lack of funding and support, the lack of access to GP records in community pharmacies, unclear indemnity insurance in GP practices, an unclear strategy and plan to develop the role, and a high workload. However, most of these challenges were resolved over time with the progression of the role, except for the high workload issue that needs more support. Some of the enablers for their roles were the Welsh Pharmaceutical Committee's (2030) vision, which included a strategy to increase the number of IPPs in community pharmacies, and support from other healthcare professionals, GP practices, and HBs in Wales. The vision and the new Pharmacy Workforce Plan published by Health Education and Improvement Wales (HEIW) may help develop the role of IPPs and allow them to use their skills more effectively. This eventually may help in improving patient care and relieving the increased pressure on primary care settings. However, these plans need to be monitored to ensure the successful development of this role and its effective integration into the future healthcare service and workforce in Wales. Future research should focus on further understanding the prescribing patterns of IPPs in both GP practices and community pharmacies in Wales, patients' satisfaction with the role of IPPs in these areas, clinical outcomes of patients managed by IPPs, and different stakeholders' and other healthcare professionals' views on the role.

GLOSSARY OF TERMS

ABMUHB	Abertawe Bro Morgannwg University Health Board	
ABHB	Aneurin Bevan Health Board	
ACT	Accuracy-Checking Technicians	
AHPs	Allied Health Professionals	
ANPs	Advanced Nurse Practitioners	
ARIMA	Auto Regressive Integrated Moving Average	
AWTTC	All Wales Therapeutics and Toxicology Centre	
AWMSG	All Wales Medicines Strategy Group	
ВСИНВ	Betsi Cadwaladr University Health Board	
BNF	British National Formulary	
CAS	Common Ailments Services	
CASPA	Comparative Analysis System for Prescribing Audit	
CCAPP	Canadian Council for Accreditation of Pharmacy Programmes	
CI(s)	Confidence Interval(s)	
CPL(s)	Community Pharmacy Lead(s)	
CMP	Clinical Management Plan	
CPD	Continuing Professional Development	
СТНВ	Cwm Taf Health Board	
CVUHB	Cardiff and Vale University Health Board	
DDDs	Defined Daily Doses	
DNs	District Nurses	
DoH	Department of Health	
EPOC	Effective Practice and Organisation of Care	
GPhC	General Pharmaceutical Council	
GPs	General Practitioners	
HbA1C	C Haemoglobin A1c levels	

HB(s)	Health Board(s)	
HCPs	Health Care Professionals	
HEIW	Health Education and Improvement Wales	
HPRAC	Health Professional Regulatory Advisory Council	
HDHB	Hywel Dda Health Board	
HVs	Health Visitors	
INP(s)	Independent Nurse Prescriber(s)	
IP(s)	Independent Prescriber(s)	
IPP(s)	Independent Pharmacist Prescriber(s)	
IPS	Independent Prescribing Service	
ITS	Interrupted Time Series	
NHS	National Health Service	
NICE National Institute for Health and Care Excellence		
NMPs Non-Medical Prescribers		
NMIPs Non-Medical Independent Prescribers		
NPEF Nurse Prescribers Extended Formulary		
NPF Nurse Prescribers Formulary		
OTC Over The Counter		
РТНВ	Powys Teaching Health Board	
RPS	Royal Pharmaceutical Society	
SBUHB	Swansea Bay University HB	
UK	United Kingdom	
UTIs	Urinary Tract Infections	
USA	United States of America	
WAPSU	Welsh Analytic Prescribing Support Unit	
WG	Welsh Government	
WGPR	Welsh GP records	

LIST OF PUPLICATIONS

Journal

- Alghamdi, S. et al. 2020. Prescribing trends over time by non-medical independent prescribers in primary care settings across Wales (2011–2018): a secondary database analysis. *BMJ Open* 10(10), p. e036379. doi: 10.1136/bmjopen-2019-036379.

Conference Paper

- Alghamdi, S. et al. 2019. A comparison of non-medical independent prescribers (NMIPs) and their prescribing in primary care across different health boards (HBs) in Wales: a secondary database analysis. Poster Abstracts. *International Journal of Pharmacy Practice*, 27: 27-60. https://doi.org/10.1111/ijpp.12533
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- Alghamdi, S. et al. 2020, Independent pharmacist prescribers' views of their role as prescribers in primary care settings in Wales. Oral Presentations. *International Journal* of *Pharmacy Practice*, 28: 4-43. https://doi.org/10.1111/ijpp.12606.
- Alghamdi, S. et al. 2021. Exploring the independent prescribing role of the community pharmacists in Wales. *International Journal of Pharmacy Practice* 29(Supplement_1), pp. i35-i35. doi: 10.1093/ijpp/riab015.042.

THESIS STRUCTURE

This thesis consists of seven chapters which are as follows:

Chapter One provides a general introduction to the topic and background information about the implementation and development of the role of non-medical prescribers, particularly independent pharmacist prescribers' (IPPs) role, in the UK throughout the PhD timeline.

Chapter Two includes the literature review that was around the role of pharmacists as prescribers in the UK and around the world, which then informed the aim and objectives of the PhD.

Chapter Three provides an overview of the research methodologies, paradigms, sampling strategy, data analysis, and the ethical considerations and necessary approval processes to conduct the studies. It also contains detailed information on the positionality and reflexivity of the researcher.

Chapter Four describes the rationale, methods, findings, and discussion of the first study in this thesis. This was a quantitative project which aimed to explore the development of the non-medical independent prescribers' (NMIPs) role in GP practices in Wales in terms of their numbers, prescribing trends, and the impact of the primary care clusters implementation on their prescribing, focusing on IPPs.

Chapter Five reports the rationale, methods, findings, and discussion of the second study in this thesis, which used a qualitative approach to explore the role of IPPs in GP practices.

Chapter Six describes the rationale, the utilised qualitative method, findings, and discussion of the third study in this thesis that aimed to investigate the role of IPPs in community pharmacies.

Chapter Seven includes a general discussion of the research, updated literature, limitations, future work, and conclusion of this thesis.

Table of Contents

ACKNO	WLE	OGEMENTS	iii
SUMM	IARY		iv
GLOSS	ARY C	F TERMS	v
LIST OF	F PUP	LICATIONS	vii
THESIS	STRU	CTURE	viii
LIST OF	F FIGU	RES	xiv
LIST OF	F TABI	.ES	xvii
1. Ch	haptei	[•] 1 - General Introduction	1 -
1.1.	=	erview of NMPs' role in the United Kingdom	
1.1	1.1.	Types of non-medical prescribing	
1.1	1.2.	Training and scope of NMPs' practice in the UK	
1.1	1.3.	Implementation of NMPs' role in Wales	
	1.4.	Primary care services in Wales	
1.1	1.5.	Initial aim of the PhD (2017)	
1.1	1.6.	Initial objectives of the PhD (2017)	
1.2.		anges to the role of NMPs since establishing the initial objectives, and durin	g the PhD
	- 1!		
	2.1.	Final aim of the PhD (2019)	
1.2	2.2.	Final objectives of the PhD (2019)	17 -
1.3.	Fui	ther development of the NMPs' role during and after the PhD hiatus	17 -
1.3	3.1.	Updated figures of IPPs' numbers and volume of prescribing in the UK	
1.3	3.2.	The developments in the community pharmacy sector in the UK	
1.3	3.3.	General new pharmacy policies in Wales	
1.3	3.4.	The development of NMIPs' Competency Framework	22 -
1.3	3.5.	Developments in the initial education and training programme (IETP) of pharmacis	
UK	<	- 23 -	
1.3	3.6.	Indemnity insurance	24 -
1.4.	Sui	mmary	25 -
2. Ch	haptei	² 2 - Literature Review	26 -
2.1.	Ov	erview	27 -
2.2.	Tyı	be of literature review	30
2.2	2.1.	USA	
2.2	2.2.	Canada	34
2.2	2.3.	New Zealand	40
2.2	2.4.	Australia	43
2.2	2.5.	UK	47
2.3.	Dis	cussion	57
2.4.	Re	search question of the PhD	60
2.5.	Air	n of the PhD	60
2.6.	Ob	jectives of the PhD	60
3. Ch	hapte	[.] 3 - Methodology	61
2.4		and the second	63

3.2.	The philosophy of research	62
3.3.	Research paradigms	62
3.3.	. •	
3.3.	· · · ·	
3.3.		
3.4.	Positionality of the researcher	
	•	
3.5. 3.5.	Mixed methods research	
	5	
3.5. 3.5.	S	
	_	
3.6.	Quantitative research methodology	
3.6.		
3.6.		
3.6.		
3.6.		
3.7.	Qualitative research methodology	
3.7.		
3.7.		
3.7.	3. Types of qualitative research methods that were considered and utilised for	or this PhD 72
3.8.	A mixed methods approach to study the role of IPPs in primary care set	tings in Wales 76
3.9.	Sampling in quantitative and qualitative research	77
3.10.	Data analysis in quantitative and qualitative research	79
3.11.	Ethical considerations	
3.11	0.11	
3.11	1.2. Informed consent	84
3.12.	Reflexivity in quantitative and qualitative research	85
3.12	2.1. The researcher's experience in this PhD	85
3.13.	Conclusion	86
4. Cho	apter 4 – Prescribing Trends Over Time by NMPs in Primary Care Set	tings in Wales
	dary Data Analysis	_
4.1.	Introduction	
4.2.	Study rationale	88
4.3.	Research question	90
4.4.	Aim and Objectives	90
4.5.	Methodology	91
4.5.	.	
4.5.		· · · · · · · · · · · · · · · · · · ·
4.5.		
4.5.		_
4.5.		
4.5.		
4.6.	Results	97
4.7.	Discussion	
4.7. 4.7.		
4.7. 4.7.		
4./.	E. LICOUIDHIS DV INIVIH 3	- ncr - ran -

4.7.	3. Prescribing by supplementary prescribers	146 -
4.7.	7.4. Prescribing by community nurse prescribers	147 -
4.7.		
4.7.	.6. Future studies	148 -
4.8.	Conclusion	149 -
4.9.	Dissemination of the first study	150 -
5. Cho	apter 5 – IPPs' Views of Their Role as Prescribers in Primary C	
151 -	upter 3 - IFFS Views of Their Role as Frescribers in Frinary C	ure settings in wates -
5.1.	Introduction	152 -
5.2.	Study Rationale	152 -
5.3.	Aim and Objectives	153 -
5.4.	Methodology	154 -
5.4.	.1. Overview	154 -
5.4.	.2. Ethical considerations	154 -
5.4.		
5.4.		
5.4.		
5.4.	.6. Data analysis	159 -
5.5.	Results	
5.5		
5.5		
5.5	5.3. Summary of the findings	180 -
5.6.	Discussion	
5.6.		
5.6.	5.2. Recommendations	188 -
5.7.	Conclusion	189 -
	apter 6 – An Exploration of The Independent Prescribing Role	•
Pharma	acists in Wales	190 -
6.1.	Introduction	191 -
6.2.	Study rationale	191 -
6.3.	Aim and Objectives	192 -
6.4.	Methodology	194 -
6.4.	.1. Overview	194 -
6.4.		_
6.4.	- P 0	
6.4.		
6.4.		
6.4.	.6. Data analysis	196 -
6.5.	Results	
6.5.	.1. Themes	199 -
6.6.	Discussion	223 -
6.6.		
6.6.	•	
6.7.	Conclusion	231 .
	anter 7 - General Discussion	_ 227 _
, Chi	anter / _ i=eneral Discussion	_ 727 .

	7.1.	Introduction 2	<u> 1</u> 33 -
	7.2.	The implementation and development of IPPs' role in primary care in Wales 2	<u> 1</u> 33 -
	7.3.	The role of IPPs within primary care settings in Wales 2	!37 -
	7.4.	Views of IPPs on their role in primary care in Wales 2	<u> 2</u> 40 -
	7.5.	Methodological considerations 2	<u> 242 -</u>
	7.6.	Future work 2	<u> 2</u> 44 -
	7.7.	Conclusion 2	<u> 246 -</u>
8.	Refe	erences 2	48 -
9.	Арр	endices 2	86 -
	Append	dix 1: Screenshots of the databases' search:2	<u> 1</u> 86 -
	Append	dix 2: Keywords used to conduct the literature search 2	<u> 1</u> 91 -
	Append	dix 3: The inclusion and exclusion criteria of literature search 2	<u> 1</u> 92 -
	Append	dix 4: The Honorary Contract (Study 1, Chapter 4)2	<u> 1</u> 93 -
	Append	dix 5: Reviewers' comments (Study 1, Chapter 4)	.298
	Append	dix 6: The ARIMA analysis of the NMIPs data (Study 1, Chapter 4)	.299
	Append	dix 7: PTHB Lead response (Study 1, Chapter 4)	.315
	Append	dix 8: CTMUHB Lead response (Study 1, Chapter 4)	.316
	Append	dix 9: CVUHB Lead response (Study 1, Chapter 4)	.317
	Append	dix 10: First study poster 1 (Study 1, Chapter 4)	.318
	Append	dix 11: First study poster 2 (Study 1, Chapter 4)	.319
	Append	dix 12: The study published in the BMJ Open (Study 1, Chapter 4)	.320
	Append	dix 13: Ethics approval of the second study (Study 2, Chapter 5)	.321
	Append	dix 14: Invitation Email (Study 2, Chapter 5)	.322
	Append	dix 15: Participant Information Sheet (Study 2, Chapter 5)	.324
	Append	dix 16: Participant consent from for interviews and focus groups (Study 2, Chapter 5)	.327
	Append	dix 17: Demographic Information Sheet (Study 2, Chapter 5)	.329
	Append	dix 18: Reminder Email (Study 2, Chapter 5)	.332
	Append	dix 19: Focus Group / Interview Schedule (Study 2, Chapter 5)	.334
	process	dix 20: A portion of transcript (extracted from IPP1 interview) of the thematic analysis that was conducted iteratively for each IPP in GP practice interview (Chapter 5, Sect	ion
		dix 21: Examples of quotes, used codes, and final sub-themes and themes of IPPs in Ges thematic analysis (Chapter 5, Section 5.5.2)	
		dix 22: Invitation letter to community IPPs and community pharmacy leads (Study 3, or 6)	.346
		dix 23: Participant information sheet for community IPPs and community pharmacy le	

Appendix 24: Participant consent form for community IPPs and community pharmacy leads (Study 3, Chapter 6)	354
Appendix 25: Reminder Email (Study 3, Chapter 6)3	57 -
Appendix 26: Interview schedule for community IPPs and community pharmacy leads (Study Chapter 7) (Study 3, Chapter 6) 3	
Appendix 27: A portion of transcript (extracted from IPP8 interview) of the thematic analysis process that was conducted iteratively for each IPP in community pharmacy interview (Chapte, Section 6.5.1.1)	ter
Appendix 28: Examples of quotes, used codes, and final sub-themes and themes of IPPs in community pharmacies thematic analysis (Chapter 6, Section 6.5.1.1)3	68 -
Appendix 29: A portion of transcript (extracted from CPL1 interview) of the thematic analysis process that was conducted iteratively for each CPL interview (Chapter 6, Section 6.5.1.3) - 3	
Appendix 30: Examples of quotes, used codes, and final sub-themes and themes of CPLs in Hithematic analysis (Chapter 6, Section 6.5.1.3)	

LIST OF FIGURES

Figure 1 Timeline of the events and changes before and during the PhD 4 -
Figure 2 The summary of the research methods that were used in each study in this
PhD77
Figure 3 The thematic analysis process (Braun and Clarke 2006)81
Figure 4 Trend of the total number of items per 100,000 population prescribed by all
prescribers by year97
Figure 5 Trend of the total number of items per 100,000 population prescribed by supplementary prescribers by year98
Figure 6 Trend of the total number of items per 100,000 population prescribed by
community nurse prescribers by year99
Figure 7 Trend of the total number of items per 100,000 population prescribed by
NMIPs by year
Figure 8 The number of NMIPs in primary care in Wales since April 2011 until March
2018101
Figure 9 Trend over time of the number of INPs who prescribed in each month in
primary care in Wales since April 2011 until March 2018102
Figure 10 Trend over time of the number of IPPs who prescribed in each month in
primary care in Wales since April 2011 until March 2018103
Figure 11 Trend over time of the number of independent physiotherapist prescribers
who prescribed in each since April 2011 until March 2018104
Figure 12 Trend of the total number of items/100,000 population prescribed by
NMIPs in different HBs by year. NB. IPs, in the figure, refer to NMIPs106
Figure 13 The total number of NMIPs (pharmacists, nurses, and physiotherapists)
who prescribed at least one item from April 2011 to March 2018 in each HB108
Figure 14 Trend of the total number of items per 100,000 population prescribed by
NMIPs in all Wales based on BNF chapters by year. NB. IPs, in the figure, refer
to NMIPs
Figure 15 Trend of the total number of items per 100,000 population of the
cardiovascular system chapter prescribed by NMIPs in each HB by year. NB. IPs, in the figure, refer to NMIPs. NB. IPs, in the figure, refer to NMIPs 112 -
Figure 16 Trend of the total number of items per 100,000 population of the
infections chapter prescribed by NMIPs in each HB by year. NB. IPs, in the
figure, refer to NMIPs 113 -
Figure 17 Trend of the total number of items per 100,000 population of the central
nervous system chapter prescribed by NMIPs in each HB by year. NB. IPs, in
the figure, refer to NMIPs
Figure 18 Trend of the total number of items per 100,000 population of the
respiratory system chapter prescribed by NMIPs in each HB by year. NB. IPs,
in the figure, refer to NMIPs 114 -
Figure 19 Trend of the total number of items per 100,000 population of the
endocrine system chapter prescribed by NMIPs in each HB by year. NB. IPs,
in the figure, refer to NMIPs 114 -
Figure 20 Trend of the total number of items per 100,000 population prescribed by
NMIPs based on top BNF categories. NB. IPs, in the figure, refer to NMIPs 116
- Figure 21 Trend of the total number of items per 100,000 population of antibacterial
drugs category prescribed by NMIPs in each by year. NB. IPs, in the figure,
refer to NMIPs118 -

Figure 22 Trend of the total number of items per 100,000 population of the
analgesic category prescribed by NMIPs in each HB by year. NB. IPs, in the
figure, refer to NMIPs 119
Figure 23 Trend of the total number of items per 100,000 population of the
bronchodilators' category prescribed by NMIPs in each HB by year. NB. IPs, in
the figure, refer to NMIPs119
Figure 24 Trend of the total number of items per 100,000 population of the drugs
used in diabetes category prescribed by NMIPs in each HB by year. NB. IPs, in
the figure, refer to NMIPs 120 -
Figure 25 Trend of the total number of items per 100,000 population of the
antihypertensive therapy category prescribed by NMIPs in each HB by year.
NB. IPs, in the figure, refer to NMIPs 120
Figure 26 Observed and predicted prescribed items by NMIPs prior to and following
the implementation of primary care clusters in October 2015 (All Wales) 122 -
Figure 27 Observed and predicted prescribed items by NMIPs prior to and following
the implementation of primary care clusters in October 2015 (All Wales,
excluding PTHB) 123 -
Figure 28 Observed and predicted prescribed items in primary care by NMIPs prior
to and following the implementation of primary care clusters in October 2015 (All
Wales, excluding PTHB and the final two months of observations) 124
Figure 29 Observed prescribed items by NMIPs prior to and following the
implementation of primary care clusters in October 2015 (HDUHB) 127
·
Figure 30 Observed prescribed items by NMIPs prior to and following the
implementation of primary care clusters in October 2015 (PTHB) 127
Figure 31 Observed and predicted prescribed items by NMIPs prior to and following
the implementation of primary care clusters in October 2015 (ABUHB) 128 -
Figure 32 Observed and predicted prescribed items by NMIPs prior to and following
the implementation of primary care clusters in October 2015 (ABMUHB) 128
Figure 33 Observed and predicted prescribed items by NMIPs prior to and following
the implementation of primary care clusters in October 2015 (BCUHB) 129
Figure 34 Observed and predicted prescribed items by NMIPs prior to and following
the implementation of primary care clusters in October 2015 (CVUHB) 129 -
· · · · · · · · · · · · · · · · · · ·
Figure 35 Observed and predicted prescribed items by NMIPs prior to and following
the implementation of primary care clusters in October 2015 (CTMUHB) 130 -
Figure 36 Observed and predicted prescribed items by medical prescribers prior to
and following the implementation of primary care clusters in October 2015 (All
Wales) 131 -
Figure 37 Observed and predicted prescribed items in primary care by medical
prescribers prior to and following the implementation of primary care clusters in
October 2015 (All Wales, y-axis truncated at 5 million prescribed items) 132 -
Figure 38 Observed and predicted percentage of all prescribed items by NMIPs prior
to and following the implementation of primary care clusters in October 2015 (All
Wales) 133 -
Figure 39 Observed and predicted percentage of all prescribed items by NMIPs prior
to and following the implementation of primary care clusters in October 2015 (All
Wales, final two months removed) 134 -
Figure 40 An overview of the gatekeepers used to recruitment participants for this
study 156 -
Figure 41 Themes of GP practice IPPs' interviews 162 -
Figure 42 Sub-themes within the professional identity theme 162 -
- induces the east distinct which in the professional identity distinct \ldots

Figure 43 Sub-themes within the practicalities and logistics with the role them	e - 171 -
Figure 44 Sub-themes within the relationships of IPPs' theme	175 -
Figure 45 Themes and sub-themes of the community pharmacy IPPs thematic	С
analysis	199 -
Figure 46 Themes of the community pharmacy leads interviews	

LIST OF TABLES

Table 1 The scope of practice of NMPs and the differences between supplementary prescribers and NMIPs in the UK. Adapted from (Stewart et al. 2017; Welsh Government 2017)
Government 2017)
Table 3 Total numbers and percentages of items as well as per population prescribed by NMIPs in each HB between April 2011 until March 2018105
Table 4 The total numbers and percentages of NMIPs as well as per population in primary care in different HBs in Wales from April 2011 to March 2018107
Table 5 Total number of items that were prescribed by NMIPs based on BNF chapters since April 2011 until March 2018109
Table 6 The percentages of the top BNF chapters of the prescribed items in primary care settings in each HB in Wales by NMIPs (N= total number of prescribed items)111 -
Table 7 Total number of items that were prescribed by NMIPs based on BNF categories from April 2011 to March 2018 115 -
Table 8 The percentages of the top BNF categories of items prescribed by in each HB in Wales (N= the total number of prescribed items) 117 -
Table 9 Parameter estimates from the interrupted time series analysis (ITSA) examining the change in level and slope of prescribed items by NMIPs following the implementation of primary care clusters in October 2015 (N = 84 months) 121 -
Table 10 All Wales ITSA excluding PTHB 123 - Table 11 All Wales ITSA excluding PTHB and the final two months of observations 123 -
Table 12 HB-specific parameter estimates from the ITSA examining the change in level and slope of prescribed items in primary care by NMIPs following the implementation of primary care clusters in October 2015 (N = 84 months) * 125
Table 13 Comparison between actual and counterfactual of prescribed items in primary care by NMIPs 126 -
Table 14 ITSA model estimates for prescribed items by medical prescribers* 131 -
Table 15 ITSA model estimates for the percentage of all prescribed items that are attributed to NMIPs 133 -
Table 16 The percentages of the IPPs in each HB in primary care in Wales 158 -
Table 17 Demographic data of the participants 161 -
Table 18 Demographic information of the community IPPs who participated in this study 198 -
Judy

1. Chapter 1 - General Introduction

In Wales, the independent prescribing role for non-medical professionals, including pharmacists, started in 2007 with the support of the Welsh Government (WG) (The National Assembly for Wales 2007). Initially, the majority of pharmacists who completed the independent prescribing course in Wales were based in secondary care settings (Courtenay et al. 2017), where many already had established services as supplementary pharmacist prescribers or clinical pharmacists running clinics such as warfarin and diabetes management (Jones 2006; Royal Pharmaceutical Society Wales 2015; Hodson 2017). There was no clear opportunity for pharmacists at that time to work as independent prescribers (IPs) in other sectors (Royal Pharmaceutical Society Wales 2015; Hodson 2017). As a result, before the introduction of primary care clusters in 2015, very few pharmacists worked in GP practices as IPs (Hodson 2018). In addition, there were no commissioned prescribing services for pharmacists in community pharmacies as the contract did not support such a role and only a very low number of independent pharmacist prescribers (IPPs) were providing private services (Courtenay et al. 2017; Hodson 2017).

In 2015, the WG published a plan entitled 'Our plan for a primary care service for Wales up to March 2018' that aimed to develop primary care services and move healthcare closer to patients' homes (Welsh Government 2015). The WG developed, and invested in, primary care clusters (n= 64) to help achieve this goal to provide more local and advanced clinical services (The National Assembly for Wales 2017). This resulted in more pharmacists joining GP clusters from other sectors, and many primary care pharmacists who worked in GP practices undertaking the independent prescribing course (Hodson 2018). This led to the foundation of the PhD, which started in October 2017 (data collection was conducted between 2018 and 2019), that aimed to explore the role of IPPs in primary care settings as it was still in its infancy. During the PhD, there was a further development in the role of pharmacists in primary care in Wales, particularly in community pharmacies. A report published in 2019 entitled 'Pharmacy: Delivering a Healthier Wales', outlined as part of their overall pharmacy strategy, a specific strategy to increase the number of pharmacists who could qualify as IPs to provide clinical services with the vision of having at least one IPP in each community pharmacy by 2030 (Welsh Pharmaceutical Committee 2019). In 2022, the WG changed the Community Pharmacy Contractual Framework which involved directing funds to clinical services within community pharmacies, including the commissioning of the Pharmacy Independent Prescribing Service (PIPS), rather than other non-clinical services such as dispensing of medications (Welsh Government 2022). This resulted in a large influx of community pharmacists enrolling on the independent prescribing course. As this development was within the primary care sector, the decision was taken to also explore the role of IPPs within community pharmacy.

Unfortunately, during the PhD, there were challenges; including the COVID-19 pandemic, as well as personal circumstances for the researcher, which needed an interruption of study on many occasions. This introductory chapter will first explore the role of non-medical prescribers (NMPs) in the UK, including Wales, since its implementation. Then, it will move into the development of the IPPs' role in primary care settings in Wales and the conception of the idea and initial aim of this PhD study. Thereafter, it will explore the development of the role of IPPs in community pharmacies in Wales, which shaped the final aim and objectives. Since there was a delay between the time that this PhD started to the submission of the thesis, the last part of this chapter will provide an update of new policies and developments, which will be referred to in future chapters. The timeline of the PhD and the subsequent developments in IPPs' role are illustrated in Figure 1.

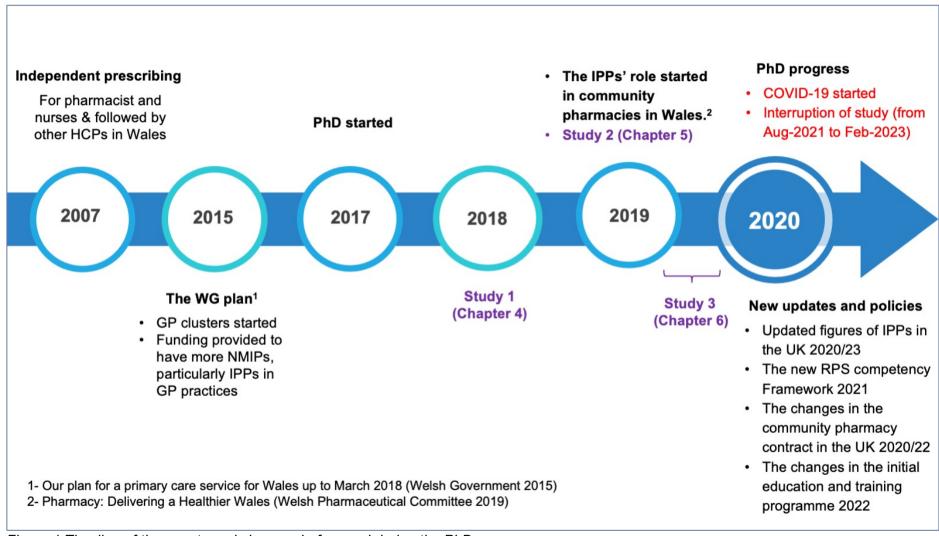


Figure 1 Timeline of the events and changes before and during the PhD.

1.1. Overview of NMPs' role in the United Kingdom

This section will provide a historical overview of NMPs and information about their role and its developments in the United Kingdom (UK).

In the UK, the right to prescribe medicines was traditionally restricted to doctors, dentists, and veterinary surgeons as per the Medicines Act 1968 (Department of Health (DoH) 1968) until the late 1980s, when the Cumberlege Report was published (Department of Health and Social Security [DHSS] 1986), recommending that community nurses should be able to prescribe. This report reviewed the care provided by district nurses (DNs) and health visitors (HVs) to patients in their homes and identified inappropriate delays in General Practitioner's (GPs) prescribing of simple items (e.g., wound dressings and ointments) to those patients. The report suggested that the health care provided to patients by DNs and HVs could be improved, access to medications could be increased, and community nurses' skills could be used effectively by enabling them to prescribe certain medicines from a limited list of items agreed upon by the Department of Health and Social Security.

Following the report, in 1989 an advisory group, under the supervision of Dr June Crown, was established by the DoH to examine nurse prescribing. The First Crown Report was published in 1989 (DoH 1989). This report reviewed the recommendations of the Cumberlege Report and suggested that the UK Government should amend the current law so that DNs and HVs could have the authorisation to prescribe from a limited list of medicines, ointments, and dressings. In 1992, the legislation was changed by the UK Government in parallel with publishing the Medicinal Products: Prescription by Nurses Act (1992), allowing DNs and HVs to legally prescribe from the Extended Formulary for Nurse Prescribers (Stephenson 2000). However, it required two more years for nurses who applied to this new practice to complete a mandatory training programme and obtain the prescribing qualification. In 1998, the Extended Formulary for Nurse Prescribers was renamed to the Nurse Prescribers Formulary (NPF) after the recognisable success of this practice and DNs and HVs were able to prescribe independently from this formulary.

The second Crown Report (DoH 1999), which was also carried out by an advisory group led by Dr June Crown, reviewed the prescribing, supply, and administration of medicines. They extensively reviewed the prescribing practice of DNs and HVs and recommended that prescribing authority should be extended to other healthcare professionals (HCPs), including pharmacists and other nurses in specific clinical areas. The aim of introducing the NMPs' role was to enhance patient care and safety, improve patient access and choice of appropriate medicines for their conditions, use the skills of the HCPs in the most effective way, and promote a more flexible teamwork environment in the NHS (DoH 2006).

The Report suggested two types of prescribing: dependent (now referred to as supplementary) and independent prescribing.

1.1.1. Types of non-medical prescribing

1.1.1.1. Supplementary prescribing

Supplementary prescribing is defined as a 'voluntary partnership between the responsible independent prescriber and a supplementary prescriber, to implement an agreed patient-specific clinical management plan (CMP) with the patient's agreement, particularly but not only in relation to prescribing for a specific non-acute medical condition or health need affecting the patient' (Medicine Control Agency 2002, p. 3). The independent prescriber (IP) in this context is either a doctor or dentist. (Welsh Government 2017).

Supplementary Prescribing by pharmacists and nurses was introduced in 2003 in England (DoH 2003), and 2004 in Wales (Welsh Assembly Government 2011). Since that time, further changes in legislation have occurred, allowing optometrists and other HCPs, known as Allied Health Professions (AHPs), including physiotherapists, podiatrists and chiropodists, radiographers, and dietitians to become supplementary prescribers once they have completed the required training programme (DoH 2005; DoH 2007). Initially, physiotherapists, podiatrists and chiropodists, radiographers, and optometrists became supplementary prescribers in 2005 (DoH 2007), followed by dietitians in 2016 (Welsh Government 2017).

1.1.1.2. Independent prescribing

Independent prescribing is defined by the DoH (2006, p. 2) as 'prescribing by a practitioner (e.g., doctor, dentist, nurse, pharmacist) responsible and accountable for the assessment of patients with undiagnosed or diagnosed conditions and for decisions about the clinical management required, including prescribing and monitoring of that prescribing'. Like supplementary prescribing, initially, nurses and pharmacists were provided the opportunity to become IPs, followed by other HCPs (except dietitians who are only able to prescribe as supplementary prescribers) who have trained to assess the clinical condition and prescribe medicines (Welsh Government 2017). Usually, pharmacists, nurses, optometrists, and AHPs (except dietitians) are referred to as non-medical independent prescribers (NMIPs) (Welsh Government 2017).

Before independent prescribing by non-medical practitioners was granted, a number of consultations and legislative changes were required. In November 2005, The Committee on Safety of Medicines reviewed the consultations made by the joint Department of Health/Medicines and Healthcare products Regulatory Agency, that studied the possibility of

introducing independent prescribing for nurses and pharmacists (DoH 2005). As a result, they recommended that appropriately trained pharmacists and nurses should be authorised to prescribe licensed medications within their clinical area of competence, which was agreed upon later in 2005 by the UK Government (DoH 2006). In 2006, a change to legislation was announced by the UK Government to introduce independent prescribing for pharmacists and nurses who completed the necessary training (DoH 2006), while in Wales it was implemented in 2007 (The National Assembly for Wales 2007). This was followed by the introduction of optometrist IPs in 2007 (DoH 2007). At that point, pharmacists who had independent prescribing authority were able to prescribe any licensed medicines within their area of competence, except for controlled drugs which could only be prescribed by supplementary prescribing pharmacists, if they were included in the CMP (DoH 2006). In contrast, independent nurse prescribers (INPs) gained the authority to prescribe any licensed medicine as well as some of the controlled medications, if they were confident and competent to prescribe them (DoH 2006). In 2012, new legislation was introduced by the UK Government allowing IPPs and INPs to prescribe, in addition to the licensed medicines, unlicensed medicines, off-label medicines, controlled drugs (except diamorphine, cocaine, and dipipanone to treat patients who are addicted to control drugs), and to mix any drugs for necessary conditions (DoH 2012).

In 2008, a scoping project conducted by NHS England entitled 'The Allied Health Professions Prescribing and Medicines Supply Mechanisms Scoping Project' investigated the necessity and benefits of supporting AHPs with independent prescribing qualification to patients and NHS services (AHPs Federation 2018). This project evaluated the potential of AHPs' prescribing, supplying, and administering required medicines to their patients. The project concluded that extending the qualification of independent prescribing to AHPs would improve their patients' experience and access to appropriate medications. Therefore, a case was made in the project to enable AHPs to obtain the independent prescribing qualification starting with podiatrists and chiropodists, and physiotherapists in 2013 (DoH 2013; AHPs Federation 2018). Three years later, independent prescribing therapeutic radiographers started (NHS England 2016). The estimated number of HCPs who have the authority to prescribe medicines in the UK in 2017 was as follows: 35,000 community nurse practitioner prescribers; 30,000 nurse prescribers (including both independent and supplementary); 3,000 pharmacist prescribers (including both independent and supplementary) and 600 AHPs (Courtenay et al. 2017).

1.1.2. Training and scope of NMPs' practice in the UK

Pharmacists, nurses, and AHPs are required to be registered with their professional

regulatory bodies. They used to have a certain minimum period of post-registration clinical experience, to be able to join an NMPs' training programme. Initially, pharmacists needed to have at least two years of clinical experience that involved patient-oriented practice. In 2021, the General Pharmaceutical Council (GPhC) changed the admissions standards for entry requirements onto a pharmacist independent prescribing course (GPhC 2021), allowing pharmacists with relevant experience in a UK pharmacy setting to apply; where relevant experience was not defined in years (see below, Section 1.3.5). Nurses, optometrists, and AHPs are required to have three years of clinical experience, with nurses spending at least a year of the three years practising in the clinical area that they plan to prescribe within. The NMPs' programme consisted of at least 38 days. It involved at least 26 days in accredited facilities, mainly universities, and practical experience, known as practice-based learning for at least 12 days. The practical experience originally required supervision by a medical practitioner (a doctor or dentist), known as a Designated Medical Practitioner (DMP) in the UK or a Designated Supervising Medical Practitioner (DSMP) in Wales, who had at least three years of clinical, teaching and supervision experience, and prescribing qualification in the same field of practice. The learning outcomes of NMPs gained from their independent prescribing course and training helped to develop and assess their initial clinical assessment, communication skills, knowledge of medicines, evidence-based practice, clinical decision making, shared decision making, care planning and follow up, documentation, legal and ethical issues, scope of practice, continuing professional development (CPD), safety of clinical practice, public health issues relating to prescribing, and complying with healthcare policy (AHPs Federation 2018; GPhC 2018; The Nursing and Midwifery Council (NMC) 2019).

All NMPs are responsible and accountable for their action of prescribing, and they should only prescribe medicines within their therapeutic area of expertise. Moreover, it is vital to seek appropriate advice or referrals if they lack the confidence to manage patients' conditions or prescribe suitable medicines for their patients (Welsh Government 2017). Supplementary prescribers are able to prescribe any medicine included in the CMP, which should be based on an agreement between the medical prescriber (doctor or dentist), patient, and supplementary prescriber. This applies to all HCPs who have been legally authorised to prescribe medicines as supplementary prescribers. Although NMIPs are authorised to prescribe medications within their area of competence, their prescribing differs depending on their profession. IPPs and INPs have the authority to prescribe any required medicine for the conditions within their scope of practice, including controlled drugs with the exceptions stated earlier in Section 1.1.1.2 (DoH 2012). However, controlled drugs are not permitted to be prescribed by therapeutic radiographer IPs, while chiropodists and physiotherapists have the authority to prescribe controlled medicines from a limited list only (Welsh Government 2017;

British National Formulary 2019). In addition, optometrist IPs are allowed to only prescribe medicines for ophthalmic diseases and related conditions. Optometrist and therapeutic radiographer IPs are not authorised to prescribe unlicensed medicines. INPs (limited), can only prescribe medicines and appliances independently from a limited formulary that is known as the Nurse Prescribers' Formulary for Community Practitioners (Welsh Government 2017). INPs (limited) are community nurse practitioners in Wales who were previously identified as District Nurses (DNs) and Health Visitors (HVs). A summary of the scope of NMPs in the UK, including the differences between the prescribing of supplementary prescribers and NMIPs, is presented in the following table (Table 1):

Table 1 The scope of practice of NMPs and the differences between supplementary prescribers and NMIPs in the UK. Adapted from (Stewart et al. 2017; Welsh Government 2017)

	Supplementary prescribers	NMIPs
HCPs	Pharmacists, nurses, physiotherapists, podiatrist, chiropodist, optometrists, diagnostic and therapeutic radiographers, and dietitians.	Pharmacists, nurses, physiotherapists, podiatrist, chiropodist, optometrists, and therapeutic radiographers.
Clinical area of prescribing	Within the CMP and their clinical area of competence.	Within their clinical area of competence.
Diagnosis	Performed by a doctor	Able to assess and prescribe medicines for diagnosed or undiagnosed patients.
Patients' CMP	Required.	Not needed.
Agreement	Required between a supplementary prescriber, patient, and physician.	Not needed.
Medicines prescribed	Supplementary prescribers can prescribe only medicines that have been included in their patients' CMP and within their therapeutic area of competence.	Pharmacists, nurses, physiotherapists, podiatrists, chiropodists, and therapeutic radiographers can prescribe any medicine for any medical condition within their therapeutic area of competence. Optometrists can only prescribe for ophthalmic diseases and surrounding tissues.
Prescribing controlled medicines	Supplementary prescribers can prescribe any controlled medicines that have been stated in their patients' CMP, except diamorphine, cocaine and Dipipanone for treating addiction.	Pharmacists and nurses can prescribe controlled medicines, expect for cocaine, diamorphine, dipipanone for treating addiction. Physiotherapists, podiatrists, and chiropodists can each prescribe from a separate (specified to each profession) limited list of controlled medicines. Therapeutic radiographers and optometrists are not allowed to prescribe controlled medicines.
Prescribing unlicensed medicines	Supplementary prescribers can prescribe unlicensed medicines that have been included in their patients' CMP.	Pharmacists, nurses, physiotherapists, podiatrists, and chiropodist can prescribe unlicensed medicine within their therapeutic area of competence. Optometrists and therapeutic radiographers are not allowed to prescribe unlicensed medicines.
Prescribing off-label medicines	Supplementary prescribers can prescribe off-label medicines that have been included in their patients' CMP.	Pharmacists, nurses, physiotherapists, podiatrists, chiropodists, and therapeutic radiographers can prescribe off-label within their therapeutic area of competence. Optometrists can only prescribe off-label medicines for ophthalmic diseases and surrounding tissues.

1.1.3. Implementation of NMPs' role in Wales

Wales is one of the devolved nations in the UK. However, the implementation of NMPs' services in this nation was slightly different than that in other UK nations due to political

aspects related to the health sector. For example, as indicated earlier (Section 1.1) the DNs and HVs prescribing of certain medications and appliances started in the early 1990s in England (DoH 1989), it was not until the end of 2000 when this role was introduced in Wales (National Assembly for Wales 2001). Thereafter, many policies were published that aimed to improve NMPs' practice in Wales. One of these reports was published in 2001 (National Assembly for Wales 2001), entitled 'Improving Health in Wales: A plan for the NHS with its Partner' and indicated that patient access to medicines should be improved as well as increasing the number of HCPs who can prescribe medicines effectively. This report, followed by another one in 2001 (National Assembly for Wales 2001, 'Report of the task and finish group for prescribing in Wales') provided recommendations to the Health and Social Services Committee to improve the quality of prescribing by HCPs. Consequently, a third report published in 2001 (National Assembly for Wales 2001, 'Improving Health in Wales: The Future of Primary Care') emphasised the need to find ways to increase patient's access to the appropriate medicines and the prescribing practice of repeat medications by pharmacists. Therefore, it highlighted the necessity for the implementation of prescribing medicines by other HCPs and addressed the legal framework associated with it.

In 2002, several proposals for the implementation of pharmacist and nurse supplementary prescribing were discussed (Medicines Control Agency 2002). Later in 2002, the Minister of Welsh Health and Social Services stated that the WG was aiming to introduce supplementary prescribing for nurses in the future (Welsh Assembly Government 2011). This was followed by the publication of a consultation document by the Welsh Assembly Government (2002) that involved a strategic plan to improve the practice of pharmacists in Wales. This document pointed out that in 2004, pharmacists, who completed the necessary training course, would be able to prescribe medicines legally as supplementary prescribers. In 2003, an amendment to the NHS Wales regulation was made, enabling supplementary prescribing of medicines by pharmacists and nurses after the completion of their training (the National Assembly for Wales 2003). In 2004, 250 pharmacists and nurses were trained to be qualified as supplementary prescribers in Wales (Welsh Assembly Government 2011).

In Wales, the extension of prescribing independently by non-medical HCPs was driven by the report entitled 'Designed for Life-Creating World Class Health and Social Care for Wales in the 21st Century, May 2005' (Welsh Assembly Government 2005). IPPs and INPs' role became effective in Wales in 2007 after changes to the National Health Service regulations were made, with the same aim as the implementation of NMPs' role in the UK (The National Assembly for Wales 2007). Following this, supplementary prescribing by physiotherapists, optometrists, podiatrists, and radiographers was introduced in the same year (The National Assembly for Wales 2007). Then, qualified, and trained optometrists were

enabled to prescribe medicines independently in 2008 (Welsh Assembly Government 2011).

Up until 2017, the following HCPs who have completed the necessary training could prescribe medicines as either IPs or supplementary prescribers: pharmacists, nurses, therapeutic radiographers, chiropodists and podiatrists, physiotherapists, and optometrists (Welsh Government 2017; UK Statutory Instruments 2018). On the other hand, the following registered professionals, including midwives, specialist community public health nurses, diagnostic radiographers, and dietitians had the authority to prescribe medicines as only supplementary prescribers once they attain the required qualifications (Welsh Government 2017). Furthermore, as highlighted in Section 1.1.2, HVs and DNs are known as INPs (limited) in Wales (Welsh Government 2017).

Whilst in 2007 any pharmacist who met the criteria could become an IP; the evidence suggested that IPPs were mainly based in the secondary care sector in Wales (Courtenay et al. 2017). The utilisation of this role was not widespread in primary care settings, which may be because there were not many pharmacists working in primary care settings. This resulted in only a few of them being qualified as IPPs in GP practices and community pharmacies (Jones 2006; Hodson 2017). This difference was because there was no drive or policies that could support the role of IPPs within the primary care sector, which led to the role being not well established in this area.

1.1.4. Primary care services in Wales

In Wales, the NHS provides its services via three NHS Trusts and seven Health Boards (HBs). The three NHS Trusts are Public Health Wales, Velindre NHS Trust, and Welsh Ambulance Service NHS Trust. The seven HBs are Abertawe Bro Morgannwg University HB (ABMUHB) (N.B. This HB was renamed a few years ago to Swansea Bay University HB), Cardiff and Vale University HB (CVUHB), Cwm Taf Morgannwg University HB (CTMUHB), Hywel Dda University HB (HDUHB), Powys Teaching HB (PTHB), Betsi Cadwaladr University HB (BCUHB) and Aneurin Bevan University HB (ABUHB). The services in each HB include:

- primary care services, which are delivered by GP practices, other practitioners in surgeries and health centres, and community care settings that are responsible for taking care of patients in their local areas (NHS Wales 2016).
- secondary care services provided via ambulance services and hospitals,
- tertiary care services associated with treating certain conditions like cancer.

Primary health care settings are the initial point of care for patients in the NHS. In Wales, it has been estimated that around 90% of people's contact with the NHS is with primary care services. GP practices are the main point of contact within the primary health care service

in Wales (Welsh Government 2015). In 2016, there were 441 GP practices in Wales and 2009 GPs (excluding, locums, retainers, and registrars) (Wales Audit Office 2018). Besides GP practices, there are some other local community services provided to the public through the primary care sector for people who have certain health needs (Welsh Government 2015). These services are delivered to patients via GPs, dentists, nurses, pharmacists, opticians, physiotherapists, and other HCPs (NHS Wales 2016).

Community pharmacies also fall under the primary care sector. There are more than 700 community pharmacies geographically distributed across Wales in areas where people live and work (NHS Wales 2021). Community pharmacies' services are provided by pharmacists, which patients can access without an appointment. Three types of services are provided by pharmacists at a community pharmacy, which are essential, advanced, and enhanced services. The essential services include advice on medications, reviewing and checking the clinical appropriateness of prescribed medications, dispensing and repeat dispensing of medications, and signposting. An example of advanced services is the discharge medicines review (DMR). The enhanced services are additional services commissioned and supported by GP practices or HBs, such as smoking cessation and Common Ailments Services (CAS) (NHS Wales 2021).

As a part of the primary care sector, the WG and HBs initiated primary care clusters (also called GP practice clusters) in 2015, which are groups of adjacent GP practices clustered together by combining their registered populations to provide their services locally (National Assembly for Wales 2017). These clusters were introduced to create specific local planning and services for the local population registered within each cluster and ensure better communication between HCPs within the local network of GP practices (Welsh Government 2015). Primary care clusters were founded to support one of the top five priorities of the primary care plan in the report published by the WG (2015) entitled 'Our plan for a primary care service for Wales up to March 2018' which was to provide healthcare services locally by different HCPs instead of being delivered via hospitals (Welsh Government 2015). The overall aim was to improve the quality of life of the Welsh population by increasing their access to treatment and overcoming GP shortages (Welsh Government 2015). Clusters were first proposed in 2010 in 'Setting the Direction: The Welsh Government's Primary and Community Services Strategic Delivery Programme' (The National Assembly for Wales 2010). However, they were not established until an agreement between the WG, and the General Practitioners Committee (GPC) occurred in 2014, and funding support was provided by the WG in 2015 (The National Assembly for Wales 2017). In 2017, there were 64 primary care clusters in Wales providing its services for a population range of 30,000 to 50,000 patients for each cluster (The National Assembly for Wales 2017).

In the UK, the NHS is endeavouring to use the skills of HCPs in the most effective way and encouraging them to work together in a multidisciplinary team (Welsh Government 2015). In Wales, a report published in 2015 entitled 'Your Care, Your Medicines: Pharmacy at the Heart of Patient-centred Care', stated that pharmacists could offer more services than they traditionally provided, particularly in the primary care sector (Royal Pharmaceutical Society Wales 2015). Therefore, pharmacists have been involved in a great deal of the services provided by primary care clusters to use their skills effectively and address the shortage of GPs and nurse practitioners (Brennan 2017 and Jones 2017). Pharmacists practise their role in primary care clusters as either IPPs, Practice-Based Pharmacists (only work in one GP practice), Primary Care Pharmacist/Prescribing Advisors, Cluster Pharmacists (work across multiple GP practice within the cluster), Community Pharmacists, Intermediate Care Pharmacists, or Clinical Specialist Pharmacists (Advanced Practitioners) (Royal Pharmaceutical Society Wales 2015). With the new policies and developments in the primary care sector since 2015 in Wales, including the WG plan (Welsh Government 2015) and primary care clusters (National Assembly for Wales 2017), many pharmacists moved from secondary care to work in GP practices and a lot of them desired to undertake the independent prescribing course to be qualified as IPPs, which may have resulted in a shift in the workforce (Hodson 2018). This represented a new role for IPPs in GP practices that had not been researched in Wales, which provided an opportunity to evaluate it in this PhD. This informed the first objective of this PhD, which was to identify the number of NMIPs, including IPPs, and their prescribing volume over time in relation to the implementation of GP clusters (Study 1; Chapter 4). In addition, it outlined the second objective, which was to explore the views of IPPs regarding their role in GP practices in Wales (Study 2; Chapter 5).

1.1.5. Initial aim of the PhD (2017)

The initial aim of this PhD was to explore the development of the prescribing role of NMIPs and their number in primary care settings in Wales, with a focus on the role of IPPs in GP practices.

1.1.6. Initial objectives of the PhD (2017)

- 1. To identify the number of NMIPs and the trends of their prescribed items that were dispensed in primary care settings in Wales from 2011 to 2018, and the impact of the primary care clusters implementation in 2015 on these trends.
- 2. To describe the roles of IPPs working within GP practices in Wales and to explore their views on how their role is embedded in primary care.

1.2. Changes to the role of NMPs since establishing the initial objectives, and during the PhD

This section presents the development of the NMPs' role during the PhD up to the end of the data collection period.

The first development is related to the introduction of the prescribing role, as either supplementary prescribers or IPs, to paramedics in 2018 in the UK, including Wales, as they are the latest AHPs to obtain this qualification (AHPs Federation 2018). Supplementary paramedic prescribers are authorised to prescribe any medicines that are stated in their patients' CMP and within their scope of practice (UK Statutory Instruments 2018; College of Paramedics 2021). On the other hand, independent paramedic prescribers are allowed to prescribe medicines autonomously, including off-label use of licensed medicines, within their clinical area of competence; except for controlled medicines that can be only prescribed from a limited list. They are not authorised to prescribe unlicensed medicines (UK Statutory Instruments 2018; College of Paramedics 2021; Community Pharmacy England 2021).

Another development is associated with the role of IPPs in community pharmacies in Wales. To continue achieving the WG plan to improve primary care (Welsh Government 2018), services within the community pharmacy sector were also targeted to be developed by the WG. The Welsh Pharmaceutical Committee's response to the plan, 'Pharmacy: Delivering a Healthier Wales in 2019' (Welsh Pharmaceutical Committee 2019) outlined the vision to include at least one community IPP in one-third of community pharmacies in Wales by 2023, and in each community pharmacy in Wales by 2030. This involved utilisation of the recognised skills of pharmacists as IPPs to enhance the services in this sector (up until this time, only a few community pharmacists had qualified as IPPs in Wales, as the service and reimbursement for providing it were not formalised). The role of the IPPs aims to enhance patient-centric care in the community pharmacy sector, alleviate the burden on GPs, and achieve better financial resource allocation of services toward more clinical roles (Welsh Pharmaceutical Committee 2019). This report also recommended an investment in community IPPs to be more involved in the clinical services that are already in place in community pharmacies, such as the CAS (Wickware 2019). The CAS is provided within local community pharmacies in Wales and is designed to provide patients with convenient and free access to advice, treatment, and medications for various minor illnesses and common health conditions, such as sore throats, acne, constipation, and colic (NHS Wales 2019). It allows patients to seek medical aid directly from their local pharmacists without the need for an appointment. Although pharmacists in this scheme are not IPs, they are trained to assess patients' symptoms, offer appropriate advice, and provide medications as needed, including over the counter (OTC) and, in certain conditions, prescription-only medications from a limited list under specifically authorised

protocols. The CAS aims to direct patients with minor health issues to community pharmacies so that they may be managed by qualified HCPs and provide them with quick access to treatment and reduce pressure on other HCPs and healthcare services, such as GPs and emergency departments (NHS Wales 2019).

As a result, in 2019, the WG informed contractors in the community pharmacy sector that the contract would change in terms of payment for different services (Community Pharmacy Wales 2019). The WG maintained the original amount of funding for the contract, but it redirected the fund to clinical services, such as the role of IPPs in community pharmacies, rather than other services, e.g., dispensing (Community Pharmacy Wales 2019). This change provided the opportunity for pharmacists to train as IPPs in this sector either by self-funding or with WG support for their training (Community Pharmacy Wales 2019). The WG also provided money to Health Education and Improvement Wales (HEIW) (the strategic workforce body concerned with training HCPs, making workforce strategies, and addressing workforce issues for NHS Wales) to fund the training of community pharmacists to be IPPs (NHS Wales 2019). HEIW started by commissioning the training of 50 IPPs in 2019 to provide a prescribing service in community pharmacies across Wales, with an expectation that the commissioned numbers would increase in the future (Community Pharmacy Wales 2019; Slawther 2019). In addition to paying the course fees, HEIW decided the funding would also include payment for the DSMPs towards the cost of training community pharmacists, acknowledging that the community pharmacists are not employed by the GP practice (Community Pharmacy Wales 2019). Some HBs chose the scope of practice for their IPPs, such as contraception in CVUHB and urinary tract infections (UTIs) in CTUHB, as there was no national guidance or specific scope of practice for community pharmacists (Hodson 2018). With the new policy that aimed to support more IPPs to be based in community pharmacies as a part of the primary care sector (Welsh Pharmaceutical Committee 2019), many pharmacists completed the independent prescribing course and qualified as IPPs in these settings. The role of IPPs in community pharmacies in Wales was still in its infancy and lacked research. This new initiative represented an opportunity to explore the implementation and development of IPPs' services in community pharmacies to inform future policies and changes, which was not accounted for in the initial objectives of the PhD since the role started in 2019. As a result, the final objectives in the PhD included a new third objective, which was to explore the views of IPPs and relevant stakeholders, who were community pharmacy leads in HBs (each HB has a community pharmacy lead and their role will be discussed in detail in Chapter Six, Section 6.2), about this role and its implementation in community pharmacies (Study 3, Chapter 6).

1.2.1. Final aim of the PhD (2019)

The aim of this PhD is to explore the development of the prescribing role of NMIPs and their number in primary care settings in Wales, with a focus on the role of IPPs in GP practices and community pharmacies.

1.2.2. Final objectives of the PhD (2019)

- 1. To identify the number of NMIPs, and the trends of their prescribed items that were dispensed in primary care settings in Wales from 2011 to 2018 and the impact of the primary care clusters implementation in 2015 on these trends.
- 2. To describe the roles of IPPs working within GP practices in Wales and to explore their views on how their role is embedded in primary care.
- 3. To explore the views of community IPPs and HB community pharmacy leads regarding the role of IPPs within a community pharmacy setting.

[NB: Interruptions of study occurred between August 2021 – February 2023]

1.3. Further development of the NMPs' role during and after the PhD hiatus

The aim and objectives of the PhD were finalised in 2019. However, interruptions of study took place between August 2021 and February 2023, in which time a number of further developments occurred in relation to the NMPs' role. This section will highlight the new information related to the development of this role, particularly the role of IPPs, during this time and up to the submission of the thesis.

1.3.1. Updated figures of IPPs' numbers and volume of prescribing in the UK

The updated figures of the number of IPPs and their prescribing volume are increasing over time in the UK. The number of IPPs increased by more than three-fold between May 2016 (n=2,781) and May 2020 (n=8,806) as obtained from the GPhC through a freedom of information request (Wickware 2021). The largest increase in the absolute number was in England, where the number of IPPs increased by 5,124 (from 2,224 in May 2016 to 7,348 in May 2020), followed by Scotland (from 390 in May 2016 to 975 in May 2020), and Wales (from 167 in May 2016 to 483 in May 2020) (Wickware 2021). The number of pharmacists with an independent prescribing qualification or who had started their prescribing training in primary care settings in England had increased significantly by 77% (n=617 in 2019/20 to 1,094 in 2020/21), with no such data available for Wales and Scotland. This highlighted the necessity of exploring the implementation of this role in primary care settings within these nations.

A more recent figure of IPPs who were registered by the GPhC in the UK showed that their numbers increased by almost two-thirds (66%) from May 2020 (n=8,806) to August 2022 (n=14,635) (Burns 2022). Similarly, most of the IPPs, as shown by the GPhC in August 2022, were based in England (n=11,863), followed by Scotland (n=1,841), and Wales (n=812), and then 199 IPPs in Northern Ireland, the Isle of Man, and the Channel Islands. However, the greatest proportion of pharmacists who had the independent prescribing qualification in the pharmacy workforce was in Scotland (34%), followed by Wales (29%) and England (22%), which may suggest that the Scotlish Government was more proactive in implementing this role compared to other nations. Although the number of IPPs is increasing over time in the UK, Burns (2022) highlighted that the findings of a recent salary survey by the Pharmaceutical Journal revealed that around 18% of IPP respondents had never prescribed any medication and almost 51% of IPP respondents were prescribing daily for their patients.

In Wales, the WG shared recent figures of IPPs who were actively prescribing (prescribed at least one item in GP practices that was dispensed in a community pharmacy in Wales on a monthly basis) (NHS Wales 2023). It showed that the number of actively prescribing IPPs in GP practices in March 2023 was 175, and their number of prescribed items was around 100,000 items.

1.3.2. The developments in the community pharmacy sector in the UK

In March 2020, the WG agreed to provide more funding support of £18.3 million over three years (2022/2025) for community pharmacies in Wales compared to only £1 million in 2021/2022 (Welsh Government 2021). This agreement aimed to secure the continuation of the funding of IPPs' education and training as well as reforming the clinical services provided in community pharmacies across HBs, aimed at expanding these services as well as the number of IPPs in this sector. Later in 2020, the WG launched a new service known as the Pharmacy Independent Prescribing Service (Pharmacy IPS), which is a free NHS local service delivered by IPPs in community pharmacies rather than GP practices (Royal Pharmaceutical Society 2021). The aim of this service is to provide advice and treatment to patients, if needed, within a wide range of conditions within the pharmacist's scope of practice (Royal Pharmaceutical Society 2021). While both the CAS and IPS involve pharmacists providing medication-related services in community pharmacies, they differ in scope, purpose, and level of pharmacist involvement. The CAS focuses on specific minor illnesses within defined protocols, whereas IPS allows pharmacists to independently prescribe medications as part of broader patient care initiatives within their prescribing competence that can be extended over time with more training. The IPS started with a pilot in 13 community pharmacies in six HBs in Wales in which the Choose Pharmacy platform was used to allow a 'read' access to patients'

Welsh GP records (WGPR) to effectively assess their medical conditions and safely prescribe medicines for them (Choose Pharmacy 2020). The Choose Pharmacy is an IT system provided by Digital Health Care Wales, which is available in almost 99% of community pharmacies in Wales to support them in providing healthcare services for patients (Choose Pharmacy 2020). Pharmacists, including IPPs, could access this platform in community pharmacies when providing a wide range of services, including the CAS, DMR, Seasonal Flu Vaccination Service, Emergency Medicine Supply Service, Contraception Services, and IPS (NHS Wales 2023). The Emergency Medicine Supply Service was the first module to allow a 'read' access to the WGPR, whereas the CAS was the first service that allowed information to be transferred to GP practices, followed by the DMR service in the Choose Pharmacy platform (Hodson 2023). The new IPS module on the Choose Pharmacy platform used the existing features of the Emergency Medicine Supply module, providing IPPs with access to the digital WGPR of patients (NHS Wales 2023).

The prescribing sessions within the pilot Pharmacy IPS were commissioned by HBs and ranged from one to three prescribing sessions per week within the IPPs' scope of practice, with a maximum of nine consultations conducted in each session. Each HB determined the appropriate clinical services for IPPs in community pharmacies based on the needs of the population and the scope of their practice, such as opioid withdrawal. Patients usually walked in or booked appointments. They could be referred by their GPs or could see an IPP if they were already aware of the role. IPPs also provided telephone and video (virtual) consultations as part of their prescribing role in community pharmacies, particularly during the COVID-19 pandemic, which is still offered by some IPPs (Welsh Government 2020; Mantzourani et al. 2023).

The Pharmacy IPS evolved into an all-Wales service in April 2022, as changes were made by the WG to the Community Pharmacy Contractual Framework in Wales, which paved the way for more clinical services, including PIPS, to be available to patients (Welsh Government 2022). These changes involved plans to continue increasing the number of IPPs in community pharmacies across different HBs in Wales (CTMUHB 2019; Allen and Mackridge 2022). This was in addition to the other prescribing services within specific therapeutic areas of need that IPPs have been responsible for within their local HBs, as stated in 'A New Prescription, the Future of Community Pharmacy in Wales' (Welsh Government 2021). Although the Welsh Pharmaceutical Committee aimed in the vision to reach a target of 30% of community pharmacies in Wales providing independent prescribing services by the end of 2022/2023, by May 2022 only about 13% had been achieved (Welsh Pharmaceutical Committee 2019; Wickware 2022). In May 2023, the number of IPPs users in the Choose Pharmacy platform was 118, while the number of community pharmacy sites was 135 (Hodson

2023). This indicates that in 2023, nearly one in six community pharmacies in Wales were providing the IPS.

As previously discussed, in terms of the financial support for the role of IPPs in community pharmacies in Wales, the WG provided funding to HEIW to manage the fund in relation to independent prescribing courses and mentors' fees. HEIW aims to offer funding to train all pharmacists who have patient-facing roles to obtain an independent prescribing qualification within the next two years (2024/2025). In the year 2021/22, funding was offered by HEIW to train 150 pharmacists as IPPs in GP practices. HEIW has also supported the role of IPPs in community pharmacies by training more than 200 pharmacists to obtain the independent prescribing qualification (Hodson 2023). In the current year (2023/24), the WG has invested up to £12 million to deliver the IPS within community pharmacies (Hodson 2023). This funding included the training of around 300 pharmacists (Hodson 2023). The estimated total number of pharmacists that HEIW has funded to train as IPs is around 700. The number of training places for IPPs in community pharmacies in Wales also increased from 50 in 2020/21 to 60 in 2021/22 (Burns 2021). Almost two-thirds of the training places that were offered to pharmacists to qualify as IPs were undertaken each year. The funding provided by the WG also included a payment of £3,000 as a training bursary to each community pharmacy to allow staff to undertake the prescribing training. The WG in collaboration with the HBs has also provided funding to DSMPs with £3,000 to train community pharmacists as IPPs.

Based on data shared by the Royal Pharmaceutical Society (RPS) in Wales in collaboration with NHS Wales and Community Pharmacy Wales, up until 2021, 33 community pharmacies (out of 713) have conducted more than 16,000 patient consultations by IPPs as part of the IPS. It involved the management of acute conditions, contraception, and drug withdrawal (Burns 2021; Welsh Government 2021). A study conducted as part of a PhD project at Cardiff University by Al Hussain (2022) analysed secondary data obtained from the Choose Pharmacy platform about IPPs' consultations and prescriptions in Wales from June 2020 to September 2022. It showed that the number of consultations and prescriptions made increased over the study period. The total number of consultations made by IPPs in community pharmacies over the study time was 30,401. The number of prescribed items was 29,256 prescribed in 24,356 out of the 30,401 consultations (most of the consultations were made in four HBs). The approach of seeing IPPs in community pharmacies highlighted that 39% (n=11,814) of patients were self-referred as they were unable to see a GP, 26% (n=8,006) were referred to the community pharmacy by GPs, and more than 6% of the consultations were made during the out-of-hours period. IPPs have also referred many patients to emergency departments, GPs, dentists, optometrists, and others. More recent figures of recorded consultations in Choose Pharmacy made by IPPs in community pharmacies in Wales, which were obtained from the WG, showed that the number of consultations between May 2022 and May 2023 was 63,278 (Hodson 2023). This represented more than double the number in the findings of Al Hussain's (2022) study over a shorter period, which shows that the IPPs' services are growing over time in community pharmacies in Wales.

Each nation in the UK has decided to initiate the services of IPPs in community pharmacies differently, except in Northern Ireland where this role has not been implemented in this sector. Scotland was at the forefront of community pharmacists becoming IPs, as the community pharmacy contractual framework changed in 2020 to implement this role (NHS National Services Scotland 2023). In addition, the Minor Ailment Service that had been conducted in community pharmacies since 2006 was replaced by the new NHS Pharmacy First Scotland service. This new service enables patients to visit or call a community pharmacy as their initial point of contact to receive treatment from IPPs (NHS National Services Scotland 2023). However, in England, the NHS is planning to fully commission and incorporate independent prescribing services by pharmacists in community pharmacies from 2026 (NHS England 2023). In 2023, NHS England announced a new programme for community pharmacies known as Independent Prescribing Pathfinder to all integrated care boards (ICBs) and planned to include 210 community pharmacies across the 42 ICBs to provide IPPs' services (NHS England 2023). This programme aimed to test and support various prescribing models to inform the development of a framework for the commissioning of independent prescribing services in community pharmacies in England. The scope of the practice of IPPs within these pathfinder sites was determined by ICBs that involved both chronic and acute conditions management, which was opposite to the role of IPPs in Wales and Scotland which was more related to acute conditions.

1.3.3. General new pharmacy policies in Wales

In 2022, the Welsh Pharmaceutical Committee published an updated policy entitled 'Pharmacy: Delivering a Healthier Wales 2025 Goals' (Welsh Pharmaceutical Committee 2022), that set out goals for 2025 that represent a significant step towards achieving the broader vision for 2030 outlined in 'Pharmacy: Delivering a Healthier Wales' (Welsh Pharmaceutical Committee 2019). It aimed to eliminate barriers across healthcare settings, ensuring patients receive seamless care. The goals also focused on creating dynamic and diverse career pathways for pharmacy professionals. This policy emphasised an innovative and collaborative approach to pharmaceutical care delivery, with a commitment to maximising the impact of pharmacy professionals in meeting the health services and the Welsh population's needs. These goals built upon the innovation and progress in pharmacy since 2019 considering the challenges posed by the Covid-19 pandemic and the subsequent

recovery efforts. Key objectives included developing the entire pharmacy team's skills across different healthcare settings, embedding pharmacy professionals in multidisciplinary care approaches, and driving innovation and technology to prioritise patient-centred care and enhance the patient experience.

Also, a new pharmacy workforce plan was launched in June 2023 in Wales entitled 'HEIW Strategic Pharmacy Workforce Plan' (NHS Wales 2023). It involved a 10-year plan that has outlined long-term goals and short-term actions as well as some principles to transform and develop the pharmacy profession in Wales. It has been developed in collaboration with the WG, education providers, professional bodies, employers, employees, independent contractors, trade unions, and charities in Wales. This plan provides 31 key actions that aim to drive the improvement and transformation in the values, support, and development of the whole pharmacy workforce, including the role of IPPs across Wales. It will help to provide more development opportunities, a stable multi-professional workforce for employers, and a better working environment. This is to ensure that Welsh citizens will get more services as well as derive the most benefit from the existing services offered by their local pharmacy. It has also been designed to promote the different pharmacy careers and to ensure that an adequate number of employees within the pharmacy workforce are highly educated, trained, and available to fulfil the services' requirements. It recognises the potential of pharmacists to take on independent prescribing responsibilities and aims to promote their role in primary care settings in Wales. In addition, HEIW aims to offer funding to train all pharmacists with patientfacing roles to obtain independent prescribing qualifications. This would help to provide a sustainable workforce of IPPs and ensure the continuation of their services in community pharmacies, GP practices, and secondary care settings in Wales (NHS Wales 2023).

1.3.4. The development of NMIPs' Competency Framework

The practice experience of NMIPs required for the programme originally had to be under medical supervision as illustrated earlier in Section 1.1.2. However, a new UK pharmacy regulation in 2019 was announced in which DSMPs changed to Designated Prescribing Practitioners (DPPs), which authorised either medical professionals or NMIPs to mentor pharmacists during their independent prescribing training course (GPhC 2021). This change aimed at providing more training opportunities for pharmacists to be qualified as IPs and increase their numbers across different healthcare sectors, as DSMPs were not always available to mentor them (GPhC 2021). The eligibility criteria to become a DPP include having at least three years of experience as an active prescriber in a patient-facing role with appropriate knowledge and expertise within the area of clinical practice, demonstrating clinical leadership and professional integrity, and possessing experience or training in teaching and

supervising (GPhC 2021).

Other developments were related to expanding the scope of practice of IPPs and other NMIPs. The RPS released new guidance in 2022 aimed at supporting NMIPs, including IPPs, seeking to expand their independent prescribing scope of practice (RPS 2022). It acknowledged the need to broaden their expertise beyond narrow specialty focuses to do more general roles as IPs. This could involve broadening their prescribing within different medical conditions, improving their prescribing confidence, initiating new pharmacy services (e.g., pain management), or transitioning into new independent prescribing roles or settings. The guidance provided a structured framework to help IPs identify new prescribing areas for further development, plan skill enhancement through self-directed learning, courses, training, and mentoring, and document their newly developed areas and expertise. This framework aims to ensure that NMIPs have the required skills and knowledge during their training to provide their independent prescribing services in a legal, effective, and safe manner. It also presented case studies illustrating scenarios where already qualified NMIPs, including IPPs, have expanded their prescribing scope.

In terms of the scope of practice of other NMIPs, a change in the legislation in 2023 was announced by the UK Government allowing paramedic IPs and therapeutic radiographer IPs to prescribe specific controlled drugs (N.B. each of these professions prescribe different kinds of controlled drugs) (The UK Government 2023).

1.3.5. Developments in the initial education and training programme (IETP) of pharmacists in the UK

The current available routes for pharmacists to obtain an independent prescribing qualification in the UK are either through independent prescribing training courses or the IETP. The independent prescribing course consists of self-directed study, face-to-face teaching sessions, and practical training that are delivered and arranged by accredited facilities (see Section 1.1.2) (GPhC 2022). As mentioned previously, there has been a change in the requirements for the independent prescribing course entry in 2021, removing the need for at least two years of clinical experience in a particular therapeutic area before undertaking the course (GPhC 2021). The other route is through the new changes in the IETP in 2021 in the UK, which incorporated prescribing training and skills into undergraduate pharmacist education in order to allow them to become IPs ready from the point of registration (GPhC 2021). These changes also involved revising the learning outcomes over the entire five years of education and training of pharmacists to focus more on clinical decision making, clinical assessment skills, risk management, and clinical supervision (GPhC 2021). The new changes may eliminate the gaps in clinical and diagnostic skills for the newly registered pharmacists.

These changes would provide them with a greater degree of confidence, knowledge, and skills when practising their prescribing role, compared to the already qualified IPPs in the meantime who had to complete an independent prescribing course after they had become registered pharmacists.

In the UK, the new 'Standards for the Education and Training of Pharmacist Independent Prescribers' published by the GPhC (2022) states that from 2026, all new pharmacists who are going to join the GPhC register will be recognised as IP ready if they have met the following criteria: 1) have completed the 2021 IETP standards, 2) have passed the GPhC registration evaluation; and 3) have met the GPhC entry criteria. In Wales, the changes to facilitate the standards for the IETP were made by the HEIW in 2022 (HEIW 2022). These changes were to offer the independent prescribing qualification to new registrants by implementing the curriculum of the post-registration foundation pharmacist programme in collaboration with the RPS, which is a programme that provides clinical knowledge and skills for early career pharmacists to practise in any area at a 'generalist post-registration foundation level' (HEIW 2022; NHS Wales 2022). This programme also focuses on two domains: the prescribing governance domain and the consultation domain (HEIW 2022; NHS Wales 2022).

1.3.6. Indemnity insurance

Before 2019, there was a lack of clarity regarding the indemnity insurance for IPPs in Wales. However, since then the issue of indemnity insurance has been resolved by the General Medical Practice Indemnity (GMPI) scheme (NHS Wales 2019). This scheme provides indemnity insurance to all medical staff in GP practices for clinical negligence claims arising from incidents. It covers the activities associated with the definition of 'primary medical services', which are healthcare services delivered under a contract, agreement, or arrangement formed following specific sections of the NHS Wales Act 2006 (NHS Wales 2019). These sections are Section 41(2) (primary medical services), Section 42(1) (general medical services contracts), and Section 50 (arrangements by local HBs for the provision of primary medical services). Therefore, the prescribing activities of IPPs employed by GP practices fall within the category of 'primary medical services', which would be captured by the GMPI scheme. The indemnity insurance for IPPs in community pharmacies also depends on their activities (NHS Wales 2019). If it also falls within the category of 'primary medical services', it will be included in the GMPI, such as their prescribing role. However, some other activities, such as the dispensing service, may not be covered by the GMPI (NHS Wales 2019).

1.4. Summary

The role of NMPs has been a fast-evolving field since its implementation. In particular, pharmacy practice has significantly developed since the second Crown report that allowed the introduction of prescribing rights to pharmacists. Initially, a very low number of IPPs were based in primary care settings, including GP practices and community pharmacies, but with the changes in the primary care plan in Wales, such as the implementation of GP clusters and the pharmacy vision, many IPPs have moved to or started their prescribing role in this sector. With these developments, there will be even more changes in the future. As a result, it's important to explore and evaluate the implementation of this role in practice, as well as the views and considerations of practitioners to inform future policy decisions and future developments. Even though the aim and objectives were defined before some of these developments, the findings of the PhD will be discussed in relation to all relevant policies and practices.

This chapter explored the implementation of NMPs', including IPPs', role in the UK since its beginning. Chapter Two will provide a literature review of research conducted on the IPPs' role around the world and in the UK to date.

2. Chapter 2 - Literature Review

2.1. Overview

The previous chapter illustrated the definitions, types, and implementation of nonmedical prescribing in the UK. However, the adoption of NMPs' role, especially the incorporation of nurses and pharmacists among prescribing professionals, fundamentally began in the United States of America (USA) and Canada and then extended to the UK, New Zealand, and Australia. In contrast, it is very limited in other countries throughout the world (Bhanbhro et al. 2011; Kroezen et al. 2011; Raghunandan et al. 2017; Walpola et al. 2024). Outside the UK, nurses and pharmacists are the main HCPs who have been granted the authority to prescribe medicines. The ability of optometrists, midwives, and surgical podiatrists to prescribe has only been implemented in a few countries, including the UK, New Zealand, and Australia (Raghunandan et al. 2017; Walpola et al. 2024). Extending the drug prescribing mandate, particularly within primary care settings, has been implemented for some reasons. In North America, Australia, and New Zealand, NMPs' practice was adopted to overcome the low numbers of HCPs who provide healthcare services, especially around rural and remote regions (Hobson 2008; World Health Organization 2016). Other reasons that have contributed to the development of this new role were the expansion in population, an increase in morbidity rates, and providing more cost-effective healthcare services (Hobson 2008; World Health Organization 2016).

As the NMPs' role has been broadly adopted only in the above countries, it is necessary to understand its implementation, the available literature that investigated its utilisation, and the views of different stakeholders on their services, particularly on pharmacist prescribing (Raghunandan et al. 2017; Walpola et al. 2024). Three types of non-medical prescribing were identified in these countries: independent prescribing (adopted across all countries, except in New Zealand), supplementary prescribing (in the UK), and collaborative prescribing (across all countries, except the UK) (Ghabour and colleagues 2023a). Independent and supplementary prescribing were defined in Chapter One (Sections 1.1.1.2 and 1.1.1.1, respectively). Collaborative prescribing is defined by Weeks and Marriott as 'any spectrum of prescribing undertaken in collaboration with a medical practitioner, including the transcribing of medication orders, prescribing by protocol, initiating and modifying medication therapy' (Weeks and Marriott 2008, p. 271). It could also involve monitoring patients' medications and discontinuing treatment once the pharmacist has gained their prescribing authority (Alberta College of Pharmacists 2013; Evans 2022; Adams et al. 2023). This model involves a partnership between a doctor (medical practitioner) who is responsible for making the diagnosis and initial treatment decisions and a pharmacist prescriber to manage patients' conditions and their medications (Pearson et al. 2002; Adams et al. 2023). However, the overall patients' conditions, outcomes, and risks are the responsibility of the head of the team

(doctor) (Ministry of Health 2021a; Pharmacy Council 2021; Adams et al. 2023). A similarity between the collaborative and supplementary prescribing models is that both involve a partnership between a pharmacist prescriber and a doctor (Weeks and Marriott 2008). However, the supplementary prescribing model involves a specified CMP agreed upon by a medical practitioner, pharmacist, and patient, in which the pharmacist can prescribe only from this plan (DOH 2003). While collaborative prescribing does not require patients' agreement to prescribe medications within the team (Weeks and Marriott 2008). There were also some other differences identified in the literature regarding the implementation of pharmacist prescribing across these countries in terms of the adopted type of pharmacist prescribing, requirements to become a prescriber, training to obtain prescribing qualifications, and their healthcare sectors of practice, which are summarised in Table 2.

The next section will discuss the type of literature review conducted, followed by detailed information regarding the implementation of this role and available literature in each country, focusing on pharmacist's prescribing roles.

Table 2 Pharmacist prescribing across the USA, Canada, Australia, New Zealand, and the UK

Country	Type of pharmacist prescribing	Requirements to obtain prescribing qualifications	Healthcare sector of practice
USA	- Mainly collaborative prescribing. A few states have implemented a very limited independent prescribing role.	 Varies across different states, but all require clinical experience and being registered with the regulatory organisation in each state. Some states require the completion of additional short courses and training. 	 Varies across different states, but collaborative prescribers are across all settings. IPPs are mainly in hospitals and community pharmacies, and a few are in outpatient primary care clinics.
Canada	- Both collaborative and independent prescribing.	 Varies across different provinces, but mainly requires one year of full-time clinical experience, having a Pharm D degree from a Canadian Council for Accreditation of Pharmacy Programmes (CCAPP), having a good collaboration with other HCPs, and continuing the development of their clinical knowledge and skills, and register with the regulatory organisation in each province. Some provinces require the completion of an online module for minor aliments scope of practice. 	- Across all healthcare settings.
New Zealand	- Only collaborative prescribing.	 Obtaining a postgraduate clinical qualification of prescribing. Having a minimum of three years of clinical experience. Completing at least 600 hours of applied pharmacotherapy. Registering with the Pharmacy Council of New Zealand. 	- Only in hospitals and outpatient clinics.
Australia	 Only collaborative prescribing. Independent prescribing is being piloted at this time in only three states. 	 Holding a bachelor's or master's degree in pharmacy via an accredited Australian university. Registering with the Pharmacy Board of Australia. Having at least two years of clinical experience. Developing a portfolio of clinical training, experience, and skills. 	Only in hospitals and outpatient clinics.The IPPs' pilot is only in community pharmacies.
UK	- Both independent prescribing and supplementary prescribing.	 Holding a pharmacy degree, being registered with the GPhC, and completing an independent prescribing training course. From 2021, there are no requirements for 2 years of experience in practice. From 2026, all new pharmacists registered with the GPhC will be recognised as IPs if they have completed the 2021 IETP standards, passed the GPhC registration evaluation, and met the GPhC entry criteria. 	- Across all healthcare settings.

2.2. Type of literature review

This chapter aims to discuss the implementation of NMPs' roles and provide a literature review focusing on the pharmacist prescribing role in the UK, the USA, Canada, New Zealand, and Australia. The literature review will highlight the studies that explored pharmacist prescribing regarding its implementation, training, and the views of the public, patients, other HCPs, stakeholders, and the pharmacist prescribers themselves. The literature review covers the time since the initiation of the pharmacist prescribing role (supplementary) in 2003 in the UK to 2024. A narrative literature review approach was utilised (also known as a traditional literature review), which is an unstructured review that is used to examine and describe the current literature. It is also used to establish a theory, identify a gap, or provide a justification for a research topic (Jesson et al. 2011; Stratton 2019). Since this literature review has not focused on a very specific topic, such as understanding the role of IPPs in managing a certain medical condition or clinic, the use of systematic, meta-analysis, and Cochrane review was deemed to be inappropriate (Munn et al. 2018). As the investigated topic is very broad, a scoping review was also not considered (Munn et al. 2018; Tricco et al. 2018). A rapid review was not utilised since the aim of this literature review was not to make evidence-based decisions about a practice issue or policy within a specific time frame (Grant and Booth 2009; Munn et al. 2018).

A narrative literature review has the advantages of reviewing very broad areas of investigation, including studies with different methodologies, providing a summary of a topic, justifying an examined research subject, and identifying a gap in the literature compared to other types of literature review (Grant and Booth 2009; Munn et al. 2018; Stratton 2019). Although narrative review lacks the use of a structured method to conduct the literature review compared to other types, it provides a more flexible approach that is considered helpful in investigating broad areas (Munn et al. 2018). Since the scope of this literature review is considered very broad (the roles of pharmacist prescribers in the USA, Australia, Canada, New Zealand, and the UK), different areas and topics may emerge from the data. This may require the use of a descriptive analysis approach, which can be conducted via the use of a narrative review that is characterised by its flexibility during data analysis (Peters et al. 2020). As a result, a narrative review was considered appropriate to conduct a literature review for this PhD thesis.

The researcher aimed to ensure transparency of the review by highlighting the steps applied. First, the PCC (Population, Concept, and Context) framework (Peters et al. 2020) was used to develop the literature review question. Based on the scope of the literature review illustrated above, the review's Population is 'pharmacist prescribers', the Concept is 'the role of pharmacist prescribers', and the Context is 'the UK, the USA, Australia, Canada, and New

Zealand'. Therefore, the research question aims to answer:

'What is the available empirical evidence of the role of pharmacist prescribers in the UK, the USA, Australia, Canada, and New Zealand?'.

No ethical approval was needed to conduct this literature review as it did not involve the use of participants to collect data; no personal or confidential data were collected. Databases searched included Ovid Medline, Ovid Embase, Ovid Emcare, Scopus, and Web of Science (Appendix 1 shows screenshots of the databases' search). These databases were chosen as they offer good coverage and a wide range of literature related to healthcare and the pharmacy profession, ensuring an effective and comprehensive search process (Bramer et al. 2017). In addition, the combined use of these databases was used to ensure relevant studies were captured, to minimise bias, and maximise the inclusion of diverse related topics (Bramer et al. 2017). The searches were performed using truncations and advanced Boolean AND/OR operators that combined keywords to identify peer-reviewed research (Gough et al. 2012). The keywords used to search were identified from the literature related to pharmacist prescribing and they are presented in Appendix 2. A specialist librarian in the pharmacy subject assisted with the use of correct search terms and searching within different databases. After searching, findings were imported into the EndNote Software (Version 20), which was used to remove duplicated articles. Thereafter, the identified studies were imported into Microsoft Excel (Version 16), in which study selection occurred. The selection criteria for relevant literature were limited to the relevant published and peer-reviewed primary research studies in English from 2003 to 2024. It is recognised that grey literature is not formally and rigorously peer-reviewed (Bramer et al. 2017). Therefore, a decision was made to not include it since the focus of this search was to specifically look for evidence-based and published peer-reviewed articles (the inclusion and exclusion criteria are presented in Appendix 3). Literature that investigated specific topics not related to the role of pharmacist prescribing was excluded. For example, studies that focused on guidelines or policies in healthcare facilities or the pharmacological properties of medications.

The process of selecting a study began with reviewing its title, followed by its abstract using the inclusion criteria. If the title and abstract indicated that it might be appropriate to be included, a full text of this potentially relevant research was further reviewed to make sure it was aligned with the inclusion criteria. The significant findings related to the purpose of this literature were narratively reported using a descriptive approach for each country in the following sections.

2.2.1. USA

In 1969, certain practitioners, including nurses and doctor assistants, in remote and rural areas in the USA, gained authority to prescribe medicines for patients in the primary care

sector under the doctors' supervision and control to increase patients' access to treatment and overcome doctors' shortage (Craig 1996). The authority of pharmacists to collaboratively prescribe medicines in the USA began early in the 1970s (Carmichael et al. 1997). Their role involved managing patients with ongoing medications for certain chronic diseases or acute conditions such as flu under the supervision of a doctor. Florida was the earliest state, in 1984, to permit individual pharmacists to prescribe drugs independently (Carmichael et al. 1997). Nonetheless, during that period, the degree to which a pharmacist may independently or dependently prescribe medicines in the USA was restricted to specific drugs, with most of them being OTC medicines that pharmacists could supply with no need for prescriptions to be issued (Eng 1987; Doering 2007). The ability to prescribe OTC medicines is similar to the role that pharmacists traditionally had within the UK where they are able to sell OTC medicines. This is distinct from the independent prescribing role of pharmacists in the UK that started in 2006 (2007 in Wales), in which they were able to prescribe any medication within their area of competence.

Since the early 1990s, the structure of the American medical prescribing practice has significantly developed. However, the right to prescribe medicines independently in the USA by nurses and pharmacists differs between states based on their individual regulations and it can only be obtained after achieving a certain postgraduate clinical qualification as either Pharm D or a postgraduate master's degree (Hammond et al. 2003; Evans 2022; Adams et al. 2023). Only a few states, such as New Mexico and Idaho, alongside Florida, have moved towards more independent prescribing rights for pharmacists after obtaining additional certifications and training (Evans 2022; Adams et al. 2023; Munger 2023). These states developed protocols that specify the medical conditions, including some acute minor conditions like hay fever, simple infections, and skin conditions, and medications that can be managed and prescribed by pharmacists, such as opioid antagonists, smoking cessation products, hormonal contraceptives, and immunisations (Evans 2022; Adams et al. 2023). The list of conditions does show some similarity to the CAS service within community pharmacies in Wales. In addition, the pharmacists' independent prescribing scope of practice is very limited across different states in the USA compared to the UK, in which IPPs can diagnose their patient's condition and also have a much wider scope of practice. In other states in the USA, pharmacists may prescribe medicines collaboratively as a member of the team under a doctor's supervision (Drug and Therapeutics Bulletin 2006; Roberts and Gainsbrugh 2010; McBane et al. 2015; Evans 2022; Adams et al. 2023).

The implementation of the pharmacist collaborative prescribing role is across all healthcare settings, while IPPs are mainly based in hospitals and community pharmacies, and to a lesser degree in outpatient primary care clinics (Hammond et al. 2003; Feehan et al. 2017;

Evans 2022; Adams et al. 2023). There was a lack of studies within the literature exploring the implementation of pharmacist prescribing in the USA across different states and healthcare sectors, their volume of prescribing, and the utilisation of this role. Most of the studies that explored pharmacist prescribing in the USA focused on the clinical effectiveness and patient outcomes of their interventions within specific areas of practice. The identified therapeutic areas of pharmacist prescribing in the literature were contraception medications (Gardner et al. 2008; Rodriguez et al. 2016; Batra et al. 2018; Anderson et al. 2019; Ahmad et al. 2022; Pelaccio et al. 2022), naloxone co-prescribing (Xu and Mukherjee 2021; Dhakal et al. 2022); statin prescribing (Haby et al. 2020; Vincent et al. 2020), managing opioid misuse (Lagisetty et al. 2020), hypertension management (Victor et al. 2018), and sitagliptin co-prescribing (McFarland et al. 2009). Most of these studies identified the significant impact and clinical effectiveness of pharmacist collaborative prescribing within these clinical areas of practice.

Similarly, almost all the studies that explored the views of pharmacists, patients, and relevant stakeholders about the collaborative prescribing role of pharmacists were related to specific services or a very narrow scope of practice, such as tobacco cessation service (Xiong et al. 2021; Berry et al. 2023), naloxone management (Skoy et al. 2021; Banawis et al. 2023), and hormonal contraception service (Borrego et al. 2006; Rodriguez et al. 2016b; Lio et al. 2018; Wilkinson et al. 2018; O'Connell et al. 2020; Rodriguez et al. 2020; Seamon et al. 2020; Rafie et al. 2021; Rodriguez et al. 2021; Gomez et al. 2022; Magnusson et al. 2022; Adgalanis et al. 2023). Only one study (Feehan et al. 2017) aimed to explore patients' preferences for the healthcare services provided by pharmacists in the USA, which was related to their role in community pharmacies, using a discrete choice experiment online survey (n= 9202). The factors that could maximise their acceptance of the role included ensuring access to their full medical records, offering appointments to see patients, providing limited physical and diagnostic assessment services (e.g., measuring vital signs and blood pressure), and drug prescribing services. Most participants provided a strong preference for administering vaccinations at community pharmacies rather than traditional healthcare settings. Almost twothirds of the participants also preferred chronic conditions to be managed by pharmacists rather than doctors or other HCPs, particularly their chronic medications management, due to the increased accessibility to treatment and shorter waiting time. They were also willing to pay additional costs for this more convenient option. However, patients implied a higher preference for the management of their conditions by pharmacists under doctors' oversight than independently.

The studies that explored the prescribing of hormonal contraceptive services by pharmacists indicated a high degree of patient satisfaction, acceptance, support, positive experience, and convenience of this role. These studies also highlighted the benefits of these

services, which were the increased access to contraceptive treatment and consultations, particularly in urban areas, as well as educating patients about medications (Wilkinson et al. 2018; O'Connell et al. 2020; Rodriguez et al. 2020; Seamon et al. 2020; Gomez et al. 2022; Magnusson et al. 2022; Adgalanis et al. 2023). Pharmacist prescribers also expressed their high confidence, capabilities, willingness, knowledge, and skills to do the role (Borrego et al. 2006; Rodriguez et al. 2016b; Lio et al. 2018; Seamon et al. 2020; Rafie et al. 2021; Rodriguez et al. 2021). They also indicated high satisfaction with their prescribing role as it improved their profession (Lio et al. 2018; Rafie et al. 2021; Rodriguez et al. 2021). However, some concerns and barriers regarding this role were highlighted, including lack of patients' awareness, competence and training (Lio et al. 2018; O'Connell et al. 2020; Gomez et al. 2022; Magnusson et al. 2022), privacy issues related to the location of the consultation (Wilkinson et al. 2018; Gomez et al. 2021), limited training opportunities and support (Rodriguez et al. 2016b; Rafie et al. 2021; Rodriguez et al. 2021), lack of funding, policies, and regulatory support (Borrego et al. 2006; Rodriguez et al. 2020; Seamon et al. 2020), lack of consultation skills (Wilkinson et al. 2018), and personal beliefs (Borrego et al. 2006).

Similar findings were reported in the studies that investigated the other prescribing services, including naloxone prescribing and tobacco cessation, provided by pharmacists (Xiong et al. 2021; Skoy et al. 2021; Banawis et al. 2023; Berry et al. 2023). However, additional barriers and concerns were identified, including governance issues (Banawis et al. 2023), lack of pharmacist prescribers' experience compared to doctors (Berry et al. 2023), and lack of time (Xiong et al. 2021). Other benefits of the role were also reported, including the delivery of healthcare services in a personalised approach, improving patient safety (Skoy et al. 2021), and involving patients in the treatment plan and decision (Xiong et al. 2021).

2.2.2. Canada

In the early 1990s, collaborative nurse prescribing was introduced in Canada for the same reason as its implementation in the USA, which was to address the shortage in the number of doctors who served the population in isolated and remote regions to improve patients' care and access to treatment (Forchuk and Kohr 2009). In 2006, the nature of nurses' prescribing practice was reassessed by the Ministry of Health in Canada, which recognised the benefits of this role within these regions. As a result, they recommended increasing the number of collaborative nurse prescribers, and the Minister of Health proposed the extension of collaborative prescribing rights to pharmacists (Sullivan 2008). Consequently, the Health Professional Regulatory Advisory Council (HPRAC) pursued the Minister's proposal of extending collaborative pharmacist prescribing, which was then implemented in 2007 (Sullivan 2008). However, the uptake of collaborative pharmacist prescribing was slow until the change in the reimbursement model in 2012/13, which allowed a lot of pharmacists to obtain

prescribing authorisation in Canada (Morton 2024). Since then, pharmacists and advanced nurse practitioners (ANPs) who have gained prescribing authority across Canada mainly prescribe collaboratively (Alberta College of Pharmacy 2013). However, the practice in Canada differs from one province to another in terms of the degree of pharmacist prescribing implementation, legal and policy frameworks, education and training, and professional requirements; these are determined by regulatory bodies in each province (Bhatia et al. 2017; Habicht et al. 2017). Alberta was the first province to initiate collaborative and independent pharmacist prescribing in Canada through the implementation of a formal Additional Prescribing Authorization (APA) model by the Alberta College of Pharmacy, which allows pharmacist prescribers to prescribe only Schedule 1 drugs (medications that require a prescription to sell and dispense) in line with Section 45 (subsections 2 and 3) of the Health Professions Restricted Activity Regulation of clinical pharmacists, ordering and reviewing laboratory tests, and administration of injectable medicines (Government of Alberta 2023; Alberta College of Pharmacy 2024; National Association of Pharmacy Regulatory Authorities 2024). Schedule 1 drugs include all federally scheduled drugs in Canada (n= 1635), such as statins and penicillin (Government of Alberta 2023; National Association of Pharmacy Regulatory Authorities 2024). Section 45 (subsection 2) of the Health Professions Restricted Activity Regulation states the need for clinical pharmacists to fulfil the council requirements to become pharmacist prescribers on the registrar. Section 45 (Subsection 3) states that clinical pharmacists can only prescribe Schedule 1 drugs if they determine the appropriateness of the required medication(s) after assessing the patient, receiving a recommendation of patient treatment from other HCPs who have the authorisation to prescribe Schedule 1 drugs, or after consultation or collaboration with other HCPs who can prescribe Schedule 1 drugs (Government of Alberta 2023). Some other provinces, such as Saskatchewan, British Colombia, Ontario, Quebec, and Manitoba followed Alberta's model of pharmacist prescribing (Alberta College of Pharmacy 2013; Canadian Pharmacists Association 2023). However, the range of medicines that they can prescribe differs based on the province's regulations, which could be restricted to certain medicines such as emergency hormonal contraception (Alberta College of Pharmacists 2013; Alberta College of Pharmacy 2014; Alberta College of Pharmacists 2021; Canadian Pharmacists Association 2023).

The requirements to qualify as pharmacist prescribers in Canada also vary across different provinces, which reflects the variation in regulations and scope of practice. However, the general requirements are having a Pharm D degree from a CCAPP, at least a full-time year of clinical and patient-facing role experience, having collaborative relationships with other HCPs, having and maintaining the essential knowledge, skills, and manners to be able to make a clinical judgment related to patient care, completing additional education and training

modules (in some provinces) related to patient assessment, clinical decision-making, and prescribing practice (Alberta College of Pharmacy 2023). Thereafter, they apply to the regulatory organisation in each province and provide evidence of these required qualifications, skills, experience, and competence (Alberta College of Pharmacy 2023). The education and training modules also vary across different provinces, for example in Ontario, an online mandatory orientation module known as Minor Ailments Prescribing Module (that can take only one hour to complete) must be completed to become prescribers (Ontario College of Pharmacists 2024), whereas in Alberta no such module is needed (Alberta College of Pharmacy 2023). In provinces such as Nova Scotia all registered pharmacists have permission to prescribe for certain minor ailments without the need for additional training. However, the University of Dalhousie in Nova Scotia offers online training and education courses for pharmacists to ensure their CPD (Habicht et al. 2017). This variation was also identified in the study conducted by Ghabour and colleagues (2023a), which highlighted the need for addressing these differences to inform various stakeholders, such as the Government and regulatory bodies, and provide a national education and training framework, in order to achieve effective pharmacist prescribing services across the country. The lack of CPD support for pharmacist prescribers in most provinces was also indicated as a barrier to the development of their role (Shearer et al. 2018).

Initially, the role of pharmacist prescribers was mainly implemented in hospitals and outpatient primary care clinics (Law et al. 2012; Habicht et al. 2017). However, one prescribing service provided by all registered pharmacists across different provinces in community pharmacies was related to emergency prescribing of a minimum and sufficient amount of patients' medications until they can see their doctors (Law et al. 2012; Canadian Pharmacists Association 2023). Some IPs were running clinics in hospitals and outpatient clinics, such as hypertension and diabetes management clinics, in which already diagnosed patients were referred by doctors for the pharmacist to initiate, adjust, stop, or change their medications (Al Hamarneh et al. 2013; Tsuyuki et al. 2015). Over the last two years, IPPs were implemented more effectively in community pharmacies across different provinces, except in Nunavut and Northwest Territories, as a walk-in service to prescribe for minor conditions such as mild acne, diarrhoea, and allergic rhinitis (Alberta College of Pharmacists 2023b; Alberta College of Pharmacy 2023c; Morton 2024). However, the range of minor conditions and prescribing authorities for pharmacists varies across provinces. For example, Alberta has a wide scope of minor conditions that pharmacist prescribers can prescribe for compared to other provinces (Alberta College of Pharmacists 2021; Canadian Pharmacists Association 2023; Morton 2024). In conclusion, three types of pharmacists' prescribing services are implemented in some provinces in Canada. First is the independent prescribing for minor and self-limited

conditions in community pharmacies. Second is collaborative prescribing in hospitals and primary outpatient clinics. Third is comprehensive drug therapy management as a collaborative (mainly) or independent prescribing in hospitals and outpatient primary care clinics (Alberta College of Pharmacists 2021; Canadian Pharmacists Association 2023; Morton 2024).

According to Pojskic and colleagues (2014), Schindel and colleagues (2017), and Grant and colleagues (2023), there has been increased recognition of pharmacists as collaborative and independent prescribers in Canada as many provinces utilise their services more to achieve better medication outcomes and reduce doctors' workload. Only a few studies in the literature have explored the integration, volume, and therapeutic areas of pharmacist prescribing in different healthcare settings in Canada. In terms of the implementation of the pharmacists' prescribing role within healthcare, Grant and colleagues (2023) identified the well-established role of pharmacists as collaborative and independent prescribers in hospitals, and their growing role as IPs in community pharmacies. The exact role of pharmacist prescribers also varied widely depending on the healthcare sector as community pharmacists were focusing more on product prescribing compared to hospital and primary care clinic pharmacists who applied a disease-focused prescribing approach (Guirguis et al. 2014). In addition, Faruquee and colleagues' (2018) study indicated that 74% of pharmacist prescribers were involved with renewing (repeat) prescribing of medications (in community pharmacies), 17% modifying prescribed medications, and only 9% initiating medications (the last two groups were mainly working in hospitals). Regarding the pharmacist prescribers' volume of prescribing, only one study used secondary data analysis to examine the volume of pharmacist prescribing (Grant et al. 2023), which revealed a significant increase in the average number of prescribed items over the study period which was mainly related to chronic medical conditions such as hypertension. Other studies, including Faruquee and colleagues' (2018) and Banh and Cave's (2021) studies, used different methodological approaches (mainly surveys) and identified chronic medical conditions as the main area of pharmacists' prescribing. However, Heck and colleagues (2015) highlighted that the pharmacists who participated in their study (n= 77) used their prescribing role as part of a multidisciplinary team, independent prescribing by pharmacists was only for a minority of patients, and their prescribing services varied across different hospitals. Similarly, some studies indicated that the utilisation of the pharmacists' prescribing role was highly variable as many pharmacist prescribers were not using their prescribing rights in specific clinical areas such as paediatric and neonatal acute care (Barton et al. 2020), oncology (Hynes et al. 2023), and inpatient department (Almawed et al. 2023). Almost two-thirds of the participants (n= 38 pharmacists, of which 13 IPPs) in the Guirguis and colleagues' (2014) study identified their care settings as

adopters of the pharmacists' prescribing role, while the work settings of the other one-third of the participants were not utilising this role.

Some challenges and enablers to the implementation and utilisation of the pharmacist prescribers' role were also reported in the literature. The factors impacting the adoption of independent pharmacist prescribing in Canada were explored in two studies (Makowsky et al. 2013; Isenor et al. 2018). Both studies identified regulatory factors (e.g., legal concerns and the existing prescribing model), pharmacy related factors (e.g., adequate work staff and available time for prescribing), healthcare system factors (such as limited remunerations, pharmacist-doctor relationship, and pharmacist-patient relationship), and individual factors (such as knowledge and skills) as the most commonly reported factors that impacted their prescribing behaviour; or their decisions to qualify as prescribers. Some other barriers reported in the literature were high workload, increased responsibilities, communication issues with other HCPs (Hughes et al. 2014; Almawed et al. 2023), lack of confidence, the need for additional education (Heck et al. 2015; Waite et al. 2018), the complex and long prescribing authorisation application process, the rigorous requirement for evidence of competency, and the difficulty in finding prescribing mentors (Charrois et al. 2012; Hutchison et al. 2012). However, Rosenthal and colleagues (2015) indicated that pharmacists who had the opportunity to work in a supportive cultural environment and those who were more passionate and open to new experiences were more likely to qualify as prescribers and overcome the challenges in order to utilise their prescribing rights. The enablers of this role were also highlighted in the literature, which were the positive dynamics of the interdisciplinary care team and the benefits of the role. Both enablers encouraged many pharmacists to obtain and utilise the prescribing rights (Hutchison et al. 2012; Hughes et al. 2014; Heck et al. 2015). Benefits of the role were also reported, including professional development, as many pharmacists believed this role represented a natural progression of their pharmacy profession (Hutchison et al. 2012; Hughes et al. 2014), providing more effective healthcare services (Hutchison et al. 2012), enhancing patient care regarding their medication optimisation and medical conditions (Charrois et al. 2012; Hughes et al. 2014), and improving their relationships with other HCPs as the role fostered a collaborative practice approach (Heck et al. 2015; Banh and Cave 2021).

The increase in the uptake of collaborative and independent pharmacist prescribing in Canada provided an opportunity for some researchers to explore the clinical effectiveness of this role. A few quantitative studies used randomised control trials to investigate this matter within certain clinical conditions (Al Hamarneh et al. 2013; Tsuyuki et al. 2015; Tsuyuki et al. 2016a; Tsuyuki et al. 2016b; Beahm et al. 2021). The findings of these studies showed a significant improvement in patient's conditions as follows: dyslipidaemia and achieving

cholesterol targets (Tsuyuki et al. 2016a), uncomplicated UTI management and following antimicrobial stewardship guidelines (Beahm et al. 2021), glycaemic management in poorly controlled type 2 diabetes (Al Hamarneh et al. 2013), hypertension control and management (Tsuyuki et al. 2015), and in the reduction of the risk of cardiovascular (CVD) events (Tsuyuki et al. 2016b).

With the extension of the pharmacist prescribing role as an initiative in Canada to expand effective healthcare services delivery, there was limited research on pharmacist prescribers, the public, patients, GPs, pharmacists, other HCPs, and other stakeholders' views on the pharmacist collaborative or independent prescribers in the country. The studies that explored pharmacist prescribers' views (Hutchison et al. 2012; Hughes et al. 2014; Heck et al. 2015; Banh and Cave 2021; Almawed et al. 2023) focused on the challenges and enablers of their role, as illustrated above. None of these studies explored the satisfaction of pharmacist prescribers or their preferred type of prescribing as either collaborative or independent prescribers. Perepelkin (2011) conducted a study to explore public opinion of pharmacist prescribing in Canada during early implementation in Saskatchewan province. The findings revealed that although the public generally trusts pharmacists in terms of their medication expertise and knowledge, there is variability in their understanding of their extent of prescribing authority. The study emphasised the need for increasing public awareness and education of this role to improve their acceptance and communication with pharmacist prescribers. Patients' satisfaction and views of pharmacist prescribers' services were examined by Mansell and colleagues (2014) for minor ailments management, Famiyeh and colleagues (2019) for different community pharmacies services, and MacDonald and colleagues (2023) for human immunodeficiency virus (HIV) prophylaxis and management. These studies indicated a high degree of patient satisfaction with and support for this role. Patients (n= 125) in the study conducted by Mansell and colleagues (2014) identified that they had better and quick access to treatment, their symptoms improved, and pharmacist prescribers were experts in medicines, therefore, they were not concerned with side effects. However, Famiyeh and colleagues' (2019) and MacDonald and colleagues' (2023) studies highlighted access to medical records and laboratory results, clinical knowledge and skills, and the degree of pharmacist and doctor collaboration as a few participants believed that prescribing should be the doctors' responsibility, as key concerns for some patients. These concerns would need to be addressed in order to improve their willingness to use and support pharmacist prescribers' services.

The different stakeholders' and HCPs' (except for doctors as the literature lacked their views on this role in Canada) views of the pharmacist prescribing role were explored by Pojskic and colleagues' (2014), Schindel and colleagues' (2017), Lewis and colleagues' (2021), and

Hutchison and colleagues' (2012) studies. These studies indicated their acceptance and support of this role highlighting its benefit in improving patient quality of care. In addition, the pharmacist participants (who did not have prescribing authority) in the Lewis and colleagues' (2021) and Hutchison and colleagues' (2012) studies showed their willingness to become prescribers as they believed this role would improve their pharmacy profession and patient care. However, the lack of a clear understanding of the pharmacists' prescribing role and their training and capabilities was also emphasised in these studies (Hutchison et al. 2012; Pojskic et al. 2014, Schindel et al. 2017, and Lewis et al. 2021). The stakeholders in Pojskic and colleagues' (2014) study added that the lack of accredited training and continuing education programmes for pharmacist prescribers may negatively affect patient safety, particularly with the lack of specific diagnostic and clinical assessment skills training. In addition, Schindel and colleagues (2017) emphasised the need for more efforts from healthcare stakeholders to effectively implement the pharmacist prescribing role, particularly as IPs.

2.2.3. New Zealand

Similar to the other countries, New Zealand's effort to adopt non-medical prescribing was mainly to improve patients' access to medications and overcome shortages of doctors (Raghunandan et al. 2017; The Royal New Zealand College of General Practitioners 2020). In 1991, midwives were the first group of NMPs in New Zealand to gain prescribing authority (Moller and Begg 2005). In 2001, prescribing rights were extended to include nurse practitioners with a postgraduate master's level qualification to prescribe independently. This was mainly in the primary care sector to deal with medical conditions such as asthma, diabetes mellitus, mental health, occupational health as well as family medicine (Moller and Begg 2005). Prescribing rights were then broadened to involve optometrists in 2005 to prescribe either independently or dependently (collaboratively). In 2013, the list of NMPs widened to legally authorise competent pharmacists who have a postgraduate degree in clinical practice to only prescribe medicines collaboratively (known as designated pharmacist prescribers) (Parliamentary Council Office 2013). Their prescribing role was implemented within a defined clinical area of practice, such as renal, oncology, and paediatric care, and only in hospitals and outpatient departments (Raghunandan et al. 2017; Ministry of Health 2021a). The aim of utlising this role is to use their skills efficiently in order to optimise patients' medication management and improve their access to appropriate treatment clinics (Parliamentary Council Office 2013; Pharmaceutical Society of New Zealand Incorporated 2014). Currently, the designated pharmacist prescribers in New Zealand are allowed to prescribe from an updated list of a total of 1,713 medications within their clinical area of practice, which includes 200 new medications that were added to their prescribing formulary in 2021 (Ministry of Health 2021b). Recently, in 2016, dietitians with a postgraduate master's degree were the last group of HCPs

permitted to prescribe medicines collaboratively in New Zealand (Raghunandan et al. 2017).

Only two universities, which are the University of Auckland and the University of Otago, are offering a postgraduate certificate in pharmacist prescribing in New Zealand and only accept a small number of candidates (Pharmacy Council 2021). This course is a postgraduate clinical qualification (Diploma) that involves both taught sessions and practical training, which is delivered over at least one year. The requirements for pharmacists to enter this course are completing at least 600 hours of applied pharmacotherapy and having a minimum of three years of recent post registration clinical experience within a collaborative healthcare team environment. Then, after completing the course, pharmacists must register with the Pharmacy Council of New Zealand in the Pharmacist Prescriber Scope of Practice (Pharmaceutical Society of New Zealand Incorporated 2014). The whole process for pharmacists to qualify as prescribers could therefore take a long time and the course is usually self-funded (Dadelszen 2019; Pharmacy Council 2021; Ghabour et al. 2023a). These factors might therefore have contributed to a low number of pharmacist prescribers in New Zealand (Pharmacy Council 2020; Pharmacy Council 2022), compared to the UK in which pharmacists can be qualified as prescribers in a much shorter time. It might also have led to a slow increase in the number of collaborative pharmacist prescribers in New Zealand over the years since its implementation (n= 15 in 2016, n= 34 in 2020, and n= 46 in 2022) (Pharmacy Council 2020; Pharmacy Council 2022). A recent study conducted by Ghabour and colleagues (2023b) also highlighted some barriers to undertaking the course that were reported by pharmacist participants, who were not qualified as prescribers. These barriers were the lack of funding and institutional support, inability to find a medical supervisor, having less than three years of clinical experience within a collaborative healthcare team, inadequate up-to-date knowledge, the length of the prescribing programme, and the lack of remuneration for practising this role. However, a new Health Workforce Plan 2023/24 (Health New Zealand 2023) indicated a significant investment (\$4 million) and commitment to increase the number of training places to allow 50 pharmacists to be registered as prescribers each year from 2024 to 2026, to have a more sustainable workforce.

A very limited number of studies were identified in the literature review that have explored the role of collaborative pharmacist prescribers in New Zealand. Only one study, which was conducted by Raghunandan and colleagues (2021b), examined the volume of prescribing by NMPs, including collaborative pharmacist prescribers, using secondary data analysis obtained from a national database between 2016 and 2020. The findings indicated that the proportion of NMP pharmacists, who issued at least one prescription, increased from 1% in 2016 to 9% in 2019. The study emphasised that although pharmacist prescribing has increased over time, their number and prescribing volume could have been utilised further to

overcome the shortage of medical practitioners and improve patients' access to treatment, particularly for chronic conditions' management in primary care settings in New Zealand. Similarly, most pharmacists in other studies (Raghunandan et al. 2021a; Ghabour et al. 2023b; Norman et al. 2023) highlighted the potential positive impact of the prescribing role of pharmacists in the primary care sector, including community pharmacies and primary care settings, that could improve the healthcare system, delivery of healthcare services, increase patients' access to treatment, and potentially relieve pressures on other HCPs and healthcare settings. Raghunandan and colleagues (2021a) added that financial incentives were a less influential factor for pharmacists to qualify as prescribers compared to factors related to their professional satisfaction and patient interaction, which they highly valued. Further benefits were identified by the pharmacist prescribers in the Norman and colleagues' (2023) studies, including spending more time with patients compared to doctors and nurses as they used a holistic approach to manage their chronic conditions, applying pharmacological and lifestyle interventions, as well as patients' education. They also highlighted the significance of considering the 'whole person' in their care approaches, as well as tailoring treatments according to individual patient requirements. Most pharmacists who participated in this study, and in the study conducted by Raghunandan and colleagues (2021a) were in favour of the independent prescribing role rather than the collaborative one as they believed they had the required skills and knowledge. Pharmacists in the Raghunandan and colleagues' (2021a) study had a strong preference for managing patients with minor acute conditions, such as for minor ailments, in community pharmacies, whereas participants in Norman and colleagues' (2023) study favoured managing patients with chronic conditions as they were more familiar with.

Public opinion on the pharmacist prescribing role in New Zealand was explored in only one study, which was conducted by Raghunandan and colleagues (2023). In this study, most participants strongly preferred pharmacist prescribers with a high level of clinical experience. The findings indicated the characteristics of the pharmacist prescribers' services that participants would prefer, which involved focusing on medication optimisation and only making changes to current medications, having a shorter waiting time with lower consultation costs, and providing their services over longer working hours, while the duration of consultation was the least important preference.

Mixed patients' perceptions about the role of pharmacists as collaborative prescribers in New Zealand were identified in the literature. Some patients in the study conducted by Officer and colleagues (2021a; 2021b) were satisfied with pharmacist prescribing services, particularly with the holistic healthcare approach, educational level and competence, personalised provision of care, and convenience of accessibility. However, many participants

displayed an unclear understanding of the role and services of pharmacists as prescribers, as well as their position within the healthcare system (Officer et al. 2021b). All participants placed doctors at the top of the practice hierarchies, followed by nurses, and put pharmacist prescribers underneath them, as they viewed doctors as managers of their healthcare. Some participants indicated that effective communication with those practitioners was a crucial factor as it would result in a better understanding of their role within the hierarchy and higher satisfaction with their services (Officer et al. 2021b). In addition, most participants emphasised the need for pharmacist prescribers to be more accessible, engage more with them, and practise their services with passion to improve their views as patients on their prescribing role (Officer et al. 2021a).

Doctors' opinions on the potential pharmacists' role as prescribers (before the implementation of their services) were highlighted in the study conducted by Hatah and colleagues (2012), which also indicated a mix of positive and cautious views. All doctors in this study were supportive of the new clinical services provided by pharmacists, such as medication review, but less supportive and protective of potential pharmacists' role as prescribers. Most doctors acknowledged the benefits of the clinical services by pharmacists as they believed it helped in improving medication management and enhanced patient education and compliance with medicines. However, the majority expressed concerns regarding their clinical knowledge and skills to undertake the prescribing role compared to doctors. Some challenges to this potential role, at that time, were identified, which were the lack of a clear boundary to the prescribing services, lack of public and patients' awareness of this role, the possibility of not fully being incorporated within existing healthcare teams and building work relationships, and uncertainty about their prescribing competence. Similar views were reported by different stakeholders in the study conducted by Wheeler and colleagues (2012), which highlighted the need for a new study to understand the current views of doctors, relevant stakeholders, and other HCPs about the pharmacist prescribing role.

2.2.4. Australia

To date, NMPs' role is a topic that has resulted in significant political debate in Australia, since there is an opinion that the country has been extremely slow in adopting this practice (Tonna et al. 2007; Hale et al. 2016; Ogilvie et al. 2022). The practice is not unfamiliar in Australia since nurses, midwives, optometrists, and surgical podiatrists have been permitted to issue prescriptions under certain circumstances and legislations in various states (RACGP 2013). For instance, since the 1990s, Advanced Nursing Practitioners, with a minimum of a postgraduate master's degree, have been conducting collaborative prescribing and also allowed to undertake independent prescribing under certain protocols (Dunn et al. 2010). That is specifically the case in remote and rural regions due to the shortage of healthcare workforce

at that time (Hope and King 2017). The aim is to deliver rapid care, especially to children and the elderly while managing particular circumstances. This will include immunisations and pain management for the elderly, and to help with the increased demand for healthcare services (Health Workforce Australia 2013).

Although independent prescribing of medicines by nurses has been incorporated into the Australian health system to some extent (RACGP 2013), pharmacists have not yet been authorised to fully prescribe medicines independently in this country. The prescribing role for pharmacists was only implemented through the collaborative approach (Freeman et al. 2016; Dolovich et al. 2018; Percival et al. 2023a). The aim was mainly to optimise medication management, ensure patients' safety, and help with the increased pressure on the medical profession (Percival et al. 2023a). In 2022, the Australian Government started piloting independent pharmacist prescribing services within community pharmacies in only four states, which were Queensland, Victoria, the Australian Capital Territory, and New South Wales. Queensland trialled their services in specific therapeutic areas, such as minor ailments (e.g., UTI) and certain chronic conditions (e.g., hypertension). In contrast, Victoria, the Australian Capital Territory, and New South Wales piloted IPPs' services in contraceptive medications, New South Wales also added some ear infections and minor skin ailments to their scope of practice (The Pharmacy Guild of Australia 2022a; The Pharmacy Guild of Australia 2022b). The training of the pilot IPPs varies across the four states. One example is in Queensland in which pharmacists need to complete an additional prescribing course that consists of two parts. The first part was delivered by the Queensland University of Technology, which includes integrated learning components and 120 hours of supervised training by an authorised prescriber over a 13-week semester. The second part provided by James Cook University involved a six-month part-time course that consisted of modules on diagnosis, clinical assessment, and management of patients' conditions that were included in the pilot (James Cook University 2024; Queensland Government 2024). However, to date, the IPPs' role has not been officially authorised in Australia as the pilot is yet to be completed, therefore, the literature lacks studies exploring pharmacists' role as IPs.

The requirements of pharmacists to obtain the collaborative prescribing qualification include holding a bachelor's or master's degree in pharmacy via an accredited Australian university, registering with the Pharmacy Board of Australia, and having at least two years of post-registration clinical experience that involves developing a portfolio that demonstrates clinical training, experience, knowledge, and skills (Australian Pharmacy Council 2020). Although pharmacists who met the above criteria could become prescribers in Australia, there is a lack of existing prescribing education and training courses that could specifically prepare pharmacists to qualify as collaborative prescribers. Weeks and colleagues (2010) indicated

the need for a new training and education programme, similar to the prescribing course in the UK, to equip pharmacists with the skills, knowledge, and professional expertise needed to practise as prescribers in Australia. This would improve their competence, communication skills, clinical knowledge and skills, and safety of their prescribing practice. Similarly, Kamarudin and colleagues (2013) and Hoti and colleagues (2014) identified the need to develop a prescribing course tailored to the pharmacists' clinical needs before commencing their prescribing services to gain more skills and knowledge in areas related to clinical assessment and monitoring, principles of diagnosis, and pathophysiology of conditions.

The degree of collaborative pharmacist prescribing adoption in Australia also varies across different states. However, collaborative pharmacist prescribers are mainly based in hospitals, while their role in primary care clinics is restricted to providing medication advice to doctors (Finn et al. 2020; Fussell et al. 2022; Ogilvie et al. 2022; Percival et al. 2023b). In the literature, there is a gap in investigating pharmacist prescribing as IPs and collaborative pharmacist prescribers' roles are yet to be fully established across different states in the country. However, there are a few studies that explored the potential implementation of collaborative prescribing roles within certain areas, including the management of patients with asthma in community pharmacies (Hanna et al. 2014), chronic conditions in GP practices (Percival et al. 2023b), opioid dependence in community pharmacies (Cheetham et al. 2022), and prescribing of oral antibiotics across different healthcare sectors (Ung et al. 2016). These studies identified the appropriateness of this role in the treatment outcomes of patients within these areas. Similar findings were reported in the few studies that investigated collaborative pharmacist prescribers' views on their role in Australia using a quantitative approach (surveys) (Hanes and Bajorek 2005; Hoti et al. 2010b; Hoti et al. 2013; Bajorek and Krass 2017; Sinkala et al. 2018). Most collaborative pharmacist prescribers in these studies also expressed their appreciation for expanding their pharmacy profession through this role. In addition, Hoti and colleagues (2010b) emphasised that most pharmacists, who were not qualified as collaborative prescribers, in Australia support the expansion of the pharmacist prescribing role as a care improvement strategy. For, example, Ung and colleagues (2016) indicated that pharmacists considered their skills as underutilised and viewed their prescribing role as key to better use of medications and reducing antibiotic resistance. However, Hoti and colleagues (2013) identified greater support for collaborative prescribing compared to independent prescribing among pharmacists in Australia. Most pharmacists in this study were based in community pharmacy. They reported a preference to conduct a potential prescribing role in hospitals in order to be involved in the management of wider medical conditions rather than being restricted to minor ones in community pharmacies. A significant enabler of collaborative prescribing by pharmacists was identified by Cheetham and colleagues (2022), which was the

already established communication between pharmacists and different stakeholders, including medical prescribers, before commencing this role. However, some challenges to the implementation of this role were also identified by community pharmacists, including the lack of pharmacist training, capability, and skills in patient assessment, diagnosis, monitoring, and prescribing guidelines; the lack of appropriate resources (such as access to patient blood test results) (Hoti et al. 2013; Bajorek et al. 2015; Cheetham et al. 2022), inappropriate remuneration, high workload, lack of awareness of their role in Australia (Hanes and Bajorek 2005; Hoti et al. 2010b; Hoti et al. 2013; Bajorek and Krass 2017; Sinkala et al. 2018), lack of facilities in community pharmacies to practise their prescribing services and accreditation requirements (Hoti et al. 2013).

The clinical safety and effectiveness of collaborative pharmacist prescribers in Australia were explored in a few studies in the literature (Taylor et al. 2019; Finn et al. 2020; Fussell et al. 2022; Ogilvie et al. 2022). Different methodological approaches were used in these studies including, randomised controlled trials in Finn and colleagues' (2020) and Ogilvie and colleagues' (2022) studies, retrospective secondary care analysis in Taylor and colleagues' (2019) study, and an intervention approach in Fussell and colleagues' (2022) study; across different areas, which were geriatric, emergency, admission, and renal departments, respectively. These studies indicated a significant reduction in medication errors and an improvement in prescribing safety by pharmacists compared to the usual medical professional model of care.

There was a gap in the literature regarding public opinion on the pharmacists' prescribing role in Australia with a limited number of studies exploring the views and perceptions of patients, other HCPs, and stakeholders. Hale and colleagues (2016), Hoti and colleagues (2010b), and Le and colleagues' (2018) explored patients' perceptions and views on this role, which both revealed positive feedback, high satisfaction, and trustworthiness with collaborative pharmacist prescribers' consultations and services. However, the patient participants in Hale and colleagues' (2016) study preferred the initial diagnosis of their conditions to be restricted to doctors. In addition, patient participants in Le and colleagues' (2018) study preferred a continued doctor contribution to the management of their conditions.

Since the role of independent pharmacist prescribing has not been officially implemented yet in Australia, the few studies (conducted in primary care) that explored doctors' perceptions of this role showed that they were more supportive of collaborative prescribing and were resistant to a potential independent prescribing role (Vracar and Bajorek 2008; Bajorek et al. 2015; Cheetham et al. 2022; Percival et al. 2023b). The older studies (Vracar and Bajorek 2008; Bajorek et al. 2015) indicated that most doctor participants believed that this role may involve issues with patient safety, lack of awareness of their training,

knowledge, and capabilities, remuneration issues, and interference with the doctor-patient relationship. In contrast, the two more recent studies (Percival et al. 2023b; Cheetham et al. 2022) highlighted a change in doctors' acceptance of such a role in this sector due to its perceived potential benefits over time. These included providing more convenient access to healthcare services, particularly in rural areas, high continuity of care, reduction of their workload, and a high level of pharmacist knowledge and skills in medication management. Most participants in these studies also believed that the presence of pharmacists as collaborative prescribers within the GP practice could provide invaluable assistance and will improve the management of chronic diseases, optimise patients' medications, and increase safety. These benefits were also highlighted by the nurses and hospital medical officers in a study conducted by Tran and colleagues (2021) that explored their views on this role.

2.2.5. UK

In the UK, two types of pharmacist prescribing have been implemented, as identified in Chapter One (Section 1.1.1), which were supplementary prescribing (initiated in different UK nations in 2003, and in Wales in 2004) (DoH 2003; Welsh Assembly Government 2011) and independent prescribing, which started in 2006 (2007 in Wales) (DoH 2006; The National Assembly for Wales 2007). Specific information about the definitions of these types and the implementation of these roles in the UK has previously been described in Chapter One.

A few studies have investigated supplementary prescribing by pharmacists in the UK, which focused on training and implementation challenges, their roles, perceptions, views, and experiences of different stakeholders. The training experience, benefits, and challenges of pharmacists to qualify as supplementary prescribers were explored in studies conducted by George and colleagues (2007a; 2007b; 2008), Stewart and colleagues (2007) Cooper and colleagues (2008a), and Tann and colleagues (2010). These studies highlighted the views of pharmacists and mentors on supplementary prescribing training, which pharmacists valued greatly, particularly the training with their DSMPs. The mentors described the pharmacists' enthusiasm and capabilities to conduct this role. Some benefits of the training were reported which were improved professional roles, more focus on patient care (George et al. 2007a), assistance in building competence and confidence in prescribing practice, and how it provided essential clinical skills (George et al. 2007b; George et al. 2008; Tann et al. 2010). Some challenges associated with the prescribing training were identified including insufficient support (George et al. 2007a), the complexity of prescribing training and curriculum (George et al. 2007b; Cooper et al. 2008a), and inadequate training (George et al. 2007a; Stewart et al. 2007). The findings of these studies emphasised the importance of providing more robust training courses and adequate support systems to enable the effective implementation of pharmacist supplementary prescribing.

Only one study examined the prescribing pattern and volume of pharmacist supplementary prescribing in the UK, conducted by Guillaume and colleagues (2008) using secondary data analysis in primary care settings in England. The findings showed a significant increase in the prescribed items by pharmacist supplementary prescribers between 2004 (n= 2,706) and 2006 (n=31,052). However, their prescribing volume represented only 0.004% of the total prescribed medications. Their most prescribed therapeutic class of medicines was related to chronic conditions, in which cardiovascular was the highest, followed by central nervous system (CNS), respiratory, endocrine, and gastrointestinal groups. Prescribing for chronic conditions, particularly cardiovascular medications, was also reported in the studies that explored the views of supplementary pharmacist prescribers on their role (George et al. 2006; Hobson and Sewell 2006; Tully et al. 2007; Cooper et al. 2008b; Weiss et al. 2009; Lloyd et al. 2010; Dawoud et al. 2011). Most participants in these studies indicated positive views and experiences of their supplementary prescribing services, reporting increased job satisfaction, professional development, providing an effective clinical (patient-facing) role, representing a step towards a more independent role, and benefits to patients and other HCPs within different healthcare settings. These advantages helped to improve patient care. However, most participants in Hobson and Sewell's (2006) and Tully and colleagues' (2007) studies emphasised that their supplementary prescribing role was more beneficial in primary care settings as it helped implement new services and clinics within a wider scope of practice than in secondary care. Some challenges to implementing or utilising their role were reported in the literature, including the lack of clear guidelines, increased responsibilities, high workload (Hobson and Sewell 2006), lack of awareness about the role, concerns about their skills and training, being replaced by IPPs (Cooper et al. 2008b), lack of diversity within their scope of practice (especially in hospitals), being disliked by junior doctors (Lloyd et al. 2010), and lack of funding support and remunerations, particularly in the primary care sector (George et al. 2006). The challenge of this role to medical dominance, particularly in the primary care sector in the UK, was also identified as a barrier by Weiss and Sutton (2009).

The threat of pharmacist supplementary prescribing to the medical domain was also reported in studies that explored the views of GPs on this role (Blenkinsopp et al. 2008; Stewart et al. 2009; Stewart et al. 2010; Cooper et al. 2012). Although GPs who participated in these studies recognised the benefits of this role in terms of medication management, access to healthcare services, and relief of their workload pressure; they expressed concerns about their professional boundaries, the threat to their professional independence as medical professionals, the adequacy of pharmacists' training, clinical knowledge, diagnostic skills, and safety of their prescribing practice. It also indicated the need for a clear role definition and more collaboration and communication between GPs and pharmacist supplementary

prescribers to effectively integrate this role into primary care settings. Cooper and colleagues (2012) also highlighted the need for a cultural shift within the healthcare structure by increasing awareness of this role and ongoing support to improve the interprofessional relationships within the team.

Patients' experiences, perceptions, and views regarding the role of pharmacist supplementary prescribing were explored in a few studies (Stewart et al. 2008; Stewart et al. 2009; Deslandes et al. 2015), which revealed patients' satisfaction and positive experiences across different healthcare settings. Most participants valued their accessibility, holistic approach to healthcare, effective communication (Stewart et al. 2008; Stewart et al. 2009; Deslandes et al. 2015), continuity of care compared to other HCPs, and their high knowledge of medications (Deslandes et al. 2015). Similar findings, including positive feedback and benefits of this role, were reported in the limited studies that investigated other HCPs, policymakers, and perceptions of pharmacist supplementary prescribing (McIntosh et al. 2012; Cooper et al. 2008b; Stewart et al. 2009; Lloyd et al. 2010).

The IPPs' role was introduced (2006) after only three years of pharmacist supplementary prescribing implementation (2003) in the UK. This new role had a huge impact on pharmacist supplementary prescribing. The focus of regulatory bodies and pharmacists changed to support and be involved with this new role rather than supplementary prescribing. This was to utilise the skills of pharmacists more effectively and improve the quality of patient care. The supplementary prescribing courses were discontinued or adjusted to educate and train pharmacists as IPs. In addition, many supplementary pharmacist prescribers undertook the independent prescribing course to qualify as IPs to avoid being replaced by IPPs and to develop their skills and knowledge. These factors led to a great reduction in the number of supplementary pharmacist prescribers. As the role of pharmacist prescribers progressed to IPs, the aim of the literature moved on from supplementary pharmacist prescribing to independent pharmacist prescribing. As a result, most of the available literature focused on the role of pharmacists as IPs, whereas the literature that examined supplementary pharmacist prescribing was limited and can be considered outdated.

The studies that explored pharmacist prescribing in the UK focused on their role as IPPs in terms of their training, implementation of their role, volume, patterns, and views of prescribing, challenges and enablers related to their independent prescribing services, clinical area and effectiveness of their prescribing, and views of the public, patients, GPs, different HCPs and stakeholders. Although the role of IPPs developed over time since its implementation, little research has been conducted on the training of IPPs in the UK, (George et al. 2006b; Tonna et al. 2010; McIntosh et al. 2011; McIntosh et al. 2012; McIntosh et al. 2015; Kauser et al. 2022; Alhawas et al. 2024). These studies highlighted the participants'

(pharmacists') willingness to qualify as IPs. A few studies identified the enablers and barriers to enrol in independent prescribing courses (McIntosh et al. 2015; Kauser et al. 2022; Alhawas et al. 2024). The enablers were only reported in the recent study conducted by Alhawas and colleagues (2024), which included the availability of comprehensive training and education independent prescribing courses across the UK and the Government's funding support for the course fees and mentors. On the other hand, the barriers to undertaking the independent prescribing course were the lack of clinical experience, lack of confidence (George et al. 2006b; McIntosh et al. 2015; Alhawas et al. 2024), time constraints due to their already high workload, and inadequate support from and funding to other pharmacists to cover their responsibilities during the course time (Kauser et al. 2022; Alhawas et al. 2024). However, the clinical experience to enrol in the prescribing course and qualify as IPs is not required anymore since 2021 as indicated in Chapter One (Section 1.3.5) (GPhC 2021). Kauser and colleagues (2022) also highlighted some other barriers for community pharmacists to undertake the course, such as the need for community pharmacy workforce restructuring and the lack of high-quality training tailored to their needs. Other studies explored the awareness and views of pharmacists on the independent prescribing course (George et al. 2006b; Tonna et al. 2010; McIntosh et al. 2012). The participants in McIntosh and colleagues' (2011) and Tonna and colleagues' (2010) studies indicated their awareness of the course and were strongly in favour of its requirements, including training (that involves clinical examination, consultation, and patient monitoring skills), and being a registered pharmacist for at least 2 years (before the new changes that excluded the 2 years of experience). However, the study conducted by George and colleagues (2006b), which can be considered outdated since it explored the views of pharmacists at the early stage of its implementation, revealed the participants' inadequate awareness of the course and this role. Some participants in George and colleagues' (2006b) study indicated the need to focus more on clinical assessment and patient monitoring skills, as they expressed their concerns about the ability of the course to prepare them to conduct clinical examinations and make the right diagnosis. Some safety concerns were also reported by some participants, particularly if there is a lack of a continuous monitoring system that could assess their competence after the course and training completion. Other studies investigated the implementation of certain modules within the independent prescribing courses or within the current undergraduate pharmacy programme that could allow pharmacists to be IPs ready in 2026 (GPhC 2022) as identified in Chapter One (Section 1.3.5). Examples of these modules were the assessment of a core set of clinical skills (Hasan Ibrahim et al. 2022), antimicrobial stewardship (Hamilton et al. 2023), prescribing safety assessment (Power et al. 2021), a training programme for IPPs in care homes (Wright et al. 2021; Birt et al. 2022), and virtual ethics discussion groups (O'Hare et al. 2020). These studies highlighted the potential benefits

of such courses within the independent prescribing training and education programme, which could improve the safety of their prescribing practice and ensure competence.

The implementation of the IPPs' role in the UK was also explored in the literature, which revealed a variation in the utilisation of IPPs' services across different nations and healthcare sectors. Most of the earlier studies were conducted in England and most participants (IPPs) in these studies indicated that they were based in hospitals (Courtenay et al. 2012; Baqir et al. 2014), and almost a third of the IPPs were not using their prescribing qualification (Courtenay et al. 2012). Similarly, in Wales, a study conducted by Courtenay and colleagues (2017a) indicated that the majority of IPPs in Wales were based in secondary care settings, the role was limited in the primary care sector, and implementation was inconsistent across HBs and NHS Trusts. Contrasting findings were revealed in an early study conducted in Northern Ireland (McCann et al. 2011), in which almost half of the IPPs' participants were based in GP practices. The findings highlighted that the uptake of pharmacist prescribing at the time of the study was not fully embedded in the different healthcare settings in Northern Ireland, which is still not utilised in community pharmacies until the current year (2024) in this country. While in Scotland, there was no available study in the literature that explored the implementation of this role. More recent studies that examined the implementation of IPPs' services in the UK identified a significant increase in the adoption of this role in primary care settings; in either GP practices (Stewart et al. 2019; Alshehri et al. 2021; Deslandes et al. 2022; MacVicar and Paterson 2023) or community pharmacies (only in Wales) (Mantzourani et al. 2023). The recent studies that examined this role in GP practices found that the majority of IPPs were involved in the management of chronic conditions and medication reviews (Stewart et al. 2019; Alshehri et al. 2021; Deslandes et al. 2022; MacVicar and Paterson 2023). Deslandes and colleagues (2022) used a retrospective secondary analysis of prescribing data obtained from a national database in Wales over a decade (2011–2021), which showed that the volume of NMPs, including IPPs, increased significantly over the study time. The prescribed items were mostly from seven therapeutic groups of medicines, including infections, cardiovascular system, respiratory system, CNS, gastrointestinal system, endocrine system, and skin conditions. In contrast, the study conducted by MacVicar and Paterson (2023), which also carried out a retrospective secondary data analysis in Scotland, investigating the prescribing activity of medical prescribers and NMPs, including IPPs, from 2013 to 2022 indicated a decrease in independent pharmacist prescribing over the study time by 20%. The reason for such a reduction was not highlighted in the study, therefore, further research needs to be conducted to investigate this matter. Mantzourani and colleagues (2023) aimed to explore the views of IPPs on the pilot module of the IPS in community pharmacies in Wales. They indicated that the prescribing of IPPs was mostly related to acute conditions

such as UTIs and ear infections. This showed the WG's and HBs' intention to support this role within the scope of minor acute conditions in community pharmacy settings to relieve pressure on GP practices, increase patient access to treatment, and improve their quality of care as highlighted in the new Community Pharmacy Contractual Framework in 2022 (Welsh Government 2022). The participants in Mantzourani and colleagues' (2023) study also believed that the IPS was convenient for their patients as they felt that patients had a good experience, and it increased their access to medical care. Only one study used retrospective secondary data analysis in hospitals, which was in England, to explore prescribing of NMPs, including IPPs, and focused on antibiotics prescribing. It revealed that NMPs accounted for almost 10% of all prescribed antibiotics and increased over the study period. It also showed that around 85% of their prescribing adhered to the antimicrobial stewardship guidelines, reflecting the high competence of NMPs in antibiotic prescribing. Similarly, IPP participants in Tonna and colleagues' (2010) study believe that they can reduce the risk of antibiotic resistance, increase access to appropriate antibiotic treatment, and effectively use evidencebased medicine even for more complex conditions related to antimicrobials in secondary care settings.

Many studies in the literature have investigated the clinical areas that IPPs were managing in the UK and the effectiveness and safety of their practice. For example, IPPs were practising safely as they helped in deprescribing of inappropriate medications, and their role was effective and well received by patients in care homes in the UK (Inch et al. 2019; Alharthi et al. 2022; Birt et al. 2023; Holland et al. 2023; Wright et al. 2023). Similarly, the prescribing of IPPs was safe in the following areas of practice: mental health services (Buist et al. 2019; Shah et al. 2021), critical care (Bourne et al. 2015; Cross et al. 2017), homeless outreach services (Johnsen et al. 2021), in management of patients with chronic kidney disease (Alraiisi et al. 2021), left ventricular systolic dysfunction following acute myocardial infarction (Forsyth et al. 2019), HIV-1 (Nicholls et al. 2013), chronic pain (Bruhn et al. 2013), diabetes (Bowron et al. 2011; Twigg et al. 2013), and prescribing of antimicrobials (Tonna et al. 2010). The appropriateness and safety of IPPs' prescribing were also examined in the literature (Latter et al. 2012; Baqir et al. 2014; Turner et al. 2020; Roberts et al. 2023), which all highlighted very low prevalence of errors in their prescribing compared to medical and other prescribers. These studies highlighted the significance of IPPs' pharmacological knowledge and their previous experience in checking prescribed medications by doctors to reduce errors and improve patient safety.

The views of IPPs on their prescribing role were also explored in limited studies in the literature. Some studies reported a high degree of satisfaction with their independent prescribing role across different healthcare settings, which was mainly related to the benefits

of their services (McCann et al. 2012a; Hill et al. 2013; Fisher et al. 2018; Stewart et al. 2019; Alshehri et al. 2021; Mantzourani et al. 2023). Most participants in these studies believed that this role enabled them to conduct a more patient-facing role, allowed them to effectively use their skills and knowledge, provided them with the opportunity to develop their profession, and enhanced their job satisfaction. They also believed it improved patient care, reduced their medication burden, and decreased doctors' workload, particularly in GP practices. This was because GP practices allowed them to do a more general prescribing role in which they were able to develop their scope of practice in wider conditions compared to hospitals. Abuzour and colleagues (2018) explored the approach of pharmacists when they practise as IPs, which was more related to examining their patients' medical notes, laboratory results, and medications compared to other prescribers, particularly INPs, who mainly focused on their interactions with patients. They indicated that IPPs need to focus more on their communication skills to improve their interactions with patients. Another comparison between the role of IPPs and INPs was highlighted by Weiss and colleagues (2015), IPPs were believed to include their patients in decisions related to their management plan to a greater extent compared to INPs.

A few studies reported the enablers and barriers that IPPs came across during their prescribing practice. The enablers were good relationships with other HCPs and patients, supportive organisational environments (Courtenay et al. 2017a; Fisher et al. 2018; Graham-Clarke et al. 2021; Graham-Clarke et al. 2022), access to patient records in hospitals (Fisher et al. 2018), and their previous experience and clinical background. All of these gave participants the confidence and competency to make their prescribing decisions (Courtenay et al. 2012; Abuzour et al. 2018). In contrast, the barriers that impacted their prescribing decisions or prevented them from using their prescribing rights were inadequate funding and resources, time-consuming paperwork related to their prescribing role, unavailable pharmacist prescription forms on computers, lack of collaboration, support, and understanding of their role by patients and other HCPs (McCann et al. 2011; Maddox et al. 2016; Courtenay et al. 2017a; Courtenay et al. 2018; Alshehri et al. 2023; Mantzourani et al. 2023), lack of support from other HCPs, lack of access to patient records on a national scale; particularly in community pharmacies, a high workload, time constraints (Graham-Clarke et al. 2021; Graham-Clarke et al. 2022; Kauser et al. 2022), inadequate training, high responsibilities (Maddox et al. 2016; Mantzourani et al. 2023), inadequate assessment skills, particularly in managing patients with complex conditions, and difficulties in fulfilling the required CPD (Roberts et al. 2023). Most participants in the study conducted by Maddox and colleagues (2016) were reluctant in some therapeutic areas to accept responsibility for prescribing due to the risk associated with it and lack of competence within these areas, which they identified as a barrier to their role that resulted in referring such patients to a medical prescriber or delaying

the prescribing of medicines. Similarly, the IPP participants in the recent study by Alshehri and colleagues (2024) also highlighted practising beyond their therapeutic scope of practice as a major challenge to their role. However, these studies were conducted within different nations in the UK in which the utilisation of IPPs' services differs as indicated in Chapter One (Section 1.3.2). For example, the role of IPPs in community pharmacies was implemented only in Wales and Scotland over recent years through the support of regulatory bodies within these nations that involved funding for their services, including remunerations (Welsh Government 2022; Mantzourani et al. 2023; NHS National Services Scotland 2023). In addition, challenges were different between these nations, and also a few have been resolved, such as the lack of access to patient medical records in community pharmacies in Wales and Scotland (NHS Wales 2023).

The general public awareness of the IPPs' role was only explored in two studies in the literature, which were conducted in Scotland (Stewart et al. 2009b; MacLure et al. 2013). Both studies highlighted that more than half of the participants were aware that trained HCPs, other than doctors, could write prescriptions for medications. Most participants' awareness of the role was related to older ages, having HCPs within their family, or being highly educated. Most participants were more comfortable with and supportive of IPPs compared to other prescribers. However, concerns related to clinical governance, education and training, privacy, and confidentiality of their data as patients were highlighted by the participants. Both studies identified the need for more public engagement, understanding, and acceptance of this role. However, both studies are considered outdated, and the literature lacks recent evidence on the public awareness of the IPPs' role that may have changed over time as the role has become more established.

In the literature, many studies investigated patients' perceptions and views on IPPs' role, which were mostly conducted in GP practices across the UK. Their views and perceptions differ greatly depending on their awareness of this role and their experiences with IPPs. A few studies that were conducted in the early stages of the implementation of this role indicated a high resistance of patients to change as they preferred the management of their conditions by GPs rather than by IPPs as they believed that pharmacists should focus only on medications and dispensing (Tinelli et al. 2009; Hobson et al. 2010). However, younger patients in these studies were more open to IPPs' role compared to older ones. Hobson and colleagues' (2010) study revealed that some patients had the perception that IPPs have less knowledge and fewer skills than doctors and INPs. Additionally, the lack of awareness and understanding of IPPs' role, training, and monitoring, as well as clinical governance and privacy issues, due to the lack of places to conduct the consultations, were matters of concern to some patients (Tinelli et al. 2009; Hobson et al. 2010). Some earlier studies (Stewart et al. 2011; Gerard et

al. 2012; McCann et al. 2012b; Tinelli et al. 2013) also showed the preferences of patients to see doctors as the first choice to manage their conditions rather than IPPs. In addition, the majority of participants in two studies (Stewart et al. 2011; Tinelli et al. 2013) would like to be managed by doctors when their health conditions were acute or seemed to deteriorate due to their high training and experience, while IPPs should be involved in the management of chronic conditions. The participants in McCann and colleagues' (2012b) study would appreciate a more multidisciplinary team approach to provide healthcare instead of being managed by IPPs alone, particularly when managing patients with more complex conditions. Hobson and colleagues' (2010) and Tinelli and colleagues' (2013) studies also highlighted that having a good and long-term therapeutic relationship with a prescriber played an important role in the patient's preference, as a result, many patients who were managed by INPs preferred their services compared to IPPs. In contrast, most participants in Stewart and colleagues' (2011) study preferred IPPs over INPs due to their knowledge and skills, particularly in medications. However, all these studies were conducted in the early years of independent pharmacist prescribing adoption, while recent views and perceptions of patients may have changed as their role has developed and their number increased over time. Therefore, new studies need to be conducted to explore their current views and perceptions of this role.

Contrasting views were reported by most patients who participated in more updated and recent studies, as they were highly satisfied with IPPs' services in general and they trusted and supported the role (Hill et al. 2013; Tinelli et al. 2013; Weiss et al. 2014; Weiss et al. 2015; Nabhani-Gebara et al. 2020; Mann et al. 2022; Alshehri et al. 2023). A few studies also reported patients' high satisfaction with IPPs within specific prescribing areas, including homelessness (Johnsen et al. 2021), mental health (Shah et al. 2021), and management of acute respiratory tract infections (Courtenay et al. 2017b; Courtenay et al. 2017c). As reported by participants in these studies, their high satisfaction was related to the positive impact of IPPs' role on them as they felt that they were holistically managed by IPPs compared to doctors and INPs' services (Tinelli et al. 2013; Weiss et al. 2015), had better medication consultations since IPPs were experts in this (Hobson et al. 2010; Gerard et al. 2012; Stewart et al. 2011; Mann et al. 2022), were provided with more detailed instructions and information about taking their medicines and possible side effects, which increased the safety of their prescribing practice (Stewart et al. 2011; Gerard et al. 2012; Mann et al. 2022), were more accessible (Stewart et al. 2011; Mann et al. 2022), had more knowledge and experience as they tend to be specialists in certain clinical areas (Tinelli et al. 2013), and provided longer appointments during which IPPs listened to them carefully (Mann et al. 2022).

A few studies in the literature have explored the views, perceptions, and experiences

of doctors with IPPs, which were related to their role within GP practices in the UK. Two studies investigated the GPs' views on the early adoption of IPPs (Blenkinsopp et al. 2008; McCann et al. 2012b). Most GPs in both studies expressed their selective acceptance of the role as they preferred to limit IPPs' decision-making and diagnosis, being only involved with supplementary prescribing, and only assigning them to routine work. Some GPs did not refer their patients to IPPs, while GPs who referred patients described the benefits of this role with some ambivalence. This was similar to the views of GPs on supplementary pharmacist prescribers highlighted earlier in this section (Blenkinsopp et al. 2008; Stewart et al. 2009). In contrast, most GP participants in recent studies reported their positive views on the IPPs' role and they were supportive of their independent prescribing services (Maskrey et al. 2018; Ibrahim et al. 2022; Johnson et al. 2022; Hurley et al. 2023a; Hurley et al. 2023b). These studies identified the benefits of the IPPs' prescribing services, which included improving medication management, continuity of healthcare, patient education and outcomes, access to appropriate care, cost savings of treatment, and evidence-based practice (Ibrahim et al. 2022; Hurley et al. 2023a; Hurley et al. 2023b); increasing communication between GP practices and community pharmacies, and alleviating pressure on themselves and GP practices, particularly in the management of patients with multiple morbidities (Maskrey et al. 2018; Ibrahim et al. 2022; Johnson et al. 2022). In addition, most GPs were in favour of increasing IPPs' prescribing sessions, highlighting their knowledge, skills, effectiveness, and safety of prescribing practice which allowed them to focus more on complex cases (Maskrey et al. 2018; Ibrahim et al. 2022; Johnson et al. 2022). However, some GPs expressed concerns about the actual impact of this role on their workload, IPPs' clinical training needs (particularly on assessment skills and clinical decisions), funding of their services, clarity of their role within the practice team (Ibrahim et al. 2022; Hurley et al. 2023a; Hurley et al. 2023b), IPPs' indemnification insurance, and the potential of this role in weakening the GP-patient relationships (Hurley et al. 2023b). Those GPs were supportive of the role of IPPs in terms of only providing medication information (as advisory) and review compared to prescribing independently.

The stakeholders' and HCPs' views on the role of IPPs in the UK were explored in a few studies in the literature, which were also conducted in the primary care sector in the UK. Most stakeholders and HCPs indicated their positive opinions and broad support of the role of IPPs due to the recognition of its benefits (McCann et al. 2012a; Hill et al. 2013; Tonna et al. 2014; Hindi et al. 2019; Ryan et al. 2019; Graham et al. 2020; Lane et al. 2020). These benefits were the same as those reported by GPs that were illustrated earlier in the previous paragraph. Most stakeholders in McCann and colleagues' (2012a) and Hill and colleagues' (2013) studies suggested recruiting more IPPs as they believed that this role represented a

better utilisation of pharmacists' knowledge and skills and helped in improving other HCPs' practices, particularly doctors. The enablers of IPPs were identified by stakeholders' participants in Hindi and colleagues' (2019) study, including support from other HCPs and staff within the team, confidence of IPPs, and good relationships and communication with patients and other HCPs. However, some concerns were highlighted, which were similar to those reported by GPs. Nevertheless, additional concerns were acknowledged, including lack of competence in specific areas of practice (Hindi et al. 2019), not providing a more general role as they were limited to their areas of practice, lack of ability to manage complex conditions, inadequate diagnostic skills (McCann et al. 2012a), lack of awareness of their exact role and responsibilities, and difficulty in their integration within the team (Lane et al. 2020).

2.3. Discussion

This narrative literature review provided a summary of non-medical prescribing, focusing on pharmacist prescribing in the UK, the USA, Canada, Australia, and New Zealand, which are the countries that utilise this role in the world. Pharmacists' and nurses' prescribing role was adopted in all these countries. Compared to the list of NMPs in the UK (Chapter 1, Section 1.1.1), doctors' assistants in the USA, midwives, optometrists, and dietitians in New Zealand, and midwives, optometrists, and surgical podiatrists in Australia were the other NMPs who can obtain prescribing authority. The narrative literature review highlighted the recognition and growth of the pharmacist prescribers' role within these countries. However, it showed the different approaches to adopting this role across these countries on their healthcare systems and regulations associated with its implementation. The UK was the only country that greatly implemented the independent prescribing role of pharmacists on a national level with a wide scope of practice across all healthcare sectors and defined national regulations of their training, education, and requirements to qualify as IPs. While Canada's practice of pharmacist prescribing was more associated with the collaborative prescribing model within hospitals and primary care clinics, some provinces have also established the independent pharmacist prescribing role in community pharmacy settings to mainly manage certain minor ailments. However, it was still very limited in terms of their scope of practice and the range of prescribing of medications compared to the UK and it significantly varies from one province to another based on their own regulations. Similarly, in the USA, it also greatly differs across the states although the independent pharmacist prescribing role is also very limited to specific conditions or even a group of medications, such as hormonal contraceptives within community pharmacies. The main type of pharmacist prescribing in the USA was the collaborative model, which is mainly based in hospitals. Likewise, Australia and New Zealand only implemented the collaborative pharmacist prescribing model within their countries, which also varies across different states. The practice of collaborative pharmacist prescribers in Australia and New Zealand was only based in hospitals and outpatient clinics. However, Australia has started to pilot independent pharmacist prescribing services in community pharmacies in four states with a very limited scope of practice to examine this role before implementing it across the country. However, the scope of IPPs in the USA, Canada, and Australia is considered narrow compared to this role in the UK. In addition, most of the IPPs' services in these countries are similar to the CAS in Wales.

The different approaches in implementing this role across different healthcare sectors within these countries might be related to the variation in their healthcare systems. In the UK, GP practices are the first point of contact for patients seeking medical care free of charge, but requiring patients' registration with GP practices to receive healthcare services (Welsh Government 2015; NHS Wales 2016; Jacob 2023). In addition, GP practices in the UK are funded by the Government via public taxation and delivered through the NHS, as is the secondary care sector. Therefore, the UK Government highly supports the prescribing role of other HCPs, including pharmacists, to overcome the shortage of GPs (Welsh Government 2016a; Brennan 2017; Jessup 2017; Jones 2017) and relieve pressure on them, which may reflect the expansion of this role in this country (Welsh Government 2015; NHS Wales 2016; Jacob 2023). This also might explain the availability of secondary databases of prescribing data, particularly in primary care settings, for healthcare services and reimbursement purposes by the Government (NHS Wales Shared Services Partnership 2021). In the other countries, the primary care sector is mainly provided and funded through healthcare insurance companies, and patient access is closely tied to insurance coverage (Phillips 2005; Salgado et al. 2020; Jacob 2023). Therefore, healthcare services are usually delivered through a specialist within the medical area of care in secondary care settings (Jacob 2023). As a result, pharmacists' role as prescribers in these countries was more dominant in hospitals (Salgado et al. 2020; Jacob 2023).

The literature review highlighted another major difference in the implementation of pharmacists' prescribing between the UK and other countries, which was related to their training to become prescribers. It indicated a lack of standardisation and a high degree of variation across countries. For example, in the UK, pharmacists do not need to have clinical experience as an entry requirement for prescribing courses since 2021 (GPhC 2021). In other countries, pharmacists are required to have two or three years of clinical experience and in some countries to have a clinical postgraduate degree (usually self-funded) to be prescribers. In the UK, pharmacists need to complete a well-established prescribing training model (usually funded by the Government) to gain the essential skills and knowledge around clinical assessments, therapeutic prescribing, legal and ethical aspects, and professional limitations.

As indicated above, the role of IPPs is a well-established practice across the UK in

terms of the regulatory system, prescribing framework, and education and training that allow them to integrate their independent prescribing services within all different healthcare sectors compared to other countries. In addition, it showed the rapid development of the IPPs' services and scope of practice in the UK, which emphasise the Government's plan to utilise pharmacists' knowledge and skills in the healthcare system to achieve the objectives of the second Crown report (DOH 1999; DOH 2006). Most studies exploring public, patients, pharmacists, and other HCPs and stakeholders' perceptions about the role of IPPs in the UK, and in other countries, showed both positive and negative views. In particular, older studies, that investigated the early adoption of this role across healthcare sectors within different countries, showed a high degree of patients, doctors, or even pharmacists' resistance to changing the prescribing culture that used to be limited to doctors. However, most recent studies reported the changing views of those practitioners and healthcare service users of pharmacist prescribers that became more positive due to its recognised benefits. The reported benefits of the role in the literature included improving patient safety and quality of care, increasing patient access to healthcare services and treatment, using their skills effectively, professional development, and high job satisfaction. The literature review has also indicated some enablers to their role, such as good relationships with other HCPs, support of other HCPs to their role, high confidence and competence, and the availability of independent prescribing education and training courses. However, some challenges to the implementation of the IPPs' services were highlighted in the literature, such as the lack of support, inadequate funding, lack of awareness and understanding of their role, access to patient medical records, high workload, time constraints, lack of confidence, CPD issues, and some other logistical challenges.

At the time of conducting studies within this PhD (2017/19), almost all the identified literature was conducted in different areas in the UK, but only one published study investigated the implementation of NMPs, including IPPs, in Wales (Courtenay et al. 2017a). This highlighted the inconsistent implementation of this role across different healthcare settings, particularly in the primary care sector. This study also identified some of the challenges that affect the implementation and practice of IPPs, such as funding issues and a delay in the delivery of their computer prescription form that may impact the implementation of their role. In Wales, and the UK as a whole (before the beginning of conducting this PhD), none of the studies that were identified in the narrative literature review, investigated the prescribing trends of IPPs. In addition, there was no available published literature on the role of IPPs in primary care settings in Wales. As indicated in Chapter One (Sections 1.1.3 and 1.1.4), the WG planned to develop the primary care sector in Wales since 2015 (Welsh Government 2015), which involved the establishment of GP clusters locally (National Assembly for Wales

2017) and the WG's strategy for primary care that included the development of this role within community pharmacies in response to the 2030 Pharmaceutical Committee's vision (Welsh Pharmaceutical Committee 2019). Therefore, a lot of IPPs started or moved to work in the primary care sector. These factors, as well as some of the more general literature being outdated, identified the need for a new study to understand the early implementation, current practice, barriers, enablers, experiences, and views of IPPs in primary care settings, including GP practices and community pharmacies in Wales, regarding these developments. This indicated the success of the narrative literature review in identifying a clear gap in the literature about the role of IPPs in primary care settings in Wales, which also helped in informing the research question, aim, and objectives of this PhD.

2.4. Research question of the PhD

- How has the NMIPs' prescribing role, with the focus on the role of IPPs, and their numbers in primary care settings in Wales developed over time?
- How has the role of IPPs been embedded in primary care settings in Wales?

2.5. Aim of the PhD

The aim of this PhD was to explore the development of the NMIPs' prescribing role and their number in primary care settings in Wales, with the focus on the role of IPPs in GP practices and community pharmacies.

2.6. Objectives of the PhD

- 1. To identify the number of NMIPs, and the trends of their prescribed items that were dispensed in primary care settings in Wales from 2011 to 2018 and the impact of the primary care clusters implementation in 2015 on their prescribing trends.
- 2. To describe the roles of IPPs working within GP practices in Wales and to explore their views on how their role is embedded in primary care.
- 3. To explore the views of community IPPs and HB community pharmacy leads regarding the role of IPPs within a community pharmacy setting.

3. Chapter 3 - Methodology

3.1. Introduction

Selecting an appropriate research methodology is a crucial step in any research project. According to Buckley and Chiang (1976), a research methodology is a strategy that involves the use of mapped-out tools to solve a specific problem. The main types of research methodological approaches are quantitative, qualitative, and mixed methods (Creswell 2014). Each one of these approaches possesses unique strengths and limitations (Creswell 2014). However, Holden and Lynch (2004) stated that research should involve factors that extend beyond the practicalities of selecting a proper methodological approach. They emphasised that the researcher's philosophical perspective and the nature of the explored research question should be considered to successfully choose the right methodology for a research project.

This chapter will provide a general overview of the research philosophy, paradigms, theoretical assumptions, and methodologies that the researcher considered to explore the development of the NMIPs' role, with the focus on IPPs, and their prescribing in primary care settings in Wales. It will also describe and justify the research strategy and design of the studies, as well as ethical considerations. Each study in this PhD will be discussed in a separate chapter, which will include a method section describing the study's specific methodological approach in further detail.

3.2. The philosophy of research

Research philosophy guides the researchers' perspective to formulate a research question, prepare a plan on how to investigate a problem, choose the appropriate research design, and determine which methods to use, as well as the way to collect, analyse, and interpret data (Bhattacherjee 2012). It is mainly influenced by the researcher's assumptions and opinions about the investigated topic, target population, and society (Bowling 2009). A researcher fundamentally starts a research project with either a deductive or inductive approach. The deductive approach is mainly applied in quantitative methodologies in which a researcher begins by generating a theory and hypothesis that can be proven or disproven by data (Bowling 2009). Whereas in the inductive approach, which is primarily used in qualitative methodologies, data, and information are collected by the investigator to generate and potentially test a hypothesis (Bowling 2009). In philosophy, paradigms represent the researcher's philosophical framework and stance on research. The following section will discuss the definition and types of research paradigms.

3.3. Research paradigms

A research paradigm is defined as a set of beliefs and agreements that serves as a

guide for researchers when conducting research to understand and address the investigated problems (Guba 1990). It consists of ontology, epistemology, theoretical perspective, and research methodology (Creswell and Clark 2018). Ontology is about answering the question of 'What is reality?' within the research. Epistemology is about answering the question of 'How can we know reality/knowledge?'. The theoretical perspective is about answering the question of 'What approach do we use to get knowledge?'. The research methodology is about answering the question of 'What procedure do we use to acquire knowledge?'. There are three main types of research paradigms, which are the positivist, interpretivist, and pragmatist paradigms (Creswell and Clark 2018).

3.3.1. The positivist paradigm

The positivist paradigm ontology assumes the presence of a single truth or fact within the investigated phenomena, which is known as a realist ontology (Bhattacherjee 2012). The epistemology of the positivist paradigm embraces the observation and measurement of a single fact without the researcher's intervention, it believes this is done as objectively as possible (Guba and Lincoln 1994). The theoretical perspective of the positivist paradigm is the deductive approach, which is only concerned with measuring variables to determine the relationship between the cause and effect without any influence from the researcher on the tested phenomenon (Tebes 2005). The research methodology of the positivist paradigm is the use of quantitative methodologies (Creswell and Clark 2018).

3.3.2. The interpretivist paradigm

The interpretivist paradigm (also known as constructivist) ontology implies that social realities are formed through people's experiences with certain phenomena (Denzin and Lincoln 2005). It assumes that social realities are not presented as discrete measurable facts. Rather, it suggests that individuals develop a social reality as they live and function in society by creating subjective and multiple interpretations for their interactions (Creswell and Clark 2018). The epistemology of the interpretivist paradigm suggests that the researcher must consider local contexts and the interpretations that people make from their experiences to acknowledge any mutual influences that may occur between the researcher and social reality (Creswell and Clark 2018). To help in understanding the social world, interpretivist demands that the researcher is at the centre of the study process (Creswell and Clark 2018). It requires the researcher's engagement with participants' narratives and experience with the investigated phenomena to find relationships in the collected data to help in understanding the meanings of phenomena from the study participants' point of view (Bowling 2014). The theoretical perspective of the interpretivist paradigm is the inductive approach, which means that the most important research tool is the researcher since the researcher role is not just to

collect data, but also to generate data that describes the phenomena in depth (Barbour 2008). The research methodology of the interpretivist paradigm is qualitative methodologies (Creswell and Clark 2018).

3.3.3. The pragmatist paradigm

The pragmatist paradigm ontology believes that reality is in the real-world practice that is continuously being renegotiated, argued, and interpreted (Creswell and Clark 2018). The epistemology of the pragmatist paradigm is to look for and use the best methods that could solve the investigated problems (Creswell and Clark 2018). The theoretical perspective of the pragmatist paradigm is the use of both inductive and deductive approaches (Winit-Watjana 2016). The research methodology of the pragmatist paradigm is using mixed methods of both quantitative and qualitative approaches (Creswell and Clark 2018). It is characterised by its flexibility since it involves the use of multiple methods to collect data, not being limited to a particular philosophical framework and the use of different data analysis approaches. This makes it favourable for researchers who do not want to be restricted when conducting research (Creswell and Clark 2018).

3.4. Positionality of the researcher

As discussed above (Section 3.3.3), the epistemology of the pragmatist paradigm is to use whatever methods are appropriate to address the research question (Creswell and Clark 2018). As there are both descriptive and exploratory objectives within this PhD, a mixed-method approach was deemed to be the most appropriate, allowing the researcher to pursue both objective (facts) and subjective (perspectives) data. The generation of findings utilised both deductive and inductive theoretical perspectives.

3.5. Mixed methods research

A beneficial alternative research method to either quantitative or qualitative approach is the use of a mixed methods approach. The mixed methods approach must utilise at least one quantitative and one qualitative methodology that are used within the same study or many related studies (Hesse-Biber and Johnson 2015). According to Creswell and Clark (2018), any researcher carrying out mixed-methods research should give a philosophical and theoretical justification for mixing the methods used; provide the purpose of utilising mixed methods approach; use a logical manner when organising data and carry out procedures; and collect, analyse, and combine data of both qualitative and quantitative methodologies in light of the research question. Researchers often mix quantitative and qualitative approaches in a study for a variety of reasons. According to Greene et al. (1989), 'triangulation', 'development', 'expansion', 'complementarity', and 'initiation' are the five reasons for merging quantitative and

qualitative methods (i.e., more than one of these five reasons can be related to one mixed methods study).

3.5.1. Benefits of using mixed methods research

Many scientists view mixed methods research as a strategy that offers complete and beneficial information that can show the entire picture of the investigated problem (Johnson et al. 2007). Therefore, researchers who conduct mixed methods research can investigate social phenomena utilising at least one methodology from both quantitative and qualitative approach. The use of mixed methods research has several benefits (Creswell and Clark 2018). Combining quantitative and qualitative methodologies in a research project could minimise the weaknesses of using either approach on its own. Another benefit of using a mixed methods approach is that it provides researchers with the freedom to examine the issue both qualitatively and quantitatively and address research questions that were difficult to answer using only one method.

3.5.2. Mixed methods design

It is vital that a researcher should focus on the design of mixed methods research. According to Teddlie and Tashakkori (2009), it is difficult to create a comprehensive typology of mixed methods research design because of its mixed nature. However, Creswell and Clark (2018) have identified three types of mixed methods designs, which are convergent design, exploratory sequential design, and explanatory sequential design. The convergent design involves conducting both quantitative and qualitative methods concurrently at the same time and, thereafter, combining both in the discussion. The exploratory sequential design is to start with a qualitative study and then to conduct a quantitative study to help with quantifying the qualitative study's findings. The explanatory sequential design is to conduct a quantitative study at first followed by a qualitative study to provide a justification and explanation for the findings of the quantitative study. An explanatory sequential mixed methods design was adopted for this PhD with a quantitative study conducted first, followed by qualitative studies (Schoonenboom and Johnson 2017).

3.5.3. Point of integration

Any moment in a study where a researcher combines more than one research component, such as qualitative and quantitative data, has been referred to as a point of integration (Schoonenboom and Johnson 2017). According to Schoonenboom and Johnson (2017), every mixed methods research must include at least a point of integration. Fetters and colleagues (2013) have identified three levels of integration in mixed-methods research. The first level is that the initial results from one study may be used to design or influence

modifications in the data collection for the following studies (e.g., developing an instrument). This occurs at the first instance of mixed-methods research design, which is called the study conceptualisation. The second level takes place at the level of methods and analysis in which integration occurs by linking the used methods for data gathering and analysis. Some of the possible ways in which this can occur are by merging (combining the two data sets, followed by analysing them, and subsequently merging), connecting (in which respondents are to be interviewed after completing a survey), embedding (linking the data collection and analysis at multiple points), and building (using the findings of one project to design the data collection method for the other projects). The third level of integration can take place when a researcher explains or discusses the findings of the quantitative and qualitative studies in reports (at the level of interpretation). For this PhD, the first (at the study design) and third (at the interpretation) levels of mixed methods research design were the points of integration of the quantitative and qualitative methodologies. Both quantitative and qualitative data were conducted using a variety of data collection tools.

3.6. Quantitative research methodology

Quantitative research methods numerically examine a theory or hypothesis via a standardised instrument to answer the how, when, and by how much something has happened or changed; it allows comparison and tracks a specific process, or system over time (Creswell and Creswell 2018, Austin and Sutton 2019). This involves collecting and analysing data that answers the research question to produce new scientific information that investigates the existence of reality within a specific social phenomenon (Bowling 2014).

Quantitative research designs cover a wide variety of specific methods, which are mainly categorised as experimental or quasi-experimental (also, known as non-experimental) methods (Trochim et al. 2016). The experimental research methods mainly analyse the causal relationship between two or more variables, whereas the quasi-experimental research methods have a mainly descriptive approach that aims to describe the variables' characteristics (Trochim et al. 2016). Both categories are explained briefly in the following subsections.

3.6.1. Experimental research methods

In natural science, researchers should ensure that experiments are conducted in a controlled environment where all conditions of the study are constant and only the independent variables (it is the cause variable that is not dependent on other values in the study) can be manipulated (Creswell and Creswell 2018). This means that the effect of confounding variables, which are any external factors that can affect the outcome of an experiment, is kept to a minimum level. Manipulation of the independent variable, as a result

of the intervention, can produce the observed effect in the experiment (Trochim et al. 2016). In the healthcare sector, the experimental research concept applied is the randomised controlled trials (Polgar and Thomas 2020).

3.6.2. Randomised controlled trials

Randomised controlled trials are mainly used to evaluate the efficacy of a new or alternative treatment for a certain medical condition (Austin and Sutton 2019). It aims to investigate the outcome of an intervention that caused a particular observed effect. It is characterised by the allocation of subjects, mainly patients in healthcare research, using random techniques to assign them to control and test (intervention) groups, which will allow independent variable manipulation (Trochim et al. 2016). To ensure an equal chance of each subject allocation in either group, random sampling is usually employed. In quantitative research statistical analyses of the data are undertaken to get inferences. Thereafter, the findings of the experiment of the investigated area of interest on a study population are considered facts or theories, particularly when the findings are replicated in other studies for different populations (Trochim et al. 2016).

The findings of a randomised controlled trial are categorised as the highest level of evidence within healthcare research since it determines the effect of an intervention with the highest level of accuracy (Trochim et al. 2016). To eliminate any effect from confounding factors, steps are taken to ensure the accuracy of the determination of a randomised controlled trial to the effect and cause between the manipulated independent variables and its outcome (Bowling 2014; Trochim et al. 2016). However, the results of a randomised controlled trial may not be applicable outside the population that the sample was taken from since the study population or group who participates may be unrepresentative (Trochim et al. 2016). Although randomised controlled trials are considered the gold standard method to evaluate longitudinal effects of interventions over time (Campbell et al. 2000; Victora et al. 2004; Bonell et al. 2009), it is not always feasible to use randomised controlled trials to evaluate certain health policies or services without a control (Victora et al. 2004; Bonell et al. 2009). In addition, randomised controlled trials lack the ability to evaluate already implemented services retrospectively (Bonell et al. 2009). Moreover, the process of the independent variables' manipulation in a randomised controlled trial that involves human subjects may not be acceptable due to ethical considerations. Therefore, this may limit the use of this method and as a result, many research questions in the health research field are investigated via the use of a quasi-experimental method depending on its aims and objectives (Trochim et al. 2016). Consequently, a randomised controlled trial was not considered an appropriate method to conduct the first empirical study (Chapter 4). If a randomised controlled trial is not possible to be conducted to evaluate the impact of an intervention over time, the data obtained from a secondary database

can be considered the best alternative method (Wagner et al. 2002, Fretheim et al. 2007).

3.6.3. Quasi-experimental research method

In quasi-experimental methods, the study participants can be allocated to two or more groups without the use of the random distribution of the subjects. It may help to investigate the causal relationships of an intervention. However, this type of research provides weaker evidence compared to experimental methods (Trochim et al. 2016). This is because quasi-experimental methods have a higher potential for external confounding factors, as well as selection bias in comparison to experimental methods. Moreover, it may not be possible to manipulate the independent variables in quasi-experimental methods. As a result, findings in quasi-experimental methods are open to different interpretations.

Quasi-experimental methods are more cost effective compared to experimental methods. It also provides quicker results as well as a better generalisation of findings in human research. The type of studies that are categorised as quasi-experimental research includes secondary database studies, descriptive surveys, analytical surveys, cohort studies and case-control studies (Trochim et al. 2016). The following sub-section will discuss the potential and utilised quasi-experimental quantitative research methods to address the aim and objectives of this PhD research.

3.6.4. The potential and utilised quantitative research methods

In this PhD, a quantitative research method was used to address the first objective (Chapter 4), which aimed to identify the number of NMIPs, and their prescribing trend in primary care settings in Wales, with the focus on IPPs. It also aimed to investigate the change in prescribing trends by NMIPs before and after the implementation of primary care clusters in Wales. The quantitative methods that were considered to achieve the study's aim were the cross-sectional questionnaire surveys and secondary database analysis.

3.6.4.1. Cross-sectional questionnaire surveys

A cross-sectional survey is one of the most common types of quantitative methods that are used to collect data at one point in time (Bowling 2014). The approach that is used to collect data in survey research is often questionnaires. There are many approaches to conducting questionnaire surveys, including online, postal, face-to-face, or telephone surveys (Creswell and Creswell 2018). The use of online and postal questionnaire surveys has the advantage of distributing the questionnaire to a wider geographical area which can increase the number of participants. In addition, it helps to remove the face-to-face contact between participants and researchers, which allows to exclude the researcher's influence on the response of participants (Bowling 2014). It has the advantage of being cost-effective and rapid

in collecting data. However, it lacks the ability to collect data retrospectively in comparison to the use of secondary database analysis (Creswell and Creswell 2018). One of the objectives of this PhD was to investigate the trend of prescribed items by NMIPs in primary care settings in Wales over time, as well as before and after the implementation of primary care clusters in 2015. Therefore, participants in a survey will be required to remember and recall a lot of information over a long time in the past. This potentially would not be possible since they will not be able to recall the exact number of items prescribed by them over the years. In addition, a survey will not address the actual significant change in prescribing by NMIPs before and after the implementation of primary care clusters. Moreover, at the time of the study, there was a lack of information about the NMIPs or a definitive list of them in primary care in Wales that could be used to send questionnaires to them. Therefore, the use of a survey to address this objective was considered inappropriate for this PhD study.

3.6.4.2. Secondary Data analysis

Secondary data is existing data that has been collected and archived by someone else over time (Andrews et al. 2012). With the availability of such data, the use of it in healthcare research has become more prevalent (Smith et al. 2011). It involves analysis and interpretation of data to present new knowledge and draw conclusions about an area of interest (Creswell and Creswell 2018). This can help researchers who lack the time and available resources to explore the area under investigation. To illustrate the relationship between variables, the data related to the variables, which consists of numbers, can be analysed descriptively or via the use of an appropriate statistical analysis.

Secondary data is a powerful and useful tool in evaluating changes over time (Gallin and Ognibene 2012). It has some advantages, such as that it has already been collected which will save time and cost to the researcher (Bryman 2016). Furthermore, it usually provides a breadth of high-quality data by providing a large sample size that is widely distributed across large geographical areas. Another advantage is that it provides an opportunity for longitudinal analysis and subgroup analysis to be undertaken as a next step (Bryman 2016).

The disadvantages associated with using secondary data analysis include the complexity of the data, that there may be some missing data, and the researcher may be unfamiliar with some data aspects, as well as lack of control with regards to the specific data collected (Bryman 2016). These disadvantages can be overcome by ensuring the researcher undertakes specific training on the use of the dataset system.

Since the objective of the first empirical study in this PhD was to identify the numbers of NMIPs and their prescribing trend of items from 2011 to 2018 and before and after the implementation of primary care clusters in 2015, it would be unrealistic to collect the required

data prospectively. Therefore, the quantitative method used to address this objective was secondary data analysis. It involved the use of descriptive analysis of the data as well as a statistical analysis to measure the change in the trends over time. Since research starts with understanding what has already been learnt about a subject, previously collected evidence and data on the subject should also be considered (Creswell and Creswell 2018; Doolan and Froelicher 2009). By reviewing the literature that was illustrated in Chapter Two, it was evident that there were no previous studies that used any database to investigate the change in the number of NMIPs and their prescribing trends of items over time in primary care in Wales at the time of the study.

The availability of a dataset that provided prescribing data of NMIPs in primary care in Wales over time presented an opportunity to address the aim and objectives of this study (Chapter 4). This dataset is known as the Comparative Analysis System for Prescribing Audit (CASPA) software system. Detailed information about this system including its advantages and limitations is discussed in Chapter Four.

3.7. Qualitative research methodology

The objectives of the other studies in this PhD are exploratory in nature (objective 2: to describe the roles of IPPs working within GP practices in Wales and to explore their views on how their role is embedded in primary care (Study 2, Chapter 5), and objective 3: to explore the views of community IPPs and HB community pharmacy leads regarding the role of IPPs within a community pharmacy setting (Study 3, Chapter 6). Therefore, qualitative research methods were more appropriate to conduct these studies. This section will discuss qualitative research methodology. It will mainly focus on the qualitative research methodology used in the PhD, as well as the potential qualitative research methodologies that could have been used to address the aim of this PhD.

In contrast to quantitative research methodology, the findings of qualitative research are produced by methods that do not involve using any statistical analysis or manipulating and numerically quantifying the relationships between variables (Creswell and Creswell 2018). Qualitative research helps in recognising a phenomenon in its social context, as it focuses on understanding the meanings that participants in a research study relate to their social world experiences (Bowling 2014). The qualitative researcher's personal experiences, presence, and involvement in the environment under review are recognised as essential to understanding the context of the subject being studied rather than just gathering data (Barbour 2007). Moreover, it involves the researcher's extensive critical analysis of collected data to produce findings that provide a thorough definition and understanding of phenomena (Barbour 2008).

3.7.1. Features of qualitative research

Qualitative research aims to explore and clarify how participants understand concepts and the mechanisms by which they incorporate these concepts into daily practices (Barbour 2008). For example, research aims to investigate patients' perceptions and responses to healthcare services provided by certain HCPs that may result in either negative or positive outcomes and experiences.

Qualitative research has the limitation of being time-consuming. This is because it has the potential of generating a large amount of data, which requires a long time to analyse (Bryman 2016). This limitation may restrict some researchers in the health services research field to use qualitative research. However, it does not diminish the benefits that qualitative research provides to this area by formulating and influencing new policies and interventions (Austin and Sutton 2019). The main benefit of a qualitative approach within healthcare is its appropriateness in studying subjects that have sensitive or complex issues, or where only a little information is available about it (Bowling 2014). Furthermore, qualitative research methods are also recognised for their benefit in understanding phenomena from the point of their natural contexts. Therefore, the results are more likely going to reflect the needs of the various stakeholders, which laboratory research with its restricted and controlled environment, will not be able to provide (Johnson and Onwuegbuzie 2004). Hence, qualitative research offers the opportunity to closely explore and analyse lived social experiences in a way that cannot be conducted using quantitative methods (Barbour 2008). This has increased the popularity of qualitative research for healthcare researchers to study complex human experiences and interactions related to health services utilisation, demand, provision, and planning (Bowling 2014).

3.7.2. Trustworthiness of qualitative research

An important aspect of qualitative research is to establish trustworthiness to ensure the quality of the research findings. Trustworthiness refers to the credibility, transferability, dependability, and confirmability of the research results (Bryman 2016). Credibility is the confidence in the truth and accuracy of the research findings that represent the participants' experiences and perspectives. It involves confirmation by the members (also known as member validation) of the investigated social world that the research is conducted using good practice and the researcher has appropriately understood the phenomena. Another way to ensure credibility is through the use of the triangulation strategy in which multiple sources of data are considered, such as using interviews, focus groups, or observations (Bryman 2016). In this PhD, the researcher engaged with the relevant expert stakeholders within the field to understand the investigated phenomena and help in the development of the data collection

tools (interview schedules in both qualitative studies; Chapter Five and Chapter Six) to ensure that the questions being asked were appropriate. Transferability is the extent to which the findings of a qualitative study can be applicable or relevant to other similar situations or populations. To enhance transferability, researchers should provide rich and detailed information (also called thick description) about the research process, participants, and context, which allows other researchers to assess the applicability of the findings to their contexts (Bryman 2016). This has been achieved by the explicit details of the methodology within each of the qualitative studies chapters (Chapters 5 and 6). Dependability is the stability and consistency of the research process and findings over time and across contexts. To ensure dependability, researchers should provide a transparent and comprehensive description of all the research steps, decisions, and any changes during the research process, allowing for verification (Bryman 2016). This has also been ensured by providing extensive details of all the research steps and any changes within it in each of the qualitative studies chapters within the methodologies' sections in Chapters Five and Six. Confirmability refers to the neutrality and objectivity of the qualitative research results. Maintaining confirmability requires researchers to acknowledge and document their own biases, values, or preconceived notions that might influence the research outcomes (Bryman 2016). In the PhD, the researcher reflected on his own experience of being neutral and objective to eliminate any kind of biases, values, or preconceived notions that might have influenced the qualitative research outcomes in a reflexivity section in this Chapter (Chapter 3, Section 3.12). In addition, after conducting each interview, the researcher reflected upon the way it was undertaken, and the way questions were asked, and then made changes as needed for the next interviews to ensure confirmability of results. In conclusion, the second and third studies in this PhD have involved the use of comprehensive documentation of all research steps and limitations, and research members' checking of the whole research to demonstrate trustworthiness and ensure transparency and rigor in this research.

3.7.3. Types of qualitative research methods that were considered and utilised for this PhD

In qualitative research, there are three main methods to collect and generate data, which are: observational research, interviews, and focus group discussions (Barbour 2007). All actively involve interactions between the researcher and research participants to collect and generate data. There are some other methods of collecting data in qualitative research that involve the analysis of documents, such as diaries and patients' files, as well as video and audio materials (Barbour 2008). However, as the objectives of this thesis related to exploring phenomena from different people's perspectives of the role of IPPs, no such documents are routinely completed by these individuals and there are no available published

qualitative studies concerning it to analyse, it was decided that it was not an appropriate method to consider.

3.7.3.1. Observational method

An observational method is the main ethnographic qualitative approach. It gives the researcher the ability to directly observe participants' behaviour in the natural environment (Barbour 2007). It observes human activity sequences in a way that helps to discover new data that can be linked to the study's local contexts (Bowling 2014). It aims to observe participants to gather more detailed information about complex phenomena that participants may not raise or explain with a researcher being as discrete as possible (Bowling 2014). Since the objectives of the second, and third studies of this PhD (Chapter 5 and Chapter 6; respectively) aimed to explore the views of participants regarding the role of IPPs, observational methods were considered inappropriate to use for these studies. This is because observational methods involve documenting events related to individuals' practices rather than exploring their opinions. In addition, observational methods have many logistical difficulties, such as requiring the presence of the researcher in one location at a time to conduct the observation. This may lead to very time-consuming data collection, as well as missing important events that occur by other participants in different sites. Moreover, the 'Hawthorne effect' may have a major limitation on the validity of the collected data, which is the effect of the researchers' presence around observed participants that may lead to a change (consciously or unconsciously) in their usual behaviour (Bowling 2014).

3.7.3.2. Focus group discussion

Focus group discussion is a qualitative data generating approach that has been applied in social research, community research, organisational research, and market research (Barbour 2005). It involves an interaction between small groups of people as well as with the group moderator, to address issues of interest and generate data (Bowling 2014). The group moderator is usually the researcher who actively encourages the group participants to be engaged in the discussion (Flick 2018). Focus group discussion has been highly utilised in health services research (Barbour 2005). It has the advantage of providing in-depth information about the discussed topic that involves the participants' views and perceptions in an efficient time and cost-effective manner (Bowling 2014). Moreover, focus group discussion provides an opportunity for participants to discuss the issues related to the topic of interest (except for some aspects, such as sensitive topics) in a way that is less threatening to them compared to one-to-one interviews (Barbour 2007). In addition, participants may be able to support each other in terms of remembering certain events and feelings, which may help them to provide more detailed information about the topic. However, when conducting this PhD

study, focus group discussion had the disadvantage of the difficulty in gathering people to sit at a table with other participants at the same time, particularly in the health services field where people are very busy with their daily duties (Green and Thorogood 2018). In addition, conducting focus groups through online software was not a recognised approach at the time of the study, therefore, was not used (Sah et al. 2020).

3.7.3.3. One-to-one interviews

One-to-one interviews are considered the most common method in qualitative research that allow for comprehensive exchange of information between the investigator and the participants (Green and Thorogood 2018). There are three types of interviews: structured, semi-structured and unstructured interviews (Bowling 2014, Flick 2018).

Structured interviews strictly follow an interview guide and protocol by the researcher to collect data from participants. It is a rigid style of interview whereby the researcher asks questions that are only available in the interview guide. This guide does not allow for many opportunities at which researchers can probe or ask more questions if they are interested to explore the investigated topic further, which are not stated in the guide (Bowling 2014, Flick 2018). Furthermore, the restricted guide of the structured interviews will not help researchers to clarify or ask questions in a different way if participants did not understand the questions (Flick 2018). However, it has the advantage of providing a comprehensive list of questions that can help to specifically target the investigated topics, phenomena, or participants' experiences. This will help to collect the information that the researcher needs, to avoid doing follow-up interviews to collect missed information or questions (Flick 2018).

In contrast, semi-structured interviews involve the use of open questions based on a loose guide that can help to provide a great deal of flexibility to the researcher but to keep the discussion within the investigated topic (Flick 2018). Although it has a guide that the researcher uses to conduct interviews with the participant, it can involve the use of appropriate prompts by the researcher that may help in gathering in-depth information regarding the participants' opinions, feelings, and thoughts (Creswell and Creswell 2018). This can help the researcher avoid doing several rounds of interviews since the interview guide can help to stay focused on the discussed topic and answer the research question (Creswell and Creswell 2018).

Unstructured interviews are designed to ensure that the discussion is driven by issues relevant to the participants, which is conducted with none or very few interview questions (Bowling 2014, Flick 2018). It is similar to a normal conversation, but it is about the research topic (Flick 2018). It does not involve the use of any formalised interview guide to develop comfort and rapport with participants. The absence of an interview guide may help the researcher probe participants to gather as much in-depth and rich information as possible.

However, this approach may require researchers to conduct many rounds of interviews with research participants to collect all the required information. This is because the conversation with the participants may get driven away from the research topic in the absence of an interview guide (Flick 2018).

As briefly discussed above, each type of interview has many advantages and disadvantages. Therefore, the selection of an interview type to conduct a research study depends on the research design, as well as the research aim and objectives (Bowling 2014, Flick 2018). In this PhD, semi-structured interviews were used to gather information from participants and the rationale for choosing this type of interview will be discussed individually in each study.

Interviews can be conducted either face-to-face, by telephone, or virtually (over the internet) (Bowling 2014, Flick 2018; Sah et al. 2020). Traditionally, face-to-face interviews have been recognised as the most common method of data gathering in qualitative research. It has the advantage of gaining both verbal and non-verbal communication with participants, which may help to obtain a deeper understanding of the data (Flick 2018). However, this method is both expensive and time-consuming (Opdenakker 2006). Telephone interviews are used less often for qualitative data collection. This is due to a number of reasons, such as lack of non-verbal communication, it may take longer to explain some of the study aspects over the phone, and technical problems that may occur at the time of the interview (Novick 2008). However, telephone interviews provide access to participants who live in diverse geographical areas, which provides a much cheaper option to conduct interviews. Moreover, telephone interviews may provide a less imposing method for participants rather than face-to-face interviews (Sturges and Hanrahan 2004, Opdenakker 2006). In addition, the quality and depth of data produced by the use of telephone interviews do not vary significantly from the data produced by face-to-face interviews (Sturges and Hanrahan 2004; Austin and Sutton 2019). As a result, at the time of the study, the use of telephone interviews had become an alternative effective tool in conducting qualitative interviews. Virtual interviews involve the use of internet technology to conduct interviews as a voice or video call (Sah et al. 2020). Skype, Microsoft Teams, Zoom, and Google Hangouts are examples of software that can be used to conduct and record interviews virtually (Sah et al. 2020). The use of this approach has increased over recent years, particularly in the healthcare field since researchers and potential participants in this area are usually busy due to their heavy workload and other life responsibilities, as well as living or working far from each other. Therefore, conducting interviews virtually can be considered a suitable approach for them to manage their time effectively and overcome geographical barriers since video calls can help eliminate the time and cost needed to travel to conduct face-to-face interviews (Sah et al. 2020). Moreover, the use of virtual interviews during compelling circumstances that restricted people from traveling, such as the COVID-19 pandemic, provided a good opportunity to conduct research. However, connectivity issues, unavailability of the appropriate video conferencing software, and possible noise and distractions in the background are disadvantages of considering the use of virtual interviews (Sah et al. 2020). Since the use of virtual interviews was not recognisable tool at the time of this PhD study, both face-to-face and telephone interviews were used to collect and generate data within the qualitative studies. The rationale for using interviews in each study will be explained in each relevant chapter (Chapters 5 and 6).

3.8. A mixed methods approach to study the role of IPPs in primary care settings in Wales

As discussed earlier in Section (3.4), the most appropriate methodology to conduct this PhD was the utilisation of a mixed methods approach. It was important to use different methodologies to appropriately address the research questions of this PhD because it focuses on understanding the development of the IPPs' role in primary care settings in Wales. This involved exploring their numbers and prescribing trends over time using a quantitative approach (secondary data analysis), followed by investigating how their role was embedded within GP practices and community pharmacies using a qualitative approach (semi-structured interviews). It was necessary to do so in order to understand the subject by conducting the quantitative study and then undertaking the qualitative studies. As a result, using a mixed methods research approach would enable the use of various research methodologies, as well as different data collection and analysis tools. Because neither quantitative nor qualitative approaches can fully address this thesis research question, a mixed methods approach was adopted. The first study (Chapter 4) was conducted using a quantitative approach (secondary data analysis of the number of NMIPs, focusing on IPPs data, and their prescribed items over seven years and in relation to the implementation of primary care clusters in 2015). This was followed by two qualitative studies (Chapter 5 and Chapter 6,). The first qualitative study was conducted using semi-structured interviews to describe the roles of IPPs working within GP practices in Wales and explore their views on how their role is embedded in primary care (Chapter 5). The second qualitative study also used semi-structured interviews to explore the views of community IPPs, and HBs community pharmacy leads regarding the role of IPPs working within community pharmacy settings (Chapter 6). The summary of the research methods that were used in each study in this PhD is presented in Figure 2.

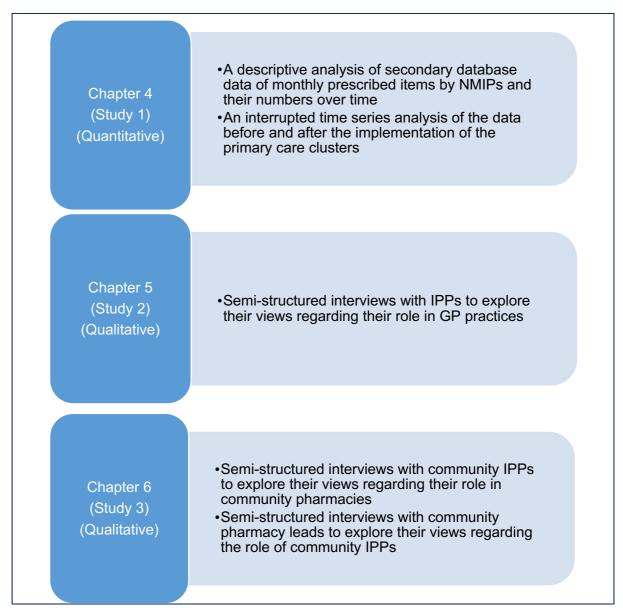


Figure 2 The summary of the research methods that were used in each study in this PhD.

3.9. Sampling in quantitative and qualitative research

Daniel (2012) has identified a process to select the appropriate sample type or use a census of the whole study population for a research study. The first step in this process is preparation before deciding on sampling choices. It involves a thorough review of the aim of the study, available resources, the nature and availability of the study's population, research design aspects, and ethical considerations of the study. The second step involves making a decision between a census and sampling by understanding and relating to the objectives and importance of the study, the nature of the study's population, and heterogeneity/homogeneity. The third step is to choose the type of sampling (once a census was considered inappropriate) as either probability, non-probability, or mixed methods sampling approach. This is followed

by the fourth step, which is to choose the type of probability, non-probability, or mixed methods sampling. The fifth step is to determine the sample size followed by the sixth step, which is to select the sample.

There are two types of sampling in research, which are probability and non-probability sampling (Byrne 2001; Creswell and Creswell 2018; Flick 2018). Probability sampling is a sampling process that involves the use of a randomisation technique so that potential participants from the study population are given equal opportunities to be included in the study as a representative sample (Byrne 2001; Creswell and Creswell 2018; Flick 2018). Probability sampling helps to generalise the findings of the study. Non-probability sampling is a method that does not involve the use of a randomisation technique for the study population (Byrne 2001; Creswell and Creswell 2018; Flick 2018).

Since quantitative research is often aimed to generalise the findings to a larger population than the study population or test hypotheses, it uses a probability sampling technique (Creswell and Creswell 2018). However, there are a few types of quantitative research that do not use probability sampling, such as evaluation or exploratory studies, which may use non-probability sampling (Creswell and Creswell 2018). In the first study of this PhD (Chapter 4) which undertook secondary analysis of the prescribing data, no sampling was required (i.e. a census approach) as the database contained the whole dataset and could be easily analysed.

On the other hand, qualitative research does not aim to generalise results or test hypotheses like quantitative research (Creswell and Creswell 2018; Flick 2018). Qualitative research aims to generate data from a few participants to investigate the complex processes that relate to a phenomenon. As a result, samples do not essentially need to be representative of the wider population in qualitative research (Flick 2018; Daniel 2012). In addition, random sampling in qualitative research is inappropriate because the human characteristics in such research do not appear to follow a normal distribution across populations (Byrne 2001). As a result, qualitative research usually uses census (selecting the whole study population) or non-probability sampling strategies to select a subset of the target population (Daniel 2012).

The most common non-probability sampling strategies that are used in health services qualitative research are purposive sampling, snowballing sampling, convenience sampling and theoretical sampling (Bowling 2014). Purposive sampling intentionally chooses participants according to specific characteristics, such as participants who had experiences related to the phenomena under the study, to generate the required data that best demonstrate the topic of research (Cooper et al. 2009). Participants who are included in a qualitative study through this sampling technique are expected to represent the different study viewpoints, including both positive and negative experiences, which will help to maximise the

study variability (Byrne 2001). Snowball sampling is based on recruiting participants at first who then recommend or help in recruiting other potential participants who meet the study characteristic of interest (Bowling 2014). This sampling technique is mostly utilised when a clear sampling strategy is not available due to the lack of information about potential participants (e.g., people injecting illegal drugs). Convenience sampling strategy (also known as opportunistic sampling strategy) is mainly used to recruit participants who are the most available and ready to be included in a qualitative study (Bowling 2014). This sampling strategy is recognised as the most resource efficient strategy since it helps researchers to save money, time, and efforts. However, it may generate data and findings with low quality (Byrne 2001). A theoretical sampling strategy is more widely used in qualitative research that involves the use of grounded theory analysis. It produces new theories and concepts that define the category of potential participants, as well as to refine and develop those theories and concepts (Byrne 2001). However, there seems to be an overlap between some of these sampling strategies since participants are often included for particular purposes according to the research objective, regardless of which of the strategies is used (Coyne 1997).

In the qualitative studies of this thesis, the population size was very small, therefore, purposive and convenience sampling were used, to recruit as many participants as possible. Further details on the sampling and the studies' population are illustrated in each chapter's methodology section for study two and study three (Chapter 5 and Chapter 6; respectively).

3.10. Data analysis in quantitative and qualitative research

Data analysis in quantitative research usually involves finding the numeric relationships between variables to identify the causal significance of an intervention (Creswell and Creswell 2018). However, this section will focus on secondary data analysis used in this PhD (Chapter 4). The analysis of data that are obtained from databases starts with the researcher understanding the datasets (software) to extract the right data to answer the research question (Creswell and Creswell 2018). Thereafter, researchers need to familiarise themselves with the data, which involves extracting data into Excel Software to make it easier to understand. Consequently, the descriptive analysis begins by describing the findings and calculating percentages of changes in the prescribing volume of NMIPs over time (Creswell and Creswell 2018). Then, if appropriate, select the suitable statistical test to identify the statistical significance of the findings, which is generally by capturing the result of the p-value. The p-value assesses the probability of the results being more than coincidence (Creswell and Creswell 2018). If the p-value is lower than 0.05, then the findings are statistically significant, and researchers can be more confident that the results are genuine (Creswell and Creswell 2018). Detailed information on the data analysis of the first empirical study in this PhD (Chapter 4) is presented in Section 4.5.6.

In contrast, the use of qualitative research to investigate phenomena, particularly using documentary analyses, interviews, and observations, relies on the collected textual data obtained from participants rather than numeric data (Bowling 2014; Creswell and Creswell 2018). To achieve this goal, qualitative research at the start of a research project mainly places little focus on a predefined hypothesis and concept. In qualitative research, hypotheses and concepts are usually developed as the research progresses (Barbour 2007). The analysis of qualitative data involves the use of an inductive, deductive, or mixed approach. An inductive approach means that the identified themes or patterns are strongly related to the data themselves that have been collected specifically for the research (Patton 1990). These themes may have little or no relation to the questions that were asked to participants (Braun and Clarke 2006). However, the deductive method (also known as the theoretical approach) is driven by the researcher's analytical or theoretical interest in the topic area (Braun and Clarke 2006).

There are different approaches to data analysis in qualitative research, such as content analysis, narrative analysis, discourse analysis, grounded theory, and thematic analysis (Creswell and Creswell 2018; Flick 2018). Content analysis is a method that is used to identify, categorise, and quantify the presence and meaning of certain themes, concepts, and words within qualitative data (such as a text) (Flick 2018). Narrative analysis is an approach in which the stories presented by participants are reformulated to understand the meaning of each case and the context behind their different experiences. It mainly involves the researcher's review of primary qualitative data (Flick 2018). Discourse analysis is a research tool that aims to study and analyse spoken language and written text to understand the social context behind it. Grounded theory is a systematic approach that only uses inductive reasoning to build and formulate theories and concepts through collecting and analysing data (Andrews et al. 2012; Flick 2018). On the other hand, thematic analysis was defined by Braun and Clarke (2006; p79), as a qualitative method for 'identifying, analysing, and reporting patterns (themes) within data'. It has the advantage of flexibility due to its theoretical freedom that can involve both inductive and deductive approaches, which may help provide detailed and rich data (Braun and Clarke 2006). Thematic analysis was used in the qualitative studies in this PhD (Chapters 5 and 6) as it was the most appropriate method out of all these approaches to identify themes and explore viewpoints of participants. It was considered appropriate as the researcher conducted the work from a pragmatic point of view that involved the use of both inductive (from the data) and deductive approaches (based on discussions between the research team and key individuals in the investigated field) (Winit-Watjana 2016). The thematic analysis process consists of six steps as presented in Figure 3.

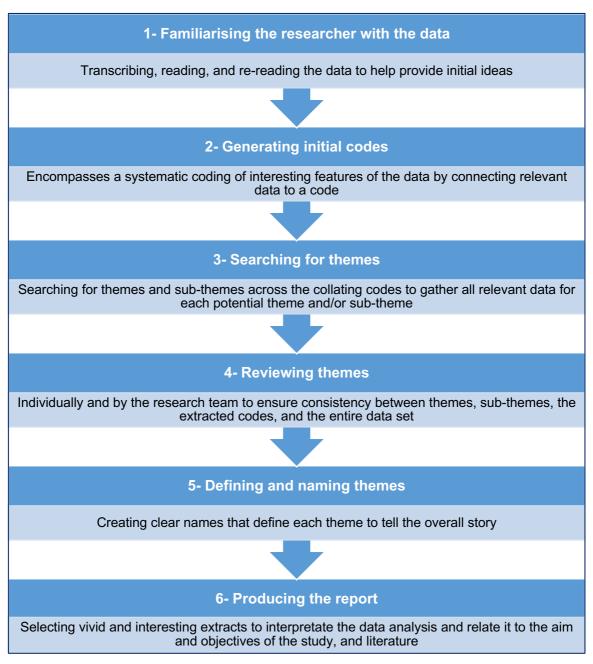


Figure 3 The thematic analysis process (Braun and Clarke 2006)

The detailed information on the thematic analysis process for the qualitative studies in the PhD (Chapters 5 and 6) is as follows:

Step one (Familiarisation): this was conducted after the interviews were recorded. It involved listening to the interviews to provide a general sense of the data and its meaning and making changes in terms of the way the questions were asked for the next interviews if needed to ensure the confirmability of the results. The interviews were then transcribed by a university-approved transcribing services company. Thereafter, the researcher listened again to the recorded interviews and read the transcript line by line to quality check, proofread the transcript, and check for inaccuracies, as well as de-identifying

- participants' information within the data. Afterward, the researcher re-read the transcript, which helped provide initial ideas.
- Step two (Generating initial codes): this involved re-reading the data line by line to make broad codes using labelling colours. Keywords were used by the researcher to describe what was interpreted. This initial coding connected relevant data to a code.
- Step three (Searching for themes): this started by reviewing the codes within the transcripts by the researcher. This involved looking for different words or phrases across the initial codes that described the same phenomenon, in which to keep only one of them. Thereafter, the codes were checked for appropriateness by other members of the research team. The researcher then looked for any connections between the codes, followed by combining these connections under an initial sub-theme. Afterward, these sub-themes were reviewed for similarity to establish connections between related ones to be grouped in a theme.
- Step four (Reviewing themes): this was associated with reviewing and adjusting these subthemes and themes by the researcher, followed by a meeting with the research team to confirm the appropriateness of the findings.
- Step five (Defining and naming themes): this involved refining, defining, and confirming the name and concept for each sub-theme and theme by the researcher, which was also checked by the research team.
- Step six (Producing the report): this involved selecting interesting quotations to write in the final report and relate to the aim and objectives of the study and literature, which also was reviewed by the research team.

3.11. Ethical considerations

Ethics are considered as one of the most important aspects in research (Austin and Sutton 2019). It is defined as 'the moral principles or values held or shown by an individual person' (Oxford University Press 2021). The term is commonly associated with an ability to distinguish right from wrong. The goal of an ethical review is to make sure that the ethical risks associated with research activities are properly considered. Research involving the participation of human subjects, collecting human data, or human research (Human Research) must undergo an ethical assessment by a relevant ethical committee that is independent, qualified, and properly constituted. The aim of research ethics committees (RECs) is to provide monitoring and educational services to enhance the quality of the research and give researchers the confidence that the proposed study will protect and maintain the safety of individuals involved in the research by taking into consideration all potential risks. This section discusses the process of obtaining the relevant ethics committee approval and other

permissions, such as the Research and Development Offices in each HB in Wales, as well as the importance and process of obtaining informed consent.

3.11.1. Obtaining approval from ethics committee

This PhD involved the use of a secondary database as well as participation of individuals in interviews, including IPPs in both GP practices and community pharmacies, as well as community pharmacy leads in HBs. As such, obtaining ethical approval was vital to ensure that the studies were conducted responsibly and safely. The type of study, as either a research or service evaluation, determines what type of approval is required and from where (Health Research Authority (HRA) 2017).

The type of study is determined by completing an online tool established by the HRA in cooperation with the Medical Research Council (MRC) Regulatory Support Centre (HRA 2020). A research study is defined as:

'The attempt to derive generalisable or transferable new knowledge to answer questions with scientifically sound methods, including studies that aim to generate hypotheses as well as studies that aim to test them' (HRA 2017, p.1).

A service evaluation is defined as a study 'designed and conducted solely to define or judge current care' (HRA 2017, p.1). If the study is considered research, the NHS REC (Research Ethics Committee) is required to review the study since participants may be using NHS services. However, service evaluation studies do not require NHS REC approval, but may require other ethics committee approval, such as university ethics committee approval.

The quantitative study in this PhD, which involved the analysis of secondary data, only required to be registered with the HB (with the Research and Development Office at CVUHB to extract the relevant data) since the data was collected as a part of routine practice, and it was anonymised with no personal information available to the researcher. The qualitative studies of this PhD were all considered service evaluations after completing the HRA decision online tool (HRA 2019; NHS Research and Development Forum 2021). This meant that there was no need to obtain NHS REC approval. However, ethical approval for the qualitative studies was obtained from the School of Pharmacy and Pharmaceutical Science Research Ethics Committee, Cardiff University. It was a requirement that all studies involving human participants must obtain School approval to be conducted, which included both research and service evaluation. The process involved completing the research integrity course that was provided online by Cardiff University. It also required the completion of the School of Pharmacy and Pharmaceutical Science online application form, which also involved the submission of the invitation and reminder emails, participant consent form, participant information sheet, and interview schedule for each study for review. The response of the committee to all the studies indicated some minor amendments before accepting the applications. These amendments

were made and final acceptance for all the studies was obtained. The approval notices are available in the relevant chapter for each study. Moreover, the Research and Development Offices in five HBs out of the seven (as there was no response from the other two HBs) in Wales reviewed and registered the second part of the third PhD study (Chapter 6), which aimed to explore the views of the community pharmacy leads in different HBs in Wales regarding the role of community IPPs. This was required since these leads were employed by their respective HBs. Those HBs also considered this part of the PhD to be a service evaluation that didn't require NHS REC approval (HRA 2017; HRA 2019; NHS Research and Development Forum 2021).

3.11.2. Informed consent

For the studies to be conducted in an ethically appropriate manner, participants must give their informed consent. This is to ensure that all the risks associated with the study, as well as the potential advantages, are clarified with potential participants (Polgar and Thomas 2020). This is by providing participants with information about the study to help them decide whether to participate or not. In this PhD, information about each study was provided to participants in the invitation letter, participant information sheet, and consent form. The invitation letter for each study included some background information about the study, the aim of the study, and some information about the researcher and supervisors (HRA 2019). Potential participants were asked to reply within two weeks and to complete, sign and send back the appropriate consent form or to bring it with them during data collection. Potential participants who did not respond to the invitation email after two weeks were sent a reminder email to increase the recruitment rate and then after a further two weeks, it was assumed they did not want to participate.

The guidance of the HRA was followed to prepare the participant information sheet for all the studies (HRA 2019). It included detailed information for participants with the title of the study, a brief introduction, and information about the researcher and supervisors with their contact information. While the rest of the information was formatted as questions and answers as follows:

- What is the purpose of this study?
- Why have I been selected to participate in this study?
- What will I have to do if I take part?
- What will occur with the information I provide in this study?
- What do I need to do to participate in this study?
- What if I no longer would like to participate in this study?
- What if I want to raise any concerns or complaints?

These questions were designed to allow the potential participant to voluntarily choose

to either participate or not, which is the most important ethical aspect of doing qualitative studies (Polgar and Thomas 2020). It was clearly stated that the participation of individuals in the studies was voluntary, and their consent was required to participate, and that if they did not want to participate or would like to withdraw from the study, they did not need to do anything further or make any kind of justification.

The consent form was also designed according to the HRA guidance (HRA 2019). It was prepared so that the participants confirmed that they had read the participant information sheet and that they were able to consider the information, ask any questions and, if appropriate, the questions had been answered to their satisfaction. The consent form also required them to confirm they were voluntarily participating and were aware that they were able to withdraw at any time. Moreover, a space was provided for their name, the date, and their signature of approval to participate. The invitation email, reminder email, participant information sheet, and participant consent form for each study are discussed and cited in each relevant chapter of this thesis.

3.12. Reflexivity in quantitative and qualitative research

Reflexivity is defined by Barrett and colleagues as 'an ongoing process that involves reflection to continuously construct (and shift) our understanding and social realities'. (Barrett et al. 2020, p.10). It involves the researcher's continual engagement and recognition of different aspects of the research and the impact that it may have on the area and individuals being studied, collected data, and its analysis and interpretation (Berger 2013). It also involves handling challenges and barriers within the research context (Barrett et al. 2020). Some factors, such as the researcher's influence, knowledge, and position, as well as the entire research process, may have an impact on the research. The process of a reflexive approach in research is represented by describing the intentional and unintentional consequences of these factors (Barrett et al. 2020). These factors are very important in qualitative research to diminish the researcher's bias (Barrett et al. 2020).

3.12.1. The researcher's experience in this PhD

It is important to discuss my experience in this field of research before and during the time of conducting this PhD to understand how it might influence my research. I obtained my bachelor's degree (a Pharm.D. degree) from a clinical pharmacy college in Saudi Arabia. Then, I worked as a teaching assistant at the same pharmacy school. Thereafter, I came to the UK (sponsored by the pharmacy school in Saudi Arabia) to obtain my master's degree (in advanced clinical pharmacy practice with an extended placement at a hospital). Even though I had no prior experience working with IPPs, since this role has not been established in Saudi Arabia, I came across IPPs who work in secondary care settings (hospitals) during my

placement in the UK. I noticed that this was a new role for pharmacists, which allowed them to prescribe medicines to their patients. Since I started my PhD, I looked at the literature that shows a lack of research about this role, particularly in GP practices and community pharmacies. Although I have no experience with the UK GP practice and community pharmacy healthcare system before starting my PhD in the UK as an international student, I am aware unity pharmacies in both countries represent the first point of contact for patients with HCPs. However, the community pharmacy settings in Saudi Arabia are focussing more on dispensing medicines to their patients, compared to the UK which can provide more services, including the role of IPPs.

For me to be fully engaged in this PhD with the phenomena under investigation, visits, meetings, and observing IPPs who work in GP practices were undertaken. This was to avoid any lack of knowledge regarding their services and discuss issues related to the role. Furthermore, I was exposed to how IPPs perform their daily tasks and consultations with their patients in GP practices. This has helped me to understand the duties of the IPPs before doing the qualitative studies. It also helped me to be familiarised with the Welsh GP practice healthcare system. Before the study, I enrolled in several workshops to understand how to conduct interviews, qualitative approaches, and thematic analysis. Furthermore, I studied primary and secondary sources to widen my understanding of the research topic and qualitative approach. My continuous engagement with my supervisory team had a huge impact that guided me on what to expect and avoid and what to integrate into my qualitative research, especially in terms of data analysis, topic guides, and conducting interviews.

In the qualitative phase of this research, the topic guide was designed in conjunction with my supervisors' and relevant experts' extensive review and opinions. With the feedback that I received from them; I was able to design more comprehensive interview schedules. Then, I analysed the interviews and looked for themes, which were then reviewed by the research team, to ensure that relevant themes related to the research topic were identified and defined. Although I was fully involved, there was a need for objectivity in presenting what the data illustrated. This research might have been influenced by my previous experience, beliefs, and perceptions of IPPs' role, but I was objective and unbiased as much as possible when conducting the qualitative research. This has assisted me in identifying themes and asking probing questions when collecting data.

3.13. Conclusion

This chapter has discussed the basis of mixed methods, quantitative, and qualitative methodologies, including their types and the research paradigms underpinning them. The following chapters will present and discuss each study that was conducted in this PhD.

4. Chapter 4 – Prescribing Trends Over Time by NMPs in Primary Care
Settings in Wales: A Secondary Data Analysis

4.1. Introduction

This chapter aims to address the first objective of this PhD, which is to identify the number of NMIPs, their prescribing trend of items in primary care settings in Wales, and the impact of the primary care clusters implementation in 2015. It will present the findings of this study, which involved the use of a quantitative approach to identify the number of NMIPs and an analysis of their prescribing trends within primary care in Wales. It will also discuss the study rationale, aim and objectives, results, discussion, and conclusion.

4.2. Study rationale

As discussed, in the Introduction Chapter (Chapter 1, Sections 1.4 and 1.6), the WG and HBs have been focusing on improving primary care services through the Government plan entitled 'Our plan for a primary care service for Wales up to March 2018' (Welsh Government 2015). It involved the development of the primary care clusters that came into being in the last quarter of 2015 (The National Assembly for Wales 2017). The WG and HBs prioritised funding for new cluster posts and for the training of other HCPs, such as IPPs and INPs (Welsh Government 2015). As some of the objectives of the Government's plan were to improve patients' access to their required medicines and information as well as to provide advice and support that could help to manage their medications in the most appropriate way, specific pharmacist cluster posts were developed (Royal Pharmaceutical Society Wales 2015; Hodson 2017), with a pharmacist working within each GP practice within a cluster. Many of these posts were initially filled with IPPs from hospital pharmacies (Hodson 2018). The number of NMIPs in primary care has increased in recent years and is expected to increase more in the future (Courtenay et al. 2017a; Hodson 2017).

The literature review chapter (Section 1.2.5) highlighted the few studies that explored the prescribing of NMPs in the UK. At the time of data collection and analysis of the PhD, only one published study investigated the implementation of NMPs' role in Wales, which was conducted by Courtenay and colleagues (2017a) using a national survey. The results of this study indicated that the majority of NMPs in Wales were based in secondary care settings and non-medical prescribing had not been implemented in all primary care services. According to the findings of this study, the utilisation of NMPs across Wales, particularly in primary care, was inconsistent. The findings also highlighted the main prescribing scope of INPs and IPPs, which was related to acute conditions for the former (INPs) and chronic conditions for the latter (IPPs). However, despite the high response rate of the participants (60%), the study had a limitation in which that the information collected through the survey was self-reported. As a result, some of the collected data (e.g., the number of prescribed items and therapeutic groups of medications) was estimated by participants. In other nations in the UK, only a few studies

explored the prescribing of NMPs in primary care in England. However, these studies used secondary data analysis to explore their volume and pattern of prescribing (Guillaume et al. 2008; Drennan et al. 2014; Courtenay et al. 2017b). Guillaume and colleagues (2008) only examined the pattern and volume of supplementary pharmacist prescribing. The findings showed an increase in their prescribed items over the study period (from n= 2,706 in 2004 to n= 31,052 in 2006). The portion of their prescribing volume was only 0.004% of the total prescribed medications in primary care settings in England. Their most prescribed therapeutic groups of medications were related to chronic conditions, including cardiovascular medications, followed by CNS, respiratory, endocrine, and gastrointestinal systems. Although this study showed an increase in the prescribing volume of supplementary pharmacist prescribers, the role has not developed as the focus has changed to support the implementation of independent pharmacist prescribing in 2006 in England (2007 in Wales) (GPhC 2013). In addition, prescribing courses related to the supplementary pharmacist prescribers have since stopped or changed to support IPPs (GPhC 2013). Similarly, Drennan and colleagues (2014) only investigated nurses' (as both independent and supplementary prescribers) prescribing volume and patterns between 2006 and 2010. The findings indicated an increase in the number of nurse prescribers from 13,391 in 2006 to 15,841 in 2010. The percentage of the total prescribed items by nurses also increased from 1.1% in 2006 to 1.5% in 2010. Their most frequently prescribed medications were related to antibiotics, mainly penicillin, followed by dressings and contraception. However, a limitation of this study was that the national database system that was used as a source for the data was limited to five years only. The last study was conducted by Courtenay and colleagues (2017b) between 2011 and 2015, investigating only one therapeutic area of prescribing by NMPs, including IPPs, that was related to antibiotic medications. The findings revealed that NMPs accounted for almost 10% of all prescribed antibiotics in primary care settings in England. Their prescribing volume of antibiotics had relatively increased over the study period by 18%. The majority of antibiotics were prescribed by nurse prescribers (almost 90% in 2015) and only a few (almost 10%) were prescribed by IPPs and other NMPs. The analysis showed that around 85% of the prescribed antibiotics by NMPs adhered to the antimicrobial stewardship guidelines, reflecting the high competence of NMPs in antibiotic prescribing. At the time of this empirical study in the PhD, the literature lacked a study in other countries aiming at examining the volume and pattern of non-medical prescribing.

As the prescribing of NMPs had not been investigated in primary care in Wales, further research was needed to investigate its volume and trends in this sector. Therefore, the purpose of the first empirical study of this PhD was to describe any changes in the prescribing of medicines undertaken by NMPs in primary care in Wales over time (from April 2011 to

March 2018). This is the first study that has reviewed the prescribing volume of NMPs in primary care in Wales by using data obtained through a national database. In addition, there are no such published studies that have been undertaken using national databases to investigate the whole prescribing volume of all NMPs in other UK nations or countries worldwide. This study involved collaboration with the Chief Pharmaceutical Officer (CPO) for Wales, the All-Wales Therapeutics and Toxicology Centre (AWTTC), the Welsh Analytic Prescribing Support Unit (WAPSU), and the NHS Wales Shared Services Partnership. The findings of this study will help to identify the clinical areas of practice that most NMPs work in.

4.3. Research question

How has the number of actively prescribing NMIPs changed from April 2011 to March 2018 within primary care in Wales and how has their prescribing of medicines evolved over time, as well as in relation to the implementation of primary care clusters?

4.4. Aim and Objectives

The aim of this research was to identify the number of NMIPs, and the associated trend of items prescribed in primary care settings in Wales and subsequently dispensed from April 2011 to March 2018. This time frame incorporated the period when primary care clusters came into practice, therefore the study aimed to examine the significance of prescribing changes by medical prescribers and NMIPs in primary care before and after the implementation of primary care clusters in Wales.

The study objectives were:

- To determine the number of NMIPs who were prescribing each month in primary care in Wales.
- To identify the number of items that were prescribed by primary care NMPs and dispensed in community pharmacies from April 2011 to March 2018.
- To describe the most common British National Formulary (BNF) chapters of medicines or medicinal products that have been prescribed by primary care NMIPs and dispensed in community pharmacies from April 2011 to March 2018.
- To identify the most common BNF categories (groups of drugs, such as analgesics and bronchodilators) or medicinal products that have been prescribed by primary care NMIPs and dispensed in community pharmacies from April 2011 to March 2018.
- To identify whether the volume of prescribing by NMIPs has significantly changed before and after the implementation of primary care clusters in each HB and across Wales as a whole.
- To investigate whether the volume of prescribing by medical prescribers has significantly changed before and after the implementation of primary care clusters across Wales.

4.5. Methodology

4.5.1. Overview

The study design was a retrospective secondary data analysis of monthly medicines dispensing data by NMPs and medical prescribers, as well as the number of NMIPs within primary care in Wales. This a quantitative research study, in which the extracted data were analysed descriptively and with the use of appropriate statistical analyses to draw a conclusion on the prescribing patterns of NMPs in primary care.

4.5.2. Rationale for choosing secondary data

The decision for choosing secondary data to address this study question was due to the advantages of using this method stated in Chapter Three (Section 3.5.4.2.1). This includes that secondary data analysis is a powerful and useful tool in evaluating changes over time in a dataset that has already been collected. This helped to save the researcher's time and cost associated with its collection (Gallin and Ognibene 2012; Bryman 2016). Furthermore, secondary data analysis addressed the aim of this study, that involved an investigation of the NMPs' prescribing in primary care across all Wales over time. This is because it provided a breadth of high-quality data that covered the study's population across a widely distributed and large geographical area. It was unrealistic to collect this volume of data prospectively.

4.5.3. Data source

The source of the data for this study was the Comparative Analysis System for Prescribing Audit (CASPA) software system (Version 4). This system was established by Primary Care Services in Wales, which is a division of the NHS Wales Shared Services Partnership that provides a variety of services on behalf of HBs, such as patient registration, contracts, and payment/reimbursement services (NHS Wales Shared Services Partnership 2021). It can be accessed by all GP practices and surgeries within HBs in Wales to record and review all the WP10 prescriptions (prescriptions for use in primary care or hospital outpatients) dispensed and forwarded for pricing by community pharmacies (Welsh Government 2017). The NHS in Wales funds all medicines prescribed for their patients following advice from the All-Wales Medicines Strategy Group (AWMSG) and the National Institute for Health and Care Excellence (NICE) (AWTTC 2014). In 2010, WAPSU was founded as a subgroup of AWMSG and as part of an 'Invest to Save' plan by the WG, which is hosted by the CVUHB (All Wales Therapeutic and Toxicology Centre 2016). The main reasons for recording the data related to these prescriptions are reimbursement to community pharmacies and monitoring of prescribing. The AWMSG and WAPSU publish reports that provide information about the prescribing pattern of GP practices of specific medications

across all HBs in Wales using the CASPA data (AWTTC 2018). The CASPA system also allows further evaluation of the prescribing data of medical practitioners and NMPs to be undertaken to improve medicines prescribing services in Wales (AWTTC 2014). Therefore, the CASPA system was the database chosen to extract the relevant data on prescribing by NMPs and medical prescribers.

CASPA data does not provide information about the number of NMIPs in Wales. As the study also aimed to identify the variation in prescribing trends amongst different HBs, the number of and type of NMIPs in each HB was needed. Therefore, another source of data that provided the number of NMIPs who prescribed at least one item on a monthly basis from April 2011 to March 2018 was obtained through the NHS Wales Shared Services Partnership, Primary Care Services Department, and descriptively analysed.

4.5.4. Ethical considerations and study approvals

The analysis of this routinely collected secondary data did not require ethical approval as patients were not involved and the data obtained from the CASPA software did not include any personal and identifiable information. However, as stated in Section 3.11.1, this study was registered with the Research and Development Office at CVUHB where AWTCC and WAPSU were based to allow for the study to be undertaken. In addition, the data obtained by the NHS Wales Shared Services Partnership did not require ethical approval since it was collected as part of routine practice. To obtain data access and training to the CASPA database software system, the researcher had an honorary contract with AWTTC at CVUHB (Appendix 4). A member of WAPSU staff trained the researcher on the use of the CASPA database and the extraction and interpretation of data. They also quality assured the extraction of the data.

4.5.5. The extracted data

In the CASPA software system, three options were available to extract the data of prescribed items by GPs and primary care NMPs which were dispensed in community pharmacies. The first option was the number of items, which refers to a single item prescribed by a prescriber on a prescription form (Prescribing and Primary Care Services 2012). If a prescription form included three medicines, it is counted as three prescription items. The disadvantage of using the number of items is due to the practice of repeat prescribing, as the number of items can be misleading because different practices use a different duration of supply, i.e., some will issue a prescription monthly, others for two months or three months and so will have different numbers of items for the same amount of medication. Even within a single GP practice, there can be differences in the duration of prescriptions. Contraceptives and hormone replacement therapy are often prescribed for six months at a time while hypnotics, which are recommended for short term use, may only be issued for a week or two.

The second option to extract the required data in the CASPA software system was Defined Daily Doses (DDDs). In this system each drug is given a value, within its recognised dosage range, that represents the assumed average maintenance dose per day for a drug used for its main indication in adults (Prescribing and Primary Care Services 2012). It is emphasised that the DDD is a unit of measurement; it is not a recommended dose and may not be a real dose (Prescribing and Primary Care Services 2012). The DDD of one drug is assumed to be functionally equivalent to the DDD of any other drug used for a similar purpose or within the same therapeutic class. Therefore, the number of DDDs for two or more such drugs can be added together. However, the DDDs tend to not recognise particular therapeutic areas, such as skin preparations (e.g., ointments and creams), vaccinations and other one-off treatments, combination preparations, mixtures and compounds, contraceptive pills, and hormone replacement therapy (HRT) regimens (Prescribing and Primary Care Services 2012). As such, the dataset would be incomplete and not truly represent the prescribing trend of GPs and NMPs. Therefore, DDDs were considered inappropriate to extract data from the CASPA software system. ¹

The cost of prescribed medicines was the third option, which also was not considered in this study since the cost of different medications fluctuates over time, as well as the aim of this PhD study was to investigate the volume and trends of the dispensed items that were prescribed by GPs and NMPs in primary care settings in Wales. Therefore, price of the dispensed items was not used to extract the data from the CASPA software system.

The number of items and DDDs have advantages and disadvantages. However, the number of items represents the actual number of medications prescribed compared to DDDs (which was based on the assumed average maintenance dose per day and not representing the actual doses of prescribed medicines). Moreover, the DDDs did not provide complete data on the prescribed items compared to the number of prescribed items. As a result, the number of items was used to extract the required data to explore the volume and patterns of dispensed medicines that were prescribed by primary care NMPs and medical prescribers, and subsequently dispensed in community pharmacies in Wales. All recorded WP10 prescriptions in the CASPA software system that were issued by GPs and NMPs in GP practices across Wales for the treatment of NHS patients and dispensed by community pharmacists from April 2011 to March 2018 were extracted, using the number of item option, and included in the study. This time period represented all the prescribing data available with regards to NMPs

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¹ At the time of this research, DDDs did not record some therapeutic areas, such as skin preparations, vaccinations ... etc. (as illustrated above). However, according to a recent review by Teal and Edelman (2021), these therapeutic areas have since been captured using the DDDs approach, which makes it possible to conduct this research differently in the future by using this option when extracting the data from the CASPA system.

and GPs across all of Wales in the CASPA software system at the time of conducting the study. The categories of data that were extracted from the CASPA software systems were as follows (prescribed in primary care and dispensed in community pharmacies in Wales on a monthly basis):

- Number of items that were prescribed by all prescribers i.e. GPs and NMPs (NMIPs, supplementary prescribers, and community nurse prescribers) on an All-Wales basis.
- Number of items of the top BNF chapters and BNF categories that were prescribed by NMIPs.
- Number of items that were prescribed by NMIPs in each HB in Wales.
- Number of items of the top BNF chapters and BNF categories in each HB that were prescribed by NMIPs.

4.5.6. Data analysis

The extracted data from the CASPA system were analysed descriptively by using the IBM SPSS (Version 25) and Microsoft Excel (version 16.15) software. Although the numbers of prescribed items were extracted from the CASPA system on a monthly basis, the total number of items per year, per 100,000 population, was calculated in order to illustrate changes in the prescribing rate each year (population data was only available on a yearly basis). The yearly population data (e.g., 2011-2012) from 2011 to 2018 in Wales was obtained from Welsh Government Stats Wales (2018a). The prescribing rate in each year per 100,000 population was calculated by dividing the total number of items in a year by the population of the same year, then multiplying the results by 100,000. It was calculated to compare the prescribing rate between HBs by excluding the impact of each HB population (since the population number varies between HBs).

In this study, a year is defined as the 12-month NHS financial year, from April to March, for example, the year from April 2011 to March 2012 is written as 11-12. Prescribing percentages were calculated on a yearly basis for the number of NMIPs, as well as for the total number of the prescribed items by NMIPs when comparing between HBs. To increase the power in identifying any underlining trends, the number of data points was maximised by choosing monthly prescribing data rather than quarterly prescribing data (Penfold and Zhang 2013).

Prescribing by NMIPs and medical prescribers in all Wales, as well as prescribing by NMIPs in each HB before and after the implementation of primary care clusters were compared by using interrupted time series (ITS) analysis. As discussed in Chapter Two, randomised controlled trials are considered the gold standard method to evaluate longitudinal effects of interventions over time (Campbell et al. 2000; Victora et al. 2004; Bonell et al. 2009).

Since randomised controlled trials lack the ability to evaluate the already implemented service retrospectively, this analysis was performed using ITS analysis. Moreover, the intervention in this study, which was the implementation of primary care clusters in Wales, occurred in all Wales, as well as in each HB in 2015 (The National Assembly for Wales 2017). As such, a randomised controlled trial was not possible for this study as there was no control available. In addition, the availability of the retrospective data of prescribing by NMIPs and medical prescribers in primary care in Wales allowed the researcher to conduct the alternative option, which is the ITS analysis, in a time efficient and cost-effective manner to address the aim and objectives of this study. Furthermore, one of the major advantages of the ITS analysis is that it allows for changes to be presented graphically to enable visual inspection of these changes over time (Wagner et al. 2002).

ITS analysis has been used to assess healthcare interventions over time (Fretheim et al. 2007, Hawton et al. 2013, Deslandes et al. 2016). It aims to assess the impact of an intervention that led to an interruption of the data at a single point of time for data that were collected at regular intervals of time to give a time series (Bernal et al. 2016). It takes into consideration the underlying trends like seasonal variation and autocorrelation in the evaluation of the intervention effect (Kontopantelis et al. 2015). If two pieces of the collected data that are close in time point are similar to each other (e.g., a high measure followed by a high measure), this is identified as a positive autocorrelation (Biglan et al. 2000). It is important to take these trends and correlations into account to prevent an overestimation of the intervention outcome (Wagner et al. 2002).

At the start of this phase of the research, the ITS analysis that was used to conduct the analysis was a series of Autoregressive Integrated Moving Average (ARIMA) Interrupted Time Series (ITS) analyses. The ARIMA analysis was initially chosen as it helps in the prevention of an overestimation of the intervention by underlying trends (Schaffer et al. 2021). The Cochrane Effective Practice and Organisation of Care (EPOC) guidance (2017) was followed, and IBM SPSS software (Version 25) used to conduct the ARIMA statistical analysis. However, after submitting the findings of the ARIMA analyses to a journal for the purpose of publication, further support from a statistician was sought (the Journal's reviewers' comments are presented in Appendix 5). This led to modification to a simpler method of analysis which is more easily accessible to a wider audience. The original methodology and findings of the ARIMA analyses are presented in Appendix Six. The amended analysis is discussed below.

The amended ITS analysis involved the use of an ordinary-least squares regression with Newey-West standard errors and a lag for the autocorrelation structure to ensure that the outcome is caused by the intervention (Linden 2015). The Cumby-Huizinga test for autocorrelation was used to determine the appropriate autocorrelation structure to be

accounted for in the model (Linden 2015). The model included pre- and post-intervention trends, as well as a coefficient to examine a change in level immediately post-intervention. The parameter estimates are presented alongside 95% confidence intervals (Cls) and pvalues. The intercept is the starting level of the outcome variable. The pre-intervention slope is the slope of the outcome until the beginning of the intervention. The level change is the change in the level within the period immediately following the start of the intervention. The post-intervention slope is the slope of the outcome after the beginning of the intervention. The counterfactual trend (i.e., the trend in the absence of the intervention) was examined, and this was compared to the actual observed trend to calculate absolute and relative differences at the end of the observed period (March 2018). The observed values represent the actual values that occurred in the presence of the intervention. The predicted values represent the prediction of the values in the absence of such an intervention. Analysis was performed using the 'ITSA' command in Stata V16.0 (Linden 2015). The findings were assumed significant at p value <0.05. Confidence Intervals (CIs) were calculated to be 95% certain that the range of values contained the true mean of the data (Field 2018). Sensitivity analyses were used to ensure that findings were robust, and the overarching conclusions unaffected by these sensitivity analyses.

The WG plan (Welsh Government 2015) encouraged local HBs to prioritise funding and development of primary care clusters in April 2015. However, the implementation of these clusters was the responsibility of each individual HB and there were no definitive time points of their establishment. To accommodate this, the researchers engaged with relevant stakeholders (the Chief Pharmaceutical Officer for Wales and Chief Pharmacists of HBs) to determine the appropriate time to use for the intervention phase. They agreed the intervention phase began six months after its initial implementation date (April 2015), meaning October 2015.

4.6. Results

4.6.1. Trend of the total number of items prescribed by all prescribers per 100,000 population

The total number of items prescribed by all HCPs (GPs and NMPs) across all Wales from April 2011 to March 2018 was 540,781,584 [17,482,150.5 per 100,000 population (Welsh Government Stats Wales (2018a)]. The total number of items per 100,000 steadily increased over time from 11-12 (n= 2,371,510.9) to 14-15 (n= 2,539,191.8) by 7.1% (Figure 4). Thereafter, the trend was steady from 14-15 to 17-18 (n= 2,556,784.4]) (Figure 4).

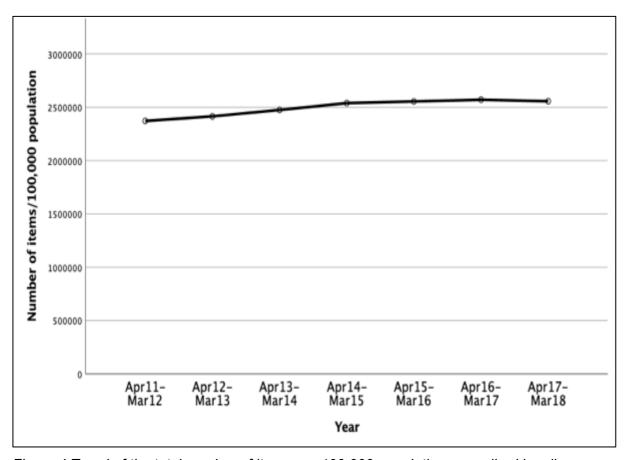


Figure 4 Trend of the total number of items per 100,000 population prescribed by all prescribers by year.

4.6.2. Trend of the total number of items prescribed by supplementary prescribers per 100,000 population

Supplementary prescribers prescribed the least number of items (0.005%; n= 28,758; n= 929 per 100,000 population) between April 2011 to March 2018 of all HCPs across Wales. Overall, the total number of prescribed items per 100,000 population decreased by approximately 9% over the study period (n= 159 in 11-12; n= 145 in 17-18) (Figure 5). No

information was found to explain the fall in prescribing in 2012-13 by supplementary prescribers.

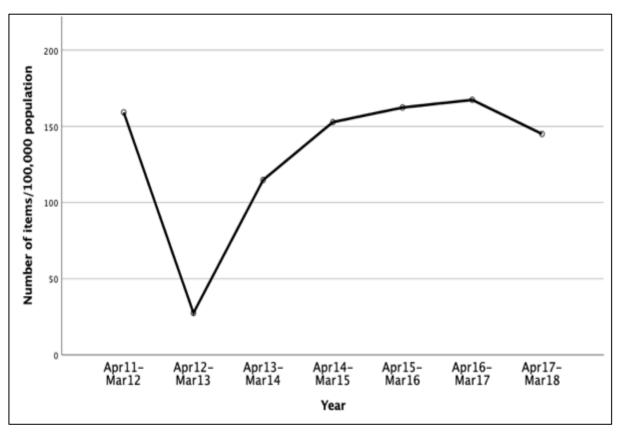


Figure 5 Trend of the total number of items per 100,000 population prescribed by supplementary prescribers by year.

4.6.3. Trend of the total number of items prescribed by community nurse prescribers per 100,000 population

Community nurse prescribers only prescribed 356,794 items (0.07%; n= 11,544 per 100,000 population) during the study period. The total number of items per 100,000 population, which is illustrated in Figure 6, decreased over time from 11-12 (n= 1936.1) to 17-18 (n= 1363.1) by 30%.

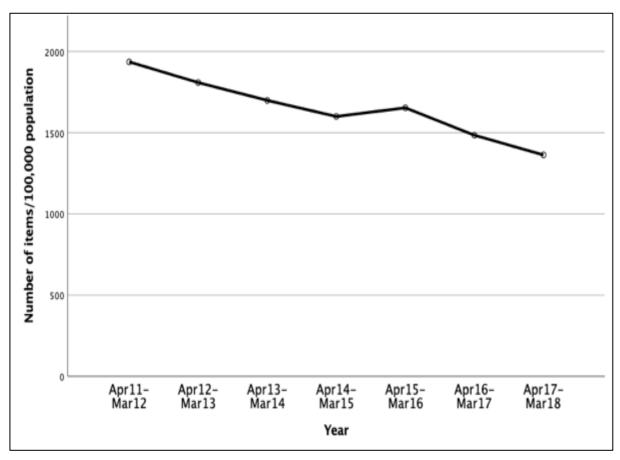


Figure 6 Trend of the total number of items per 100,000 population prescribed by community nurse prescribers by year.

4.6.4. Trend of the total number of items prescribed by NMIPs per 100,000 population

The total number of items prescribed by NMIPs between April 2011 and March 2018 was 5,088,405 (n= 164,130 per 100,000 population). This represented approximately 1% of all items prescribed by all prescribers in the same period. However, the percentage of prescribed items by NMIPs compared to all prescribers increased from 0.57% in 11-12 to 1.7% in 17-18.

The total number of items per 100,000 population per year increased over time from 11-12 (n= 13,622.1) to 17-18 (n= 40,123.9) by 194.5%. The largest increase started from the last quarter of 2015 to 17-18 (Figure 7).

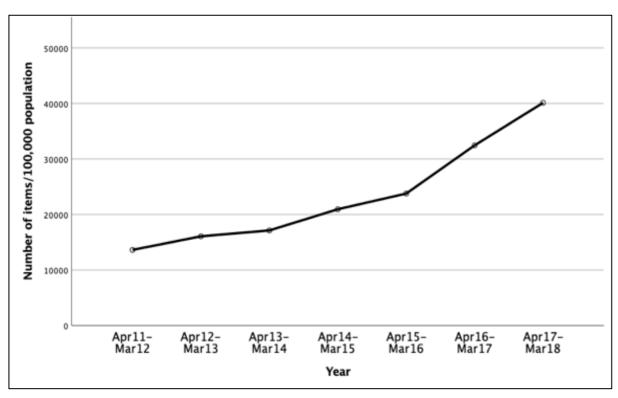


Figure 7 Trend of the total number of items per 100,000 population prescribed by NMIPs by year.

4.6.5. The total number of NMIPs

The data obtained by the NHS Wales Shared Services Partnership showed that the total number of NMIPs who prescribed at least one item from April 2011 to March 2018 was 600. This number, per month, increased by approximately 140% between April 2011 (n=174) and March 2018 (n=414); the number of prescribers of each profession (nurses, pharmacists, and physiotherapists) in April 2011 and in March 2018 are illustrated in Figure 8.

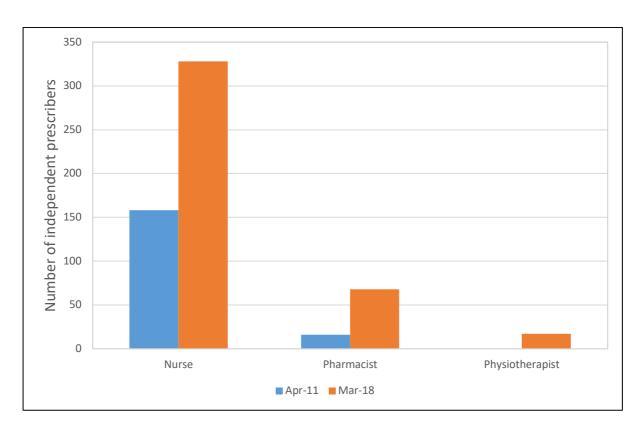


Figure 8 The number of NMIPs in primary care in Wales since April 2011 until March 2018

4.6.5.1. INPs

The majority of NMIPs, who had prescribed at least one item from April 2011 to March 2018, were INPs (n= 474). The number of INPs who prescribed during a given month was 158 in April 2011 which increased by 108% to 328 in March 2018 (Figure 9).

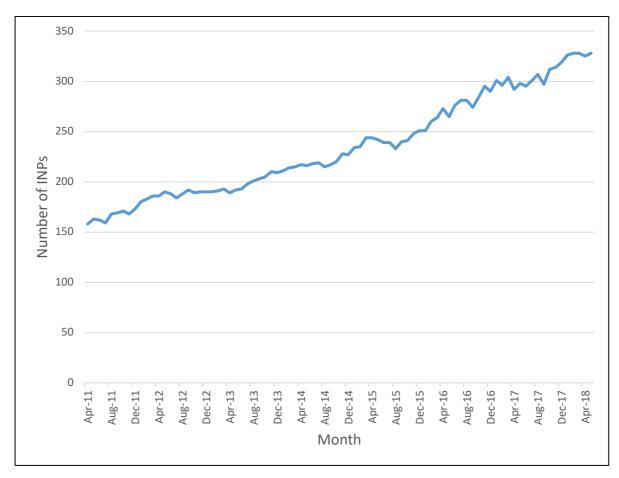


Figure 9 Trend over time of the number of INPs who prescribed in each month in primary care in Wales since April 2011 until March 2018

4.6.5.2. IPPs

The total number of IPPs, who had prescribed at least one item between April 2011 and March 2018, was 104. The number of IPPs increased over time from April 2011 (n=16) to March 2018 (n=68) by 325% (Figure 10). However, the largest increase was from July 2015 (n=20) to March 2018 (n=68) by 240% (Figure 10).

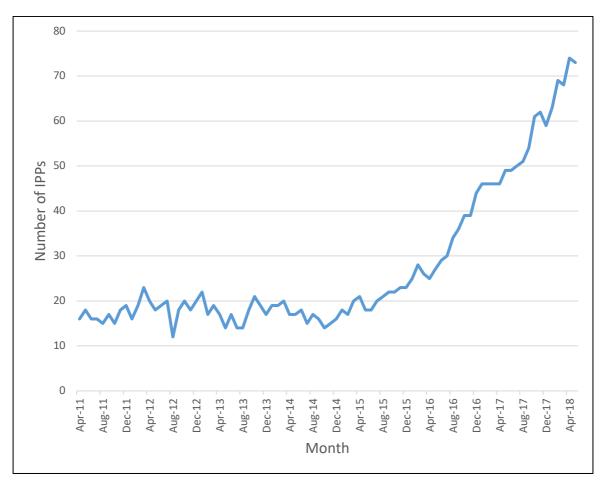


Figure 10 Trend over time of the number of IPPs who prescribed in each month in primary care in Wales since April 2011 until March 2018

4.6.5.3. Independent physiotherapist prescribers

The last category of NMIPs, who had prescribed at least one item between April 2011 and March 2018, was independent physiotherapist prescribers, where 21 were identified in this data. The first independent physiotherapist prescriber started to prescribe in January 2015. Thereafter, the number increased to 17 prescribers in March 2018 (Figure 11).

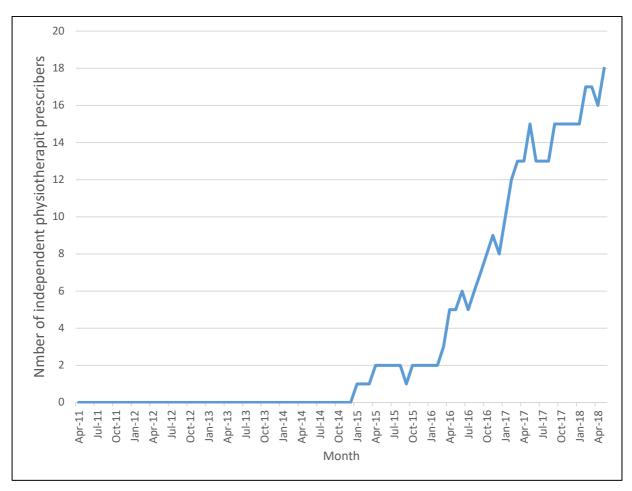


Figure 11 Trend over time of the number of independent physiotherapist prescribers who prescribed in each since April 2011 until March 2018

The data obtained from the NHS Wales Shared Services Partnership did not identify any other HCPs as NMIPs. However, there was one NMIP with unknown profession.

4.6.6. Trend of the total number of items per 100,000 population prescribed by NMIPs in different HBs

The total number and percentage of prescribed items, as well as the number of prescribed items per 100,000 population in each HB is presented in Table 3. Between April 2011 and March 2018, approximately one third of prescribed items were within BCUHB (Table 3). Figure 12 illustrates the trends of the total number of items per 100,000 population prescribed by primary care NMIPs in Wales from April 2011 to March 2018 within each HB. BCUHB showed a continuous increase in the total number of items per 100,000 population with an increase of 196% between 11-12 (n= 17,903.8) and 17-18 (n= 53,078.3). The trend in PTHB showed a large increase of 570% from 16-17 (n= 12,898.9) to 17-18 (n= 86,345.7). The trends of the other HBs showed a large increase starting from 15-16, except for CVUHB which showed a steady trend over time.

Table 3 Total numbers and percentages of items as well as per population prescribed by NMIPs in each HB between April 2011 until March 2018

НВ	Total number of items prescribed by NMIPs	% Of the total prescribed items by NMIPs in each HB	Number of prescribed items by NMIPs per 100,000 population*
ВСИНВ	1,711,949	33.64%	240,742.5
ABUHB	834,879	16.41%	139,396.5
СУИНВ	711,805	13.99%	145,069.9
HDUHB	686,166	13.48%	172,782.9
ABMUHB	573,624	11.27%	106,813.2
СТМИНВ	371,315	7.30%	122,620.2
РТНВ	198,667	3.90%	137,000.6
All Wales	5,088,405	100%	-

^{*}Population in each HB for the last 7 years, (Welsh Government 2018a)

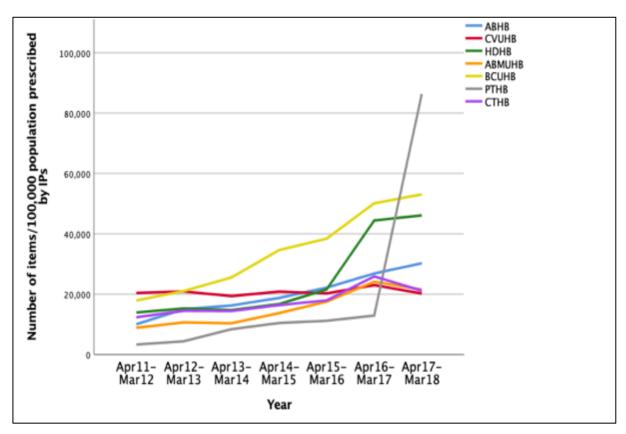


Figure 12 Trend of the total number of items/100,000 population prescribed by NMIPs in different HBs by year. NB. IPs, in the figure, refer to NMIPs.

The total number and percentages of NMIPs as well as per 100,000 population in primary care in different HBs in Wales from April 2011 to March 2018 are presented in Table 4. More than 40% of the NMIPs were practising within BCUHB and only 6% in PTHB. Figure 13 illustrates the total number of NMIPs (pharmacists, nurses, and physiotherapists) who prescribed at least one item from April 2011 to March 2018 in each HB. It demonstrates that 43% of INPs, 27% of IPPs, and 67% of independent physiotherapist prescribers were based in BCUHB. However, only 6% of INPs were based in each of CTMUHB and PTHB. In addition, the lowest number (4%) of IPPs were in PTHB. The data did not identify any independent physiotherapist prescribers in CVUHB or CTMUHB.

Table 4 The total numbers and percentages of NMIPs as well as per population in primary care in different HBs in Wales from April 2011 to March 2018

НВ	Total number of NMIPs	Percentage of NMIPs across Wales	Total number of NMIPs per 100,000 population*
ВСИНВ	246	41%	5.08
ABUHB	75	13%	1,84
CVUHB	75	13%	2.22
HDUHB	67	11%	2.49
ABMUHB	64	10%	1.75
СТМИНВ	39	7%	1.88
PTHB	33	5%	3.55
All Wales	600	100%	18.81

^{*}Population in each HB for the last 7 years, (Welsh Government 2018a)

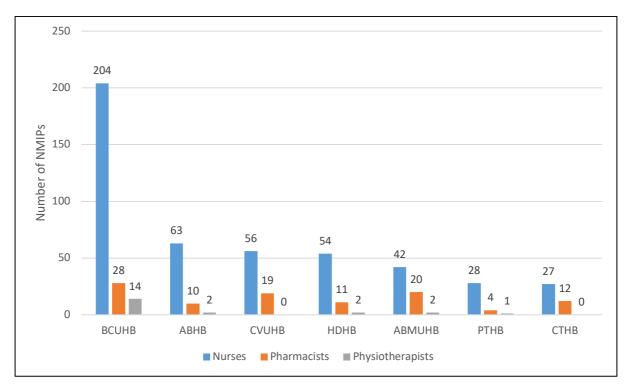


Figure 13 The total number of NMIPs (pharmacists, nurses, and physiotherapists) who prescribed at least one item from April 2011 to March 2018 in each HB.

4.6.7. Trend of the total number of items (including per 100,000 population) prescribed by NMIPs based on BNF chapters

The top seven BNF chapters where the greatest number of items were prescribed by NMIPs are presented in Table 5. These seven chapters represent more than 75% of all prescribed items from April 2011 to March 2018. The trends of these top seven BNF chapters showed an increase in the total number of items per 100,000 population prescribed by NMIPs over time in all Wales (Figure 14). The largest increase in these trends was from 15-16 to 17-18, particularly for the cardiovascular system, central nervous system, and gastro-intestinal system chapters (Figure 14). For the cardiovascular system chapter, the total number of items per 100,000 population in 15-16 was 3,491.7 which increased by approximately 155% to 8,884.5 in 17-18. While the total number of items per 100,000 population for the central nervous system chapter in 15-16 was 2,817.3 which increased to 6,018.4 in 17-18 by 114%. For the gastro-intestinal system chapter, the total number of items per 100,000 population in 15-16 was 1,394.7 which increased to 3,113.6 in 17-18 by 123%.

Table 5 Total number of items that were prescribed by NMIPs based on BNF chapters since April 2011 until March 2018

Number	BNF chapter	Total number of items	Percentages of the total number of items	Prescribed items per 100,000 population*
1	Cardiovascular System	824,419	16.20%	26,551
2	Infections	711,702	13.99%	22,986
3	Central Nervous System	655,430	12.88%	21,129
4	Respiratory System	576,727	11.33%	18,616
5	Endocrine System	417,238	8.20%	13,448
6	Skin	376,286	7.39%	12,153
7	Gastro-Intestinal System	314,260	6.18%	10,124
8	Obstetrics, Gynaecology and Urinary Tract Disorders	227,667	4.47%	7,363
9	Appliances	218,683	4.30%	7,014
10	Musculoskeletal & Joint Diseases	178,262	3.50%	5,782
11	Ear, Nose and Oropharynx	156,888	3.08%	5,098
12	Nutrition and Blood	154,610	3.04%	5,014
13	Dressings	107,291	2.11%	3,469
14	Eye	103,613	2.04%	3,398
15	Malignant Disease & Immunosuppression	22,554	0.44%	703
16	Immunological Products & Vaccines	12,420	0.24%	421
17	Stoma Appliances	10,335	0.20%	352
18	Incontinence Appliances	7,914	0.16%	316
19	Anaesthesia	7,200	0.14%	289
20	Other Drugs and Preparations	4,906	0.10%	203

^{*} Population in Wales for the last 7 years, (Welsh Government 2018a)

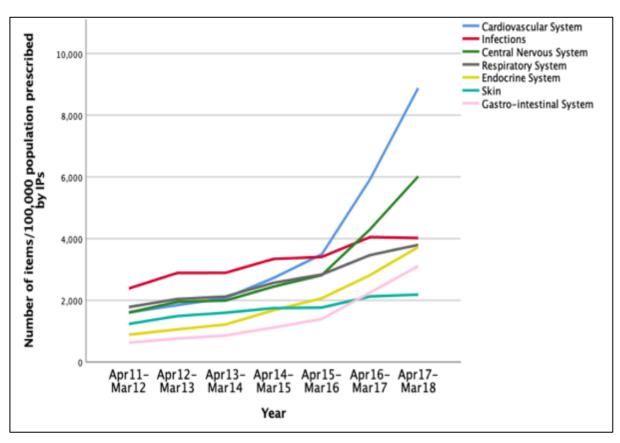


Figure 14 Trend of the total number of items per 100,000 population prescribed by NMIPs in all Wales based on BNF chapters by year. NB. IPs, in the figure, refer to NMIPs.

The percentages of the top BNF chapters of the prescribed items in each HB in Wales from April 2011 to March 2018 are presented in Table 6. It is noted that the top seven BNF chapters of the prescribed items by NMIPs in all Wales were similar in the majority of HBs as follows (the top prescribed chapter in all HBs was cardiovascular system, except in BCUHB which was infections followed by cardiovascular system):

Table 6 The percentages of the top BNF chapters of the prescribed items in primary care settings in each HB in Wales by NMIPs (N= total number of prescribed items).

НВ	всинв		ABUHB		СУИНВ		HDUHB		АВМИНВ		СТМИНВ		РТНВ	
ПБ	N= 1,711,949	9	N= 834,879)	N= 711,805		N= 686,166		N= 573,624		N= 371,315		N= 198,667	
1	Infections	16 %	Cardiovascular System	19 %	Cardiovascular System	16 %	Cardiovascular System	16 %	Cardiovascular System	19 %	Cardiovascular System	16 %	Cardiovascular System	19 %
2	Cardiovascula r System	14 %	Infections	13 %	Respiratory System	14 %	Central Nervous System	15 %	Infections	13 %	Central Nervous System	16 %	Central Nervous System	15 %
3	Central Nervous System	12 %	Central Nervous System	13 %	Central Nervous System	12 %	Infections	15 %	Central Nervous System	12 %	Infections	12 %	Respiratory System	10 %
4	Respiratory System	11 %	Respiratory System	11 %	Infections	12 %	Respiratory System	11 %	Respiratory System	11 %	Respiratory System	10 %	Infections	9 %
5	Endocrine System	8 %	Endocrine System	8%	Endocrine System	10 %	Endocrine System	8 %	Skin	8%	Endocrine System	9 %	Endocrine System	8 %
6	Skin	8 %	Skin	7%	Skin	7%	Gastro- Intestinal System	7 %	Endocrine System	7%	Skin	7 %	Gastro-Intestinal System	7 %
7	Gastro- Intestinal System	6 %	Gastro- Intestinal System	7%	Gastro- Intestinal System	5%	Skin	7 %	Gastro- Intestinal System	6%	Gastro- Intestinal System	7 %	Skin	6 %

NB. Each colour represents a BNF chapter. The table is organised for each HB in descending order of frequency of prescribed items per BNF chapter.

In each HB, the total number of items per 100,000 population of the top five BNF chapters (since they were the majority of prescribed BNF chapters) prescribed by NMIPs from April 2011 to March 2018 are illustrated in Figures: 15 (cardiovascular system), 16 (infections), 17 (central nervous system), 18 (respiratory system), and 19 (endocrine system). All these chapters showed a continuous increase in the BCUHB trend over time. Whereas these chapters largely increased only in the last two years in PTHB. The trends of these chapters in the other HBs largely increased between 15-16 and 17-18, except in CVUHB where most of these chapters' trends did not change over time, except for the respiratory system chapter, which decreased over time.

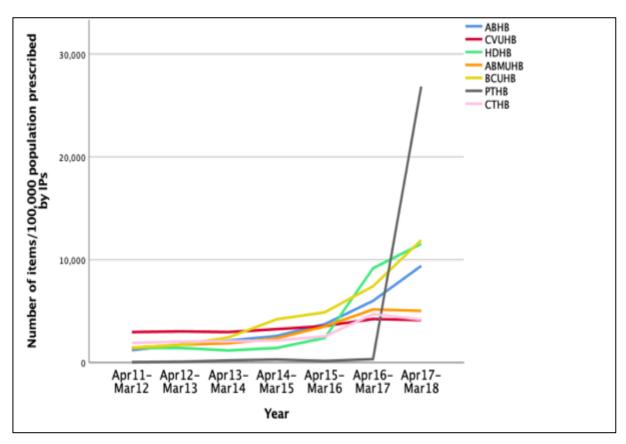


Figure 15 Trend of the total number of items per 100,000 population of the **cardiovascular system chapter** prescribed by NMIPs in each HB by year. NB. IPs, in the figure, refer to NMIPs. NB. IPs, in the figure, refer to NMIPs.

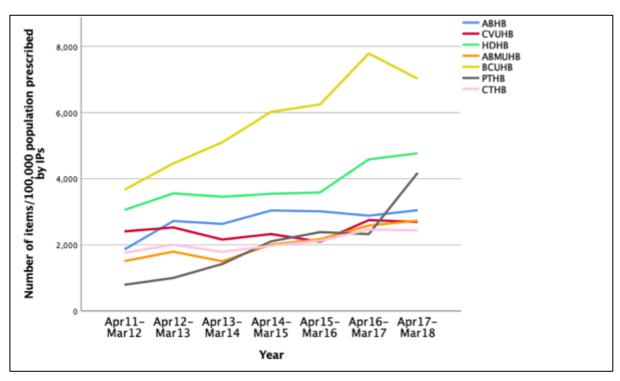


Figure 16 Trend of the total number of items per 100,000 population of the **infections** chapter prescribed by NMIPs in each HB by year. NB. IPs, in the figure, refer to NMIPs.

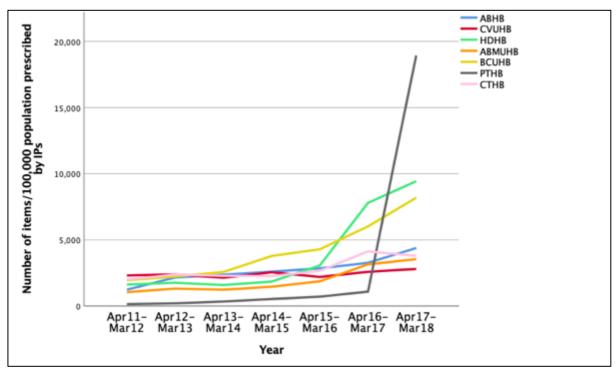


Figure 17 Trend of the total number of items per 100,000 population of the **central nervous system** chapter prescribed by NMIPs in each HB by year. NB. IPs, in the figure, refer to NMIPs.

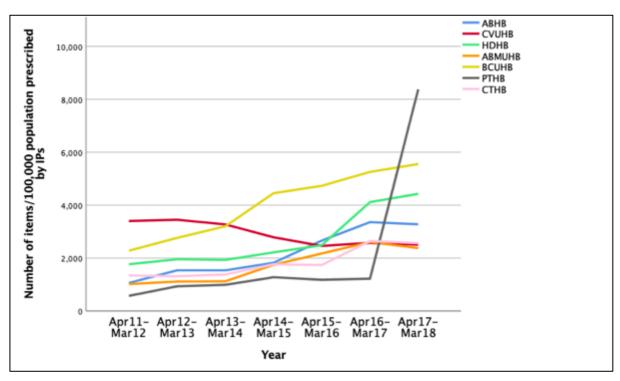


Figure 18 Trend of the total number of items per 100,000 population of the **respiratory system** chapter prescribed by NMIPs in each HB by year. NB. IPs, in the figure, refer to NMIPs.

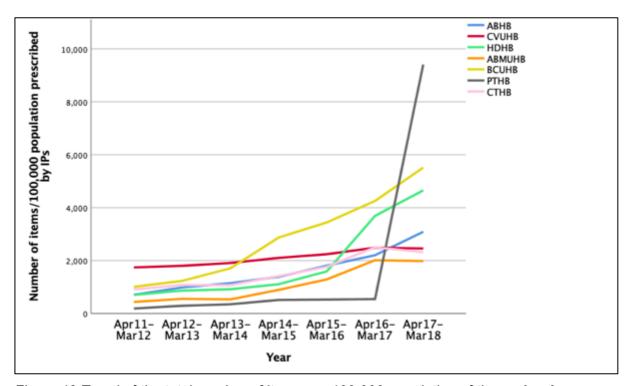


Figure 19 Trend of the total number of items per 100,000 population of the **endocrine system** chapter prescribed by NMIPs in each HB by year. NB. IPs, in the figure, refer to NMIPs.

4.6.8. Trend of the total number of items per 100,000 population prescribed by NMIPs in all Wales based on the top BNF categories

The top BNF categories (group of medicines) of the prescribed items by NMIPs in primary care in Wales between April 2011 and March 2018 are presented in Table 7. The trends of these BNF categories, based on the total number of items per 100,000 population prescribed by NMIPs, showed an overall increase during this timeframe (Figure 20). The antibacterial category showed the largest increase over time by 66% compared to other BNF categories from 11-12 (n= 2,221.1) to 17-18 (n= 3,697.6) (Figure 20). Most of the other categories showed similar trends with a largest increase between 15-16 and 17-18 (Figure 20).

Table 7 Total number of items that were prescribed by NMIPs based on BNF categories from April 2011 to March 2018

Number	BNF categories	Total number of items prescribed by NMIPs	Percentages of the total number of items prescribed by NMIPs in all Wales	Prescribed items per 100,000 population*
1	Antibacterial Drugs	658,136	16.98%	21,257
2	Analgesics	282,775	7.30%	9,120
3	Bronchodilators	251,894	6.50%	8,129
4	Drugs Used in Diabetes	207,566	5.36%	6,691
5	Antihypertensive Therapy	195,864	5.05%	6,308
6	Ulcer-Healing Drugs	184,595	4.76%	5,945
7	Corticosteroids (respiratory)	183,480	4.73%	5,923

^{*} Population in Wales for the last 7 years, (Welsh Government 2018a)

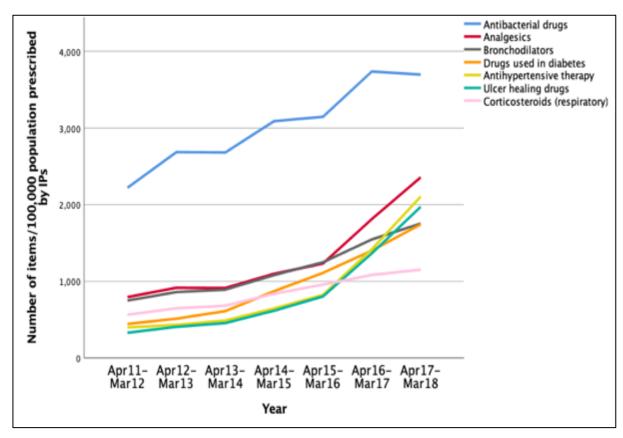


Figure 20 Trend of the total number of items per 100,000 population prescribed by NMIPs based on top BNF categories. NB. IPs, in the figure, refer to NMIPs.

Similar to the general findings across all Wales, the antibacterial BNF category was the most prescribed by NMIPs in each HB. Table 8 presents the percentages of the top BNF categories prescribed by NMIPs in each HB in Wales from April 2011 to March 2018.

Table 8 The percentages of the top BNF categories of items prescribed by in each HB in Wales (N= the total number of prescribed items).

No	всинв		всинв авинв		СУИНВ		HDUHB		АВМИНВ		СТМИНВ		РТНВ	
No.	N= 1,711,94	9	N= 834,879		N= 711,805		N= 686,166	;	N= 573,624		N= 371,315	j	N= 198,667	
1	Antibacterial Drugs	15%	Antibacterial Drugs	17%	Antibacterial Drugs	11%	Antibacterial Drugs	17/19/2	Antibacterial Drugs	12%	Antibacterial Drugs	11%	Antibacterial Drugs	9%
2	Analgesics	5%	Analgesics	5%	Drugs Used in Diabetes	7%	Analgesics	7%	Analgesics	6%	Analgesics	7%	Analgesics	6%
3	Bronchodilators	5%	Bronchodilators	5%	Bronchodilators	6%	Bronchodilators	5%	Anticoagulants and Protamine		Antidepressant Drugs		Ulcer-Healing Drugs	5%
4	Corticosteroids (respiratory)	4%	Antihypertensive Therapy	5%	Corticosteroids (respiratory)	~ ~	Ulcer-Healing Drugs	4%	Bronchodilators	5%	Bronchodilators	5%	Antihypertensive Therapy	4%
5	Drugs Used in Diabetes	4%	Lipid-Regulating Drugs	4%	Antihypertensive Therapy		Antidepressant Drugs	4%	Antidepressant Drugs		Drugs Used in Diabetes	4%	Bronchodilators	4%

NB. Each colour represents a BNF categories. The table is organised for each HB in descending order of frequency of prescribed items per BNF category.

The total number of items per 100,000 population of the top five BNF categories (since they were the majority of the prescribed BNF categories) prescribed by NMIPs in each HB from April 2011 to March 2018 is illustrated in Figures: 21 (antibacterial drugs), 22 (analgesics), 23 (bronchodilators), 24 (drugs used in diabetes), and 25 (antihypertensive therapy). All of these categories showed a continuous increase within BCUHB, over time. In contrast, in PTHB, these categories largely increased in the last two years. The trends of the majority of these categories in the other HBs largely increased between 15-16 and 17-18, except in ABHB where most of these categories' trends did not change over time, except for bronchodilators and drugs in diabetes that has increased over time. Whereas the bronchodilator prescribing trend in CVUHB decreased over time.

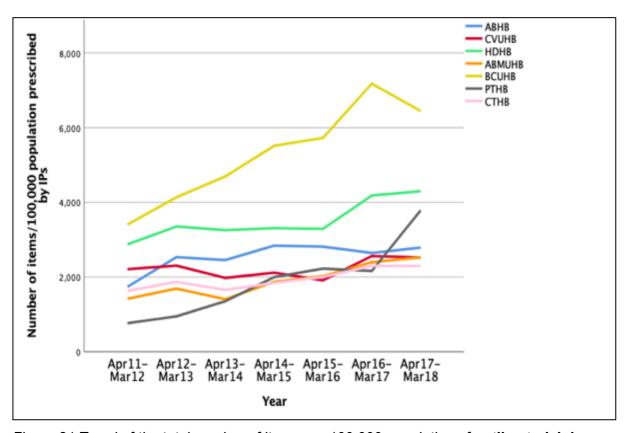


Figure 21 Trend of the total number of items per 100,000 population of **antibacterial drugs** category prescribed by NMIPs in each by year. NB. IPs, in the figure, refer to NMIPs.

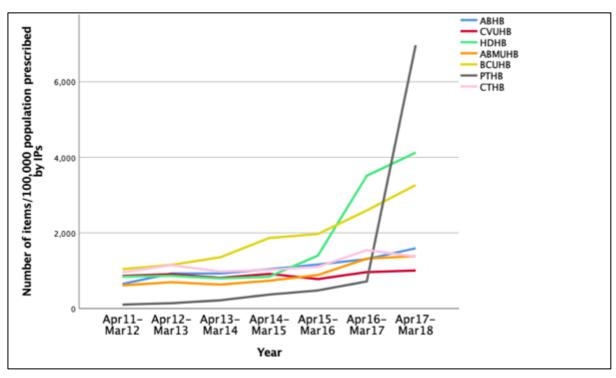


Figure 22 Trend of the total number of items per 100,000 population of the **analgesic** category prescribed by NMIPs in each HB by year. NB. IPs, in the figure, refer to NMIPs.

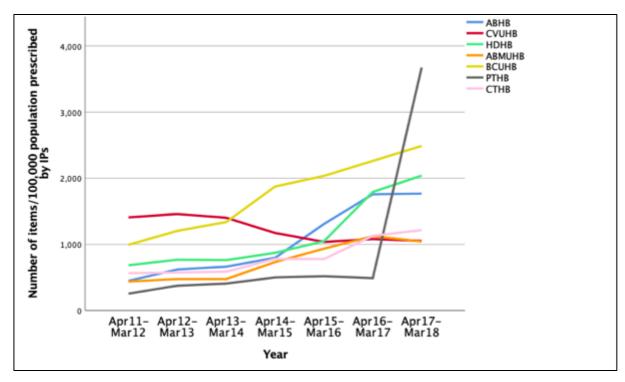


Figure 23 Trend of the total number of items per 100,000 population of the **bronchodilators**' category prescribed by NMIPs in each HB by year. NB. IPs, in the figure, refer to NMIPs.

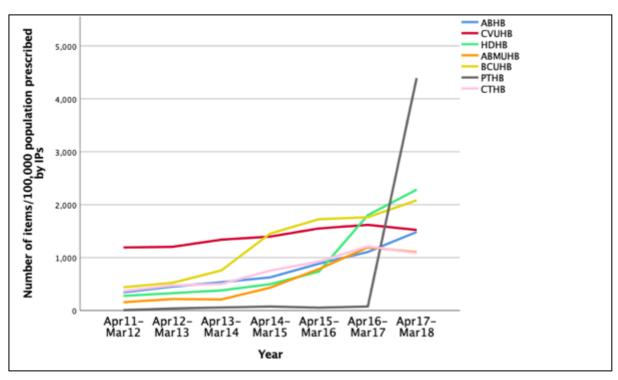


Figure 24 Trend of the total number of items per 100,000 population of the **drugs used in diabetes** category prescribed by NMIPs in each HB by year. NB. IPs, in the figure, refer to NMIPs.

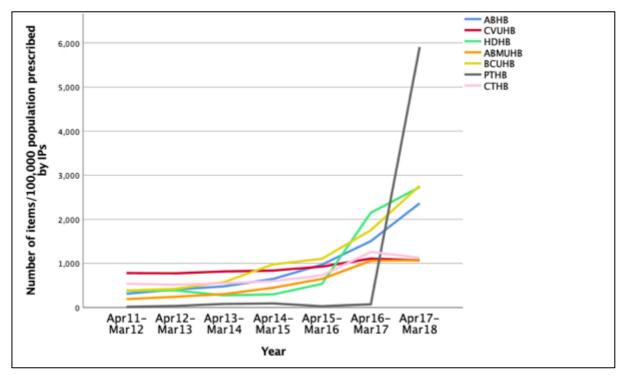


Figure 25 Trend of the total number of items per 100,000 population of the **antihypertensive therapy** category prescribed by NMIPs in each HB by year. NB. IPs, in the figure, refer to NMIPs.

4.6.9. Trend of the total number of prescribed items by NMIPs across all Wales and in different HBs pre and post primary care clusters

As shown in Table 9, dispensed items that were prescribed by NMIPs in primary care in Wales started at 31,756 and increased, on average per month prior to the implementation of primary care clusters, by 496 (95% CI: 445 to 548, p < 0.001). There was no evidence to suggest a variation in the level change immediately at the time of the implementation of primary care clusters in October 2015. However, following this implementation (post-intervention), there was an increase in prescribed items per month, relative to pre-implementation trends, of 1,380 on average (95% CI: 904 to 1855, p < 0.001). Figure 26 illustrates the observed and predicted prescribed items in primary care in Wales by NMIPs prior to and following the implementation of primary care clusters in October 2015.

Table 9 Parameter estimates from the interrupted time series analysis (ITSA) examining the change in level and slope of prescribed items by NMIPs following the implementation of primary care clusters in October 2015 (N = 84 months)

Variable	Coefficient	Lower 95% CI	Upper 95% CI	p-value
Intercept	31755.5	30208.3	33302.8	<0.001
Pre-intervention slope	496.3	444.8	547.8	<0.001
Level change	3023.4	-2151.5	8198.2	0.248
Post-intervention slope	1379.7	904.4	1855.1	<0.001

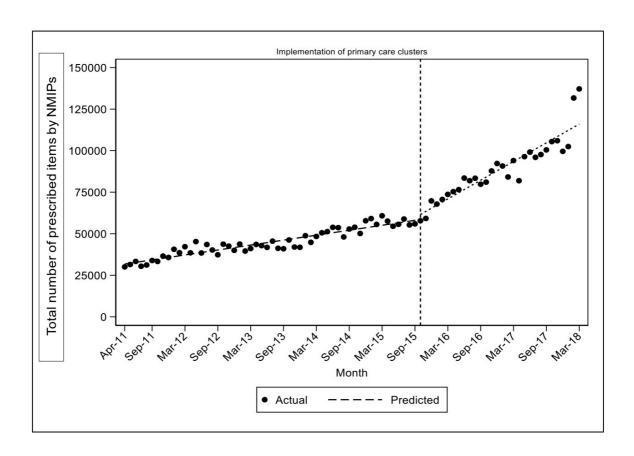


Figure 26 Observed and predicted prescribed items by NMIPs prior to and following the implementation of primary care clusters in October 2015 (All Wales)

Assuming the pre-implementation trend would have continued in the absence of the introduction of primary care clusters, the expected number of items prescribed by NMIPs at the end of the observation period (March 2018) was 73,443 (95% CI: 70,260 to 76,627). With the model predicting an expected number (in the presence of primary care clusters) of 117,859 (95% CI: 108,049 to 127,670), there was a 60% relative increase in the number of prescribed items by NMIPs following the implementation of primary care clusters over and above what would have been expected in the absence of such a scheme (95% CI: 46 to 75, p < 0.001). Although the PTHB observations and the observations of the last two months of all Wales data show a sharp increase, the findings were robust to the two sensitivity analyses 1: excluding the final two months of observations in PTHB (Table 10 and Figure 27) and 2: excluding PTHB and the final two months of observations of all HBs (Table 11 and Figure 28). This can exclude any overestimate in the above findings since these data were very high compared to other data.

Table 10 All Wales ITSA excluding PTHB.

Variable	Coefficient	Lower 95% CI	Upper 95% CI	p-value
Intercept	31490.9	29914.3	33067.5	<0.001
Pre-intervention slope	477.5	426.4	528.5	<0.001
Level change	7353.0	1450.0	13255.9	0.015
Post-intervention slope	826.4	314.7	1338.1	0.002

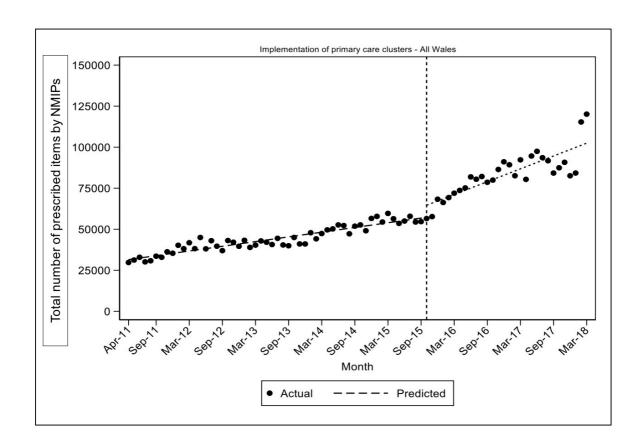


Figure 27 Observed and predicted prescribed items by NMIPs prior to and following the implementation of primary care clusters in October 2015 (All Wales, excluding PTHB)

Table 11 All Wales ITSA excluding PTHB and the final two months of observations.

Variable	Coefficient	Lower 95% CI	Upper 95% CI	p-value
Intercept	31490.9	29489.3	33492.6	<0.001
Pre-intervention slope	477.5	416.1	538.8	<0.001
Level change	9762.5	2570.3	16954.6	0.008
Post-intervention slope	563.5	44.0	1083.1	0.034

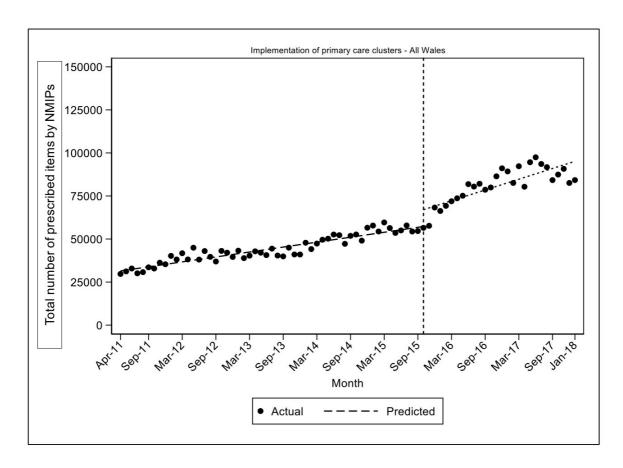


Figure 28 Observed and predicted prescribed items in primary care by NMIPs prior to and following the implementation of primary care clusters in October 2015 (All Wales, excluding PTHB and the final two months of observations)

The trends in prescribed items by NMIPs across HBs show significant change (p < 0.05) after the implementation of primary care clusters in the post-intervention slope in ABUHB, BCUHB and CVUHB (Table 12). The changes in the post-intervention slope in ABMUHB and CTMUHB are not significant (p > 0.05). Table 13 provides a comparison between actual and counterfactual (the counterfactual represents predicted values and trends in the absence of the implementation of primary care clusters in October 2015 (i.e., assuming the pre-implementation trends would have continued in the same way) prescribed items in primary care by NMIPs from April 2011 to March 2018. The linear modelling assumptions were not fulfilled for HDUHB and PTHB and findings are illustrated graphically in Figures 29 and 30, respectively. Figure 31 to Figure 35 presents the findings of the other five HBs.

Table 12 HB-specific parameter estimates from the ITSA examining the change in level and slope of prescribed items in primary care by NMIPs following the implementation of primary care clusters in October 2015 (N = 84 months) *

НВ	Variable	Coefficient	Lower 95% CI	Upper 95% CI	p-value
	Intercept	4639.4	4019.8	5259.0	<0.001
ABUHB	Pre-intervention slope	109.9	89.7	130.1	<0.001
ABUND	Level change	-27.5	-1321.8	1266.8	0.966
	Post-intervention slope	144.7	40.9	248.5	0.007
	Intercept	3268.9	2833.5	3704.3	<0.001
ADMILLD (log 2)	Pre-intervention slope	65.4	47.2	83.6	<0.001
ABMUHB (lag 3)	Level change	1954.3	534.6	3374.0	0.008
	Post-intervention slope	28.6	-52.4	109.7	0.484
	Intercept	8480.1	7791.3	9168.9	<0.001
ВСИНВ	Pre-intervention slope	239.7	208.3	271.1	<0.001
БСОПБ	Level change	2634.6	3.1	5266.0	0.050
	Post-intervention slope	195.4	2.7	388.1	0.047
	Intercept	7976.3	7458.2	8494.4	<0.001
CVUHB (lag 8)	Pre-intervention slope	6.1	-6.6	18.9	0.342
CVURB (lag o)	Level change	-266.1	-876.5	344.4	0.388
	Post-intervention slope	65.4	12.6	118.1	0.016
	Intercept	2998.4	2689.6	3307.4	<0.001
CTMUHB (lag 4)	Pre-intervention slope	22.7	13.1	32.3	<0.001
CTWOTE (lag 4)	Level change	1104.3	-310.2	2518.7	0.124
	Post-intervention slope	16.6	-75.0	108.2	0.720

^{*}Models fitted with a lag of order 1 (the lag time is the time of correlation between two time series data) unless otherwise specified (choosing the lag time was based on its ability to be fitted in the linear modelling). Note that linear modelling assumptions were not fulfilled for HDUHB and PTHB.

Table 13 Comparison between actual and counterfactual of prescribed items in primary care by NMIPs

НВ	Estimate	Coefficient	Lower 95% CI	Upper 95% CI
All Wales	Absolute difference at March 2018	44415.5	34086.8	54744.1
All wales	Relative difference at March 2018	60.5	45.6	75.3
АВИНВ	Absolute difference at March 2018	4313.3	1924.1	6702.5
ABUND	Relative difference at March 2018	31.1	12.7	49.5
ABMUHB	Absolute difference at March 2018	2813.2	751.1	4875.4
ADMOTID	Relative difference at March 2018	32.1	6.1	58.1
ВСИНВ	Absolute difference at March 2018	8496.7	4136.1	12857.3
ВСОПВ	Relative difference at March 2018	29.7	13.5	45.9
СУИНВ	Absolute difference at March 2018	1694.8	332.9	3056.7
CVUID	Relative difference at March 2018	20.0	3.4	36.5
СТМИНВ	Absolute difference at March 2018	1601.9	-78.1	3281.9
CIMORD	Relative difference at March 2018	32.7	-2.9	68.2

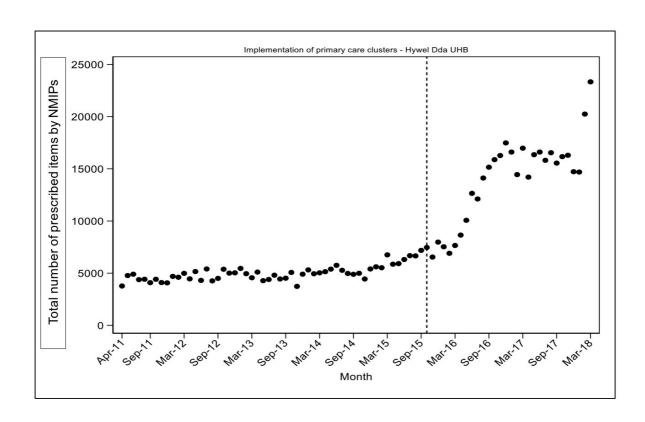


Figure 29 Observed prescribed items by NMIPs prior to and following the implementation of primary care clusters in October 2015 (HDUHB)

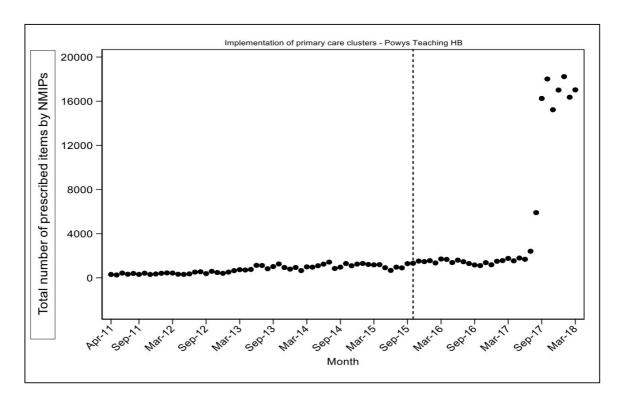


Figure 30 Observed prescribed items by NMIPs prior to and following the implementation of primary care clusters in October 2015 (PTHB)

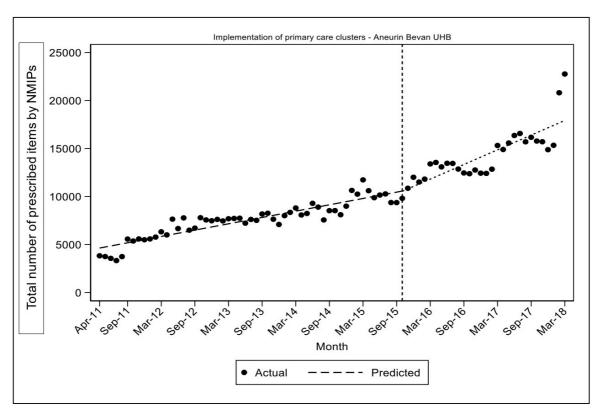


Figure 31 Observed and predicted prescribed items by NMIPs prior to and following the implementation of primary care clusters in October 2015 (ABUHB)

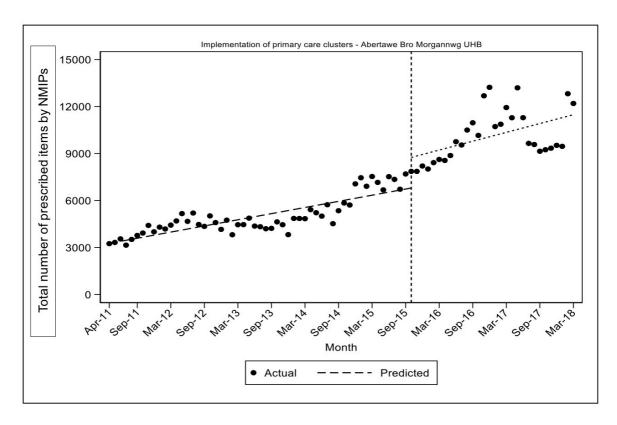


Figure 32 Observed and predicted prescribed items by NMIPs prior to and following the implementation of primary care clusters in October 2015 (ABMUHB)

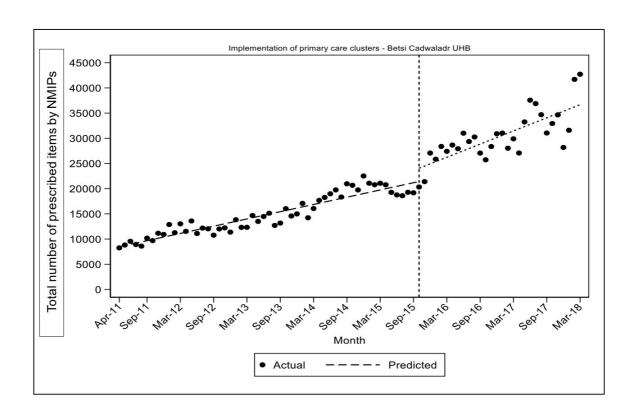


Figure 33 Observed and predicted prescribed items by NMIPs prior to and following the implementation of primary care clusters in October 2015 (BCUHB)

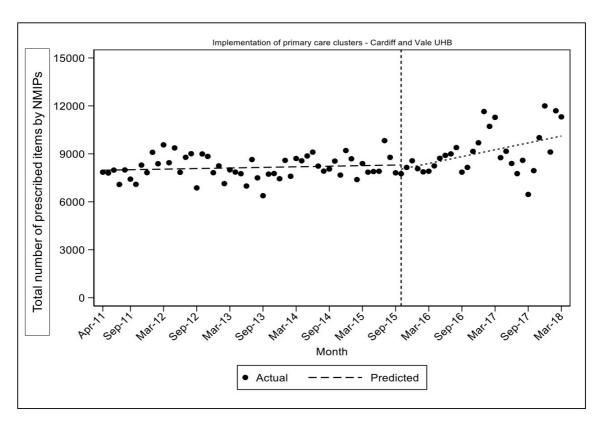


Figure 34 Observed and predicted prescribed items by NMIPs prior to and following the implementation of primary care clusters in October 2015 (CVUHB)

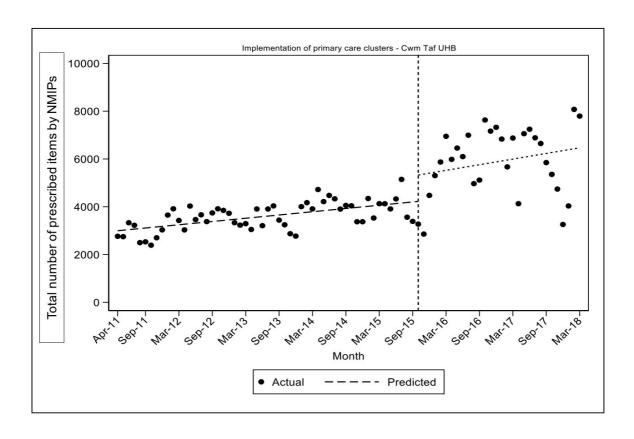


Figure 35 Observed and predicted prescribed items by NMIPs prior to and following the implementation of primary care clusters in October 2015 (CTMUHB)

4.6.10. Impact of the introduction of primary care clusters in Wales on prescribed items by medical prescribers and NMIPs

The ITSA model estimates for prescribed items by medical prescribers suggests that prior to the implementation of primary care clusters, there was a positive trend in prescribed items by medical prescribers (Table 14). Following the implementation of primary care clusters in October 2015, there was no evidence of an immediate change in the level of prescribed items. However, there was evidence of a change in the post intervention slope (with a negative trend observed). Assuming the pre-implementation trend would have continued in the absence of the introduction of primary care clusters, there was a 5.6% (relative) reduction in prescribed items by medical prescribers than what would have been expected (95% CI: -9.0 to -2.1%). Figure 36 presents the observed and predicted prescribed items by medical prescribers in primary care prior to and following the implementation of primary care clusters. Figure 37 presents the same data as Figure 36 with the y-axis truncated at 5 million prescribed items to eliminate the overestimation impact.

Table 14 ITSA model estimates for prescribed items by medical prescribers*

Variable	Coefficient	Lower 95% CI	Upper 95% CI	p-value
Intercept	5956675.0	5956675.0 5858495.0		<0.001
Pre-intervention slope	11534.5	8035.8	213098.2	<0.001
Level change	20790.0	-171518.2	213098.2	0.830
Post-intervention slope	-13546.4	-22333.4	-4759.3	0.003

^{*}The model corrects for an autocorrelation lag of order 4

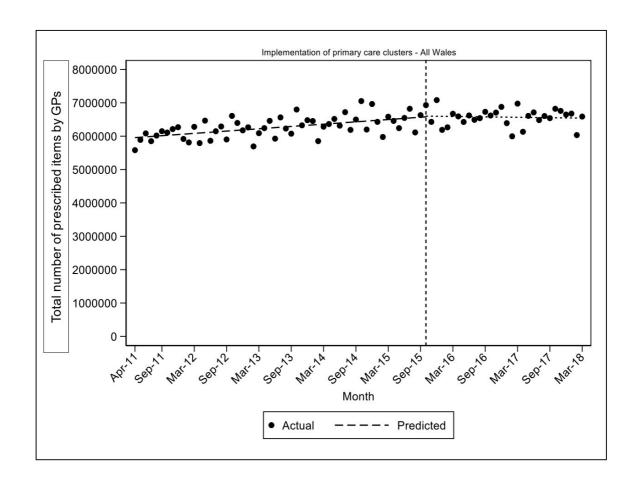


Figure 36 Observed and predicted prescribed items by medical prescribers prior to and following the implementation of primary care clusters in October 2015 (All Wales)

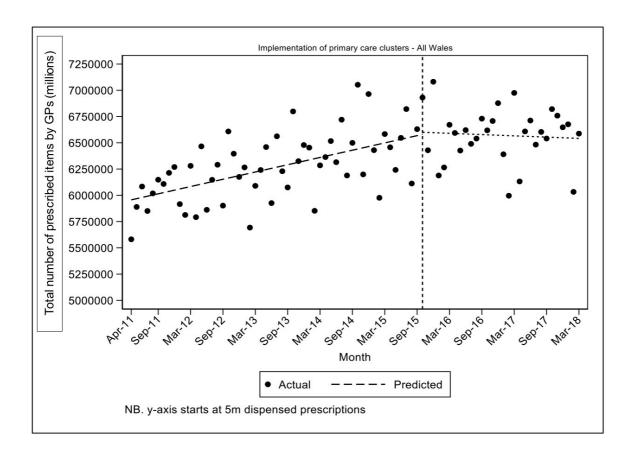


Figure 37 Observed and predicted prescribed items in primary care by medical prescribers prior to and following the implementation of primary care clusters in October 2015 (All Wales, y-axis truncated at 5 million prescribed items)

The ITSA model estimates for the percentage of all prescribed items that are attributed to NMIPs suggested that prior to the implementation of primary care clusters, there was a positive trend in prescribed items by medical prescribers (Table 15). After the implementation of primary care clusters in October 2015, there was no evidence of an immediate change in the level of prescribed items. However, there was evidence of a change in slope (with a sharper positive increase in the trend observed). There was evidence with and without including the final two data points (Figures 38 and 39, respectively). When excluding the final two data points, there was some evidence of an immediate change in the level, as well as the slope.

Excluding the final two data points, and assuming the pre-implementation trend would have continued in the absence of the introduction of primary care clusters, there was a 53% (relative) increase in the percentage of prescribed items by NMIPs than what would have been expected (95% CI: 43 to 62%). With these two data points included, there was an estimated 63% increase (95% CI: 45 to 81%).

Table 15 ITSA model estimates for the percentage of all prescribed items that are attributed to NMIPs.

Variable	Coefficient	Lower 95% CI	Upper 95% CI	p-value
Intercept	0.54	0.51	0.56	<0.001
Pre-intervention slope	0.01	0.01	0.01	<0.001
Level change	0.04	-0.06	0.13	0.460
Post-intervention slope	0.02	0.01	0.03	<0.001

^{*}The model corrects for an autocorrelation lag of order 1

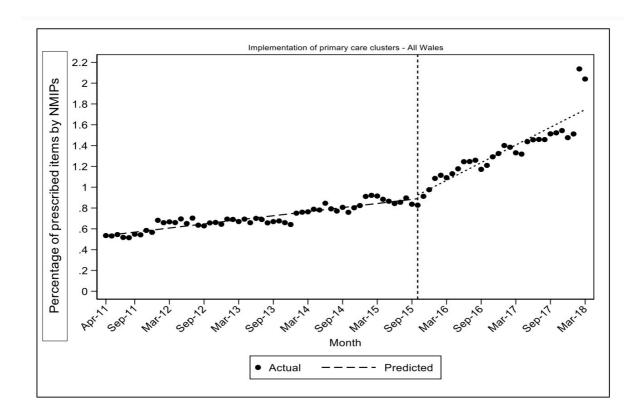


Figure 38 Observed and predicted percentage of all prescribed items by NMIPs prior to and following the implementation of primary care clusters in October 2015 (All Wales)

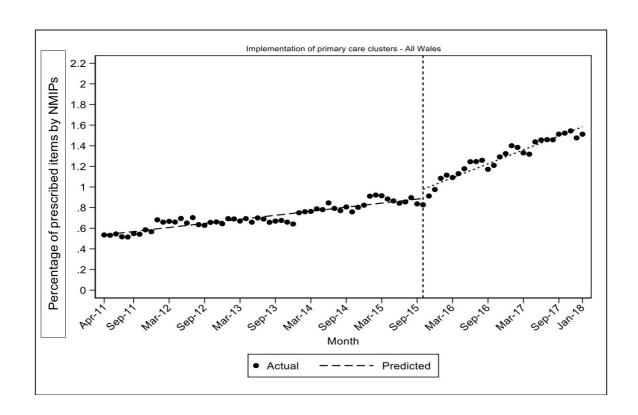


Figure 39 Observed and predicted percentage of all prescribed items by NMIPs prior to and following the implementation of primary care clusters in October 2015 (All Wales, final two months removed)

4.6.11. Key findings

Over the study period:

- 600 NMIPs had prescribed at least one item that had been dispensed, nearly 40% were based in BCUHB and only 6% in PTHB.
- INPs increased by 108%, whereas IPPs increased by 325% (increased by 240% from July 2015 to March 2018).
- The total number of items per 100,000 population per year prescribed by NMIPs increased by almost 200%; the largest increase (90%) was between the last quarter of 2015 and March 2018.
- The highest percentage of prescribed items by NMIPs was within BCUHB (34%; 240,742.5 items per 100,000 population), while the lowest percentage was in PTHB (4%; 137,000.6 items per 100,000 population).
- In each HB, the top BNF chapter prescribed by NMIPs was cardiovascular, except in BCUHB where it was infection. The top BNF category prescribed was antibacterial.
- The ITS analysis showed that the number of items prescribed by NMIPs increased over time by an average of 1,380 per month (95% CI: 904 to 1855, p < 0.001) after the implementation of primary care clusters compared to 496 (95% CI: 445 to 548, p < 0.001) prior its implementation.
- There was a 60% relative increase in the number of prescribed items by NMIPs following the implementation of primary care clusters over and above what would have been expected in the absence of such a scheme in all Wales (95% CI: 46 to 75, p < 0.001).
- The HB trends in prescribed items by NMIPs after the implementation of primary care clusters showed a significant change (p < 0.05) in ABUHB, BCUHB and CVUHB. While the changes in ABMUHB and CTMUHB were not significant. The linear modelling assumptions were not fulfilled for HDUHB and PTHB.
- The ITSA model estimates for prescribed items by medical prescribers showed that there was evidence of a change in the post intervention slope (with a negative trend observed). Assuming the pre-implementation trend would have continued in the absence of the introduction of primary care clusters, there was a 5.6% (relative) reduction in prescribed items by medical prescribers than what would have been expected (95% CI: -9.0 to -2.1%).

4.7. Discussion

4.7.1. Overview

This study has investigated the prescribing pattern of NMIPs and how it has changed over time, as well as the number of NMIPs in primary care in Wales. The data obtained from the NHS Wales Shared Services Partnership provided information about the numbers of NMIPs in primary care settings in Wales as well as the HB they were performing their duties within. The CASPA data provided information about the trend of prescribed items by all prescribers, including NMPs over time. Moreover, it allowed identification of the most common BNF chapters and categories of medicines prescribed by NMIPs in all Wales, as well as in each HB.

This study also aimed to examine the trend of items prescribed by NMIPs pre- and post-implementation of primary care clusters in Wales, using an ITS analysis. Initially, a series of ARIMA analyses were used to analyse the prescribing trends of NMIPs in all Wales, as well as in each HB before and after the implementation of primary care clusters. However, following reading about these tests, as well as peer review and consultation with an expert statistician, the researchers reflected on the ARIMA analysis and determined that a simpler ITS analysis (the ordinary-least squares regression) was more suited. Interestingly, the findings of both analyses were similar, which proves the initial appropriateness of the ARIMA analysis. The ordinary-least squares regression is less complex than the ARIMA analysis and was therefore chosen to present the findings of this study. Another difference between these approaches is that there is a chance in the ordinary-least squares regression analysis that the model may not fit all the serial correlations in the presence of large values compared to the ARIMA model (Sedgwick 2012; Linden 2015). This occurred in this study with the HDUHB and PTHB NMIPs' data due to outliers in the number of items prescribed by NMIPs from April 2016 to March 2018. However, in the ARIMA analysis, there was no significant correlation with these outliers and therefore, it did not have an impact on the findings.

4.7.2. Prescribing by NMIPs

The NHS Wales Shared Services Partnership data revealed that most NMIPs in primary care settings in Wales from April 2011 to March 2018 were nurses, followed by pharmacists, and physiotherapists. Although the number of nurse prescribers was much greater than pharmacist prescribers, they represented 5% of the nursing workforce (Courtenay 2018), while pharmacist prescribers represented 7% of the pharmacist profession (GPhC 2016). The fact that there were more nurses than other professions is consistent with the findings of other studies that investigated the implementation of NMPs in England (Latter et al. 2011; Courtenay et al. 2012) and Wales (Courtenay et al. 2017a). The difference between

these studies and this PhD study is that they used surveys to collect data from their participants, which may have the disadvantage of not reflecting the actual numbers of NMIPs depending upon the response rates (all had response rate of 55% or over). Whereas this study used the national database for all NMIPs in primary care in Wales. This database includes all prescribers in primary care who have prescribed a medicine in Wales that has been subsequently dispensed in community pharmacies. Interestingly, the database did not identify other HCPs who have prescribing authorisation in Wales, including therapeutic radiographers, chiropodists and podiatrists, and optometrists (Welsh Government 2017). Therapeutic radiographer prescribers are based within secondary or tertiary care settings in Wales and therefore, they would be unlikely to be included in the database. However, other professions could potentially be working in primary care settings but have not prescribed medicines that have been dispensed.

Between April 2011 and March 2018, the number of NMIPs who prescribed in primary care in Wales each month increased. This may suggest that the primary care sector is recognising the skills of these practitioners, improving the skill-mix in the sector, and hopefully reducing the pressure on GPs. All of these were consistent with the reasons for the introduction of NMPs, as outlined in the second Crown Report (DOH 1999). Interestingly, in Wales since the last quarter of 2015, the increase in the percentage of IPPs was higher than the increase in the percentage of INPs (325% vs 108%). This could be explained by the implementation of the WG plan that aimed to overcome the shortage in GPs that has led to the increased pressure on the primary care sector (Welsh Government 2015). The plan focused on enhancing patient access to appropriate health care advice and treatment as well as information related to medication use and possible side effects. Therefore, the WG put one of the objectives in this plan to train more pharmacists as NMIPs. Based on the findings of this study, this may suggest that the WG are working on achieving this plan.

Some reports have drawn attention to the issue of GP shortages in Wales, particularly in North Wales. Brennan (2017) reported that there was a 'recruitment crisis' as a lot of GPs in North Wales had moved to other work opportunities in secondary or tertiary care settings, retired or emigrated to other countries, and that there was difficulty in recruiting new GPs in Wales. An example of the crisis was provided by Jones (2017), who explained that there were only three GPs providing health care services for 8,000 people in Conwy in BCUHB. A shortage of GPs was not just an issue in BCUHB but also in other HBs in Wales (Jessup 2017). Much effort has been put into finding solutions to overcome this issue to provide the required quality of health care for the population of Wales. One solution by HBs has been to increase support to their GP practices by revising the GP Sustainability Assessment Framework, to recognise the vulnerable GP practices (Welsh Government 2016a). HBs, especially in North Wales, have been encouraging the training of other health care providers

(e.g., pharmacists, nurses, and physiotherapists) to obtain their prescribing qualification to overcome the shortage of GPs, particularly in the affected GP practices (Brennan 2017; Jones 2017). This may explain the increase in the number of NMIPs in primary care in Wales, particularly in BCUHB. Data from this study identified that the highest percentage of NMIPs was in BCUHB (41%), whereas the lowest percentage was in PTHB (6%).

The increased number of IPPs since the last quarter of 2015 could also be explained by the establishment of primary care clusters in Wales. Although primary care clusters were implemented in 2015, the exact date of implementation varied from one HB to another, due to the flexibility of funding by the WG (The National Assembly for Wales 2017). Funding was provided to the 64 primary care clusters late in 2014 (£6 million) which was then topped up in April 2015 to £10 million for primary care clusters and £26 million to support HBs to implement their local plans and train health care providers, which then became effective (Welsh Government 2016b).

The establishment of these clusters was also one of the WG plans that aimed to improve primary care services. As part of the implementation of 'Setting the Direction and Delivering Local Health Care' plan in primary care in Wales and the WG plan (Welsh Government 2015), changes to the GP contract for 2014/15 were made to strengthen primary care clusters. A three-year development programme, starting in 2014, was set out for the primary care cluster network to recognise local health requirements and priorities; provide a local action plan; improve the coordination and integration of health and social care through working with partners; and decrease health inequalities by working with local communities and networks (NHS Wales 2014). The local HBs supported the development of primary care clusters across Wales to improve their services to meet local needs and maintain sustainability. In addition, they aimed to enhance patient access to treatment and other services, develop a collaborative working environment to map where required services were available and facilitate referrals across practices, provide a mix of skills within different practices, and improve the communication between primary and secondary care (NHS Wales 2014). These objectives aligned with the objectives of NMPs' role implementation in the UK (DOH 2006). HBs and GP practices recruited many NMIPs, such as pharmacists, nurses, and physiotherapists in primary care clusters to achieve the primary care WG plan (Welsh Government 2015). This clinical role, based within clusters, was an exciting new role for pharmacists and as the workforce based in primary care was not present to fulfil these positions, many of the secondary care based IPPs and pharmacists wanting to become prescribers moved into these positions (Hodson 2018). This may have led to a shortage of pharmacists within secondary care and highlighted the need for a pharmacy workforce plan for Wales to overcome such an issue. As identified in the introduction chapter (Chapter 1, Section 1.2.3), a new pharmacy workforce plan was published in 2023 in Wales that outlined

goals to develop the pharmacy profession, including IPPs, and increase their numbers across all healthcare sectors.

The WG plan, introduction of primary care clusters, and the shortage of GPs in Wales could explain the large increase in the number of NMIPs since the last quarter of 2015. This increase of NMIPs, particularly IPPs, may explain the increased rate of medicines prescribed by these practitioners over the same period. Whilst the total number of dispensed items that were prescribed by NMIPs between April 2011 to March 2018 was nearly 1% of the total number of items prescribed by all prescribers, the percentage of these items increased from 0.57% in 11-12 to 1.7% in 17-18. This increase did not affect the rate of prescribing by all HCPs in primary care over the last four years of the study period, which was consistent, even with the increase in the population rate and the increase of those over 65 years in the same period in Wales (Welsh Government 2018a). However, the ITS analysis indicated that a significant negative trend of the post-intervention slope was observed and that, assuming the absence of the introduction of primary care clusters, there was a 5.6% (relative) reduction in prescribed items by medical prescribers than what would have been expected. This may suggest that NMIPs are prescribing medicines for patients that were traditionally prescribed by GPs, and hence reducing GPs' workload, an aim of the second Crown Report (DOH 1999). However, there is lack of evidence to show the actual potential of NMIPs to reduce the increased demand on GPs (National Assembly for Wales 2017). In addition, other confounding factors, such as deprescribing initiatives and the potential decrease in the number of GPs, may have contributed to the decrease in prescribing by medical prescribers over the study period. It is therefore difficult to establish the impact of prescribing by NMIPs on medical prescribing and this requires further research. Further research is also needed to investigate whether patient outcomes, as well as the cost-effective impact of the NMIPs' role, is comparable to that provided by GPs in terms of the quality and safety of prescribing. In addition, patient views and their acceptance of NMIPs' services should be explored.

According to the findings of this study, the total number of items prescribed by NMIPs in different HBs has also increased over time, with the largest increase occurring in BCUHB (34%), which also had the highest rate of prescribed items per population (2.4 items/population). This could be explained by the higher number of NMIPs in BCUHB (246 NMIPs) compared to other HBs and the issue of recruiting GPs in North Wales, which has been outlined above. Another possible explanation for the high prescribing of medicines in BCUHB by NMIPs is that BCUHB may have been an early adopter of NMIPs' services by looking at the increase in their prescribing and total numbers in Figures 12 and 13, as well as Tables 3 and 4 in the result section. The number of NMIPs' prescribing in BCUHB has increased over the study period, compared to PTHB which has only seen a large increase since the last quarter of 2015.

Statistically significant changes in NMIPs' prescribing trends pre- and post-implementation of the primary care clusters were observed across all Wales and in three HBs (ABUHB, BCUHB and CVUHB) out of seven. The two HBs where the utilisation of NMIPs did not change significantly were CTMUHB and ABMUHB. The model didn't fit the data of HDUHB and PTHB due to the sharp increase in the last few years. However, this sharp increase may suggest that the change was significant at these two HBs. It could be argued that the increase in the utilisation of NMIPs' services is represented by the increase in the number of items prescribed by NMIPs. As a result, the intervention may have been the driver for the utilisation across these five HBs. However, the number of prescribed items by NMIPs is not necessarily indicative of an increase in the utilisation of NMIPs. The utilisation of NMIPs would have been appropriately measured by using the number of actively prescribing NMIPs in each HB. However, as discussed in the methodology section, one of the limitations of the CASPA data is that it does not include the number of NMIPs over the study time. In addition, this information is also not available in the data obtained from the NHS Wales Shared Services Partnership. Therefore, it was not possible to make causal inferences.

As illustrated above, it might be possible to consider that BCUHB is an early adopter of NMIPs' services based on their prescribing trends during the study period compared to other HBs, particularly PTHB and HDUHB in which this role was utilised over the last two years of the study period. BCUHB and HDUHB represent the largest geographical area in Wales compared to other HBs (NHS Wales 2017). However, both HBs have the lowest number of GPs per 10,000 population compared to other HBs (6.1 and 5.8, respectively) (Welsh Government 2018b). This may suggest that people in these HBs, particularly people in rural areas, may find it difficult to access healthcare services. As discussed above, the low number of GPs in these HBs could be related to issues of recruitment, as well as the difficulty in keeping those who are already employed in their positions (Brennan 2017 and Jones 2017). Therefore, GPs have been offered financial incentives by the WG over the last five years to train and work in specific HB areas, particularly rural areas that meet the eligible criteria (GP National Recruitment Office 2018). These issues, which may have led to the shortage of GPs in these HBs, may have been the reason for the early adoption of NMIPs in BCUHB. Nevertheless, CTMUHB has the same number of GPs per 10,000 as BCUHB (6.1) (Welsh Government 2018b). Therefore, CTMUHB would have also been expected to be an early adopter of NMIPs, which questions the argument outlined above.

There is nothing published in the literature about the uptake of NMIPs across the different HBs in Wales. Therefore, information was obtained from pharmacist leads in each HB to see if they could clarify why there was a change in the pattern of prescribing by NMIPs within their HBs or if there were any polices that could explain these changes. As a result of this enquiry only PTHB, CTMUHB and CVUHB leads responded. The response of the PTHB

lead (Appendix 7) suggested that due to the recruitment of an IPP who had taken on repeat prescribing for patients with ongoing long-term conditions, the rate of prescribing largely increased over the last year (Smith 2018). In addition, a community pharmacist trained as a NMIP to extend the scope of the CAS (Smith 2018). This service was implemented in collaboration with local GP practices in Llanidloes in 2016 and is also likely to have accounted for the increase in the prescribed items by NMIPs in PTHB. Therefore, the significant increase in prescribing before and after the intervention in PTHB was unlikely to have been caused by the intervention itself. This service has decreased the demand for appointments with GP practices for patients suffering from common conditions by 21% (Welsh NHS Confederation 2017). This is a novel model of care that illustrates the potential of how community pharmacy can use NMIPs' services within the pharmacy, which could help to relieve the increased pressure on GPs.

The response received from the CTMUHB lead (Appendix 8) revealed that there were no known polices regarding NMIPs' practice which correlated with the study period that could explain the changes (Scott-Thomas 2018). However, the lead of this HB indicated that there were significant service improvements since the implementation of primary care clusters, which increased multidisciplinary teamwork and other professions working in primary care, including NMIPs. IPPs were also recruited as cluster-based pharmacists across three of the four localities. However, this didn't align with the prescribing trend of NMIPs in CTMUHB, particularly after October 2015. Other HB leads including BCUHB, ABMUHB, ABHD, and HDHB did not respond to the contact, while the response of the CVUHB lead (Appendix 9) focused on the BNF chapters and categories prescribed by NMIPs, which will be discussed later in this section.

Based on the findings in this PhD study, there was variation in the trend of prescribing by NMIPs in different HBs in Wales. This is consistent with the study conducted by Courtenay and colleagues (2017a) which stated that the implementation of NMIPs' services was inconsistent across Wales. Although the literature lacks evidence regarding the barriers of implementation of the NMIPs' role in HBs in Wales, many reasons may have contributed to the lack of utilisation of this service in CTMUHB and ABMUHB from previous UK studies. In the survey conducted by Courtenay and colleagues (2017a), some participants reported that the development of NMIPs' services is restricted by a lack of funding. However, it could be argued that these findings did not provide quantifiable evidence as feedback was provided subjectively via respondents on free text comments. Other studies conducted by Cooper and colleagues (2008), Hacking and Taylor (2010), and Latter and colleagues (2011) provided the same barrier for the development of NMIPs' role, although they were conducted in other countries in the UK, not in Wales. In addition, Latter and colleagues' (2011) study revealed that only one half of the trusts in England included in the study reported a plan or strategy to

develop the NMPs' service. However, these studies can be considered outdated and may not reflect recent practice and policies. Due to the lack of evidence of policies and research regarding the impact of these barriers on the implementation of NMIPs' role in each HB, further research is required to investigate this matter. Therefore, this study provides the initial evidence for such research, for instance, to target the two HBs to investigate the barriers to the development of this service.

The findings of this PhD study revealed that the therapeutic areas in which NMIPs prescribed the most in primary care in Wales were infections, cardiovascular, pain, and respiratory conditions. This is consistent with the findings of other published studies in this area (Latter et al. 2011; Courtenay et al. 2012; GPhC 2013; Drennan et al. 2014; Carey et al. 2017; Courtenay et al. 2017a; Courtenay et al. 2017b). However, most of these studies were conducted in England. Although these studies revealed that NMIPs were prescribing medicines for a wide range of clinical areas, it was found that most INPs prescribed for infections. On the other hand, most IPPs prescribed for cardiovascular, particularly anticoagulants, and pain management, while independent physiotherapists prescribed for musculoskeletal conditions and pain management. These studies did not identify the sector of practice of NMIPs as either primary, secondary, or tertiary care settings, a limitation that must be acknowledged. In addition, the information collected in these studies was selfreported by participants, which may have been estimated and therefore may not reflect actual practice. The studies conducted by Latter and colleagues (2011), Courtenay and colleagues (2012), Carey and colleagues (2017), and Courtenay and colleagues (2017) provided a similar demographic profile to this empirical PhD study in terms of the high number of nurses compared to pharmacists and AHPs. The study by Drennan and colleagues (2014) investigated the prescribing pattern of nurse prescribers. All these studies provided similar findings for each healthcare prescribing profession. Unfortunately, the CASPA data used in this PhD study did not differentiate between the different professions and therefore was not able to identify if one profession prescribed more in one area than another. This makes a direct comparison with the literature more challenging. For example, whilst the main area that NMIPs are prescribing within primary care in Wales is infections, it is unknown whether it is nurses, pharmacists, or both professions prescribing in this area. As the majority of NMPs in the UK are nurses (NHS Digital 2017) and based on the findings of previous studies (Latter et al. 2011; Courtenay et al. 2012; GPhC 2013; Drennan et al. 2014; Carey et al. 2017; Courtenay et al. 2017a; Courtenay et al. 2017b), it may be inferred that most of the antibacterial drugs may have been prescribed by INPs. However, the findings of this PhD study as well as that of the study conducted by Courtenay and colleagues (2017b) suggest that the rate of antibiotic prescribing by NMPs has decreased in recent years. This may be related to the plan developed by the WG for the NHS and its partners, which aims to improve

antibiotic prescribing and prevent antimicrobial resistance in Wales (NHS Wales 2016). The results of the study may suggest that the majority of NMIPs are aware of the WG's recommendations and are following them in their practice. One of the WG plan's themes focused on increasing public awareness about the risk of antimicrobial resistance. It also focused on improving HCPs' education and training on the appropriateness of antibiotic prescribing, antimicrobial stewardship, and the issues that may be raised by antimicrobial resistance. Moreover, it promoted and supported the role of antimicrobial IPPs' role in primary care to optimise antibacterial prescribing by using the right antibacterial drug for the right condition and patient, and at the right time. As per the findings of this study, although the rate of antibacterial prescribing by NMIPs decreased in most of the HBs, it increased in PTHB and ABMUHB over time. This may indicate that NMIPs within these HBs need more awareness and training on the use of antimicrobial stewardship and local guidance, in line with the WG plan, to prescribe antibacterial drugs appropriately. It could also be related to the late start of NMIPs' services in these HBs as the number of NMIPs who prescribe antibacterial drugs is still increasing or that their scope of practice was not focusing on infections. The appropriate prescribing of antimicrobials by NMIPs may prevent or slow down the development of antimicrobial resistance. However, most existing studies have focused on the appropriateness of antimicrobials prescribed by GPs. Therefore, this represents an opportunity for further investigation to explore the appropriateness and efficiency of antibacterial drugs prescribed by NMIPs.

Although the antibacterial BNF category represented the highest category prescribed by NMIPs, the cardiovascular BNF chapter (which includes many BNF categories such as antihypertensive therapy and anticoagulant drugs) had the highest rate of prescribing. This may reflect that many HBs have prioritised this area for IPPs (Hodson 2018). The response of the CVUHB lead (Appendix 9) indicated that the increase in the number of new NMIPs, particularly IPPs, was more in clinical areas such as anticoagulant management, hypertension, and heart failure, which may be the reason behind the increased trend of cardiovascular system prescribing (May 2018). May (2018) also explained that the differences in prescribing areas may be related to the different professions and what they have the authority to prescribe. For example, some NMIPs, such as physiotherapists, who predominantly prescribe for pain management caused by muscle spasms, have a very restricted scope of medicine prescribing, which is unlikely to expand even when they are more experienced.

NMIPs, such as pharmacists and nurses in the primary care sector, could extend their scope of prescribing practice into many chronic or minor conditions, depending upon the population demographics and healthcare needs, as well as pressures on GPs. An example has been provided by May (2018) who suggested that the presence of local Chronic

Obstructive Pulmonary Disease (COPD) guidance in CVUHB has encouraged IPPs and INPs to review corticosteroids and ensure that the most appropriate and minimum effective dose is used. It also helped them to identify and review asthma patients who were using many bronchodilators. Thereafter, NMIPs helped in stepping up the treatment of asthma patients for better control, and thus fewer bronchodilators were needed, which may explain the decrease in the prescribing rate of bronchodilators and corticosteroids BNF categories, and therefore, the respiratory BNF chapter in CVUHB (May 2018). It may also suggest that the presence of appropriate guidance for each chronic or minor condition may help NMIPs and other healthcare prescribers to prescribe medicines only when necessary. This will help in providing high quality healthcare for patients with the least number of medicines. As also indicated in Chapter One (Section 1.2.4), the RPS published a new guidance in 2022 to support NMPs, including IPPs, in extending their scope of practice (RPS 2022). This guidance may help IPPs to identify new therapeutic areas of prescribing and provide a structured framework on how to expand their scope of practice within these areas.

In addition, some of the NMIPs in CVUHB were involved in the management of diabetes patients in a community model where GP practices were linked to a named consultant (May 2018). This model aimed to improve the skills of the team in the management of diabetic patients to reduce the need for referrals to GPs or secondary care settings. NMIPs who are specialists in diabetes management prescribed more medicines in this model than GPs (May 2018), which may explain the increased rate of drugs used in diabetes treatment, as seen over the period of this study. Another example of the management of chronic conditions by NMIPs is indicated by the CTMUHB lead (Appendix 8) who implied that some IPPs are running anticoagulant clinics since the implementation of primary care clusters (Scott-Thomas 2018). This may explain the increase in the prescribing trend of the cardiovascular chapter by NMIPs in this HB. Such models may help reduce the pressure on GPs and decrease the rate of referral to secondary care settings by using the high skills of NMIPs in the management of certain chronic conditions.

As indicated earlier in this section, other HB leads did not respond to the contact made by the researcher, and there is a lack of evidence in the literature about the therapeutic areas of prescribing by NMIPs within different HBs in Wales. However, based on the findings of this study, the therapeutic areas in which NMIPs prescribed the most were similar across different HBs in primary care in Wales. Therefore, the responses received by the CVUHB and CTMUHB leads may reflect some of the current practice of NMIPs across Wales. These responses align with the findings of this study may suggest that the majority of IPPs have been involved in the management of chronic conditions, such as cardiovascular diseases and diabetes.

The literature review (Chapter 2) highlighted a few very recent studies that examined the prescribing volume and trends of items prescribed by NMPs. In Wales, similar findings to

this empirical study in the PhD were presented by Deslandes and colleagues (2022), who conducted a secondary data analysis of NMIPs' prescribing of items using the same source of the data in this PhD study (CASPA) in GP practices in Wales over a longer period (between April 2011 and March 2021). They found that the number of items being prescribed by NMIPs had increased significantly over the 10-year period of the study by 430%. Overall, the findings showed that NMIPs were likely to prescribe certain types of medicines, with almost 80% of the prescribed items over the study time being from seven BNF chapters, specifically, cardiovascular system, infections, central nervous system, respiratory system, gastrointestinal system, endocrine system, and skin, which were the same BNF chapters that were identified in this PhD study (Chapter 4, Section 4.6.7). This study also had the same limitations as the CASPA database, which will be discussed in much detail later in this chapter in Section 4.7.5. Hence, it would not independently and conclusively show the specific prescribing by IPPs in Wales since it included all NMIPs' data as a whole. The continued increase in the number of NMIPs, including IPPs, and their volume and trends of prescribing highlights the WG high support and interest in developing this role in primary care. In England, the increase in the number of prescribed items by IPPs in primary care was highlighted by Wickware (2021), which increased by more than five-fold between 2016/17 and 2020/21 (from 6,164,982 in the year 2016/17 to 32,479,133 in the year 2020/21). Although this period was not the same as in this empirical study in the PhD, which was between 2011/12 and 2017/18, it showed that the number of items that they prescribed had still been increasing over recent years in other parts of the UK. A recent study by Brett and Palmer (2022) used a quantitative approach by conducting a secondary data analysis to explore the changes in the NMPs' population and their patterns and the volume of antibiotic prescribing between 2016 and 2021 in primary care settings in England. The findings indicated that NMIPs prescribed almost 6% of the total prescribed items over the study period, and their prescribing increased by 109% per 100,000 population between 2016 and 2021 in England. Almost 98% of antibiotics prescribed by NMPs were prescribed by INPs and IPPs. Over the study period, the number of prescribed antibiotics per 100,000 by NMPs fell by almost 6.5%, while their prescribing of high-risk antibiotics increased by around 15%. They found that NMPs are more likely to appropriately prescribe antibiotics compared to medical prescribers, while their prescribing of antibiotics adhered to antimicrobial stewardship and national guidelines. The increase in prescribing volume by IPPs may suggest that the Governments in some UK nations are focusing on training more IPPs and supporting their roles in the primary care sector. However, the study conducted by MacVicar and Paterson (2022) found that the total prescribing volume by IPPs/independent physiotherapy prescribers decreased by 20.5%, while INP's prescribing volume increased by 125% between 2013 and 2022 in primary care in Scotland. The study sought to investigate and compare the prescribing of common drugs by medical prescribers and NMPs dispensed

in community pharmacies by analysing the secondary data of their ten most prescribed medications. They found that NMPs prescribed 2.5% of the total prescribed medicines in primary care (0.6% by INPs and 1.9% by IPPs and independent physiotherapy prescribers) over the study period and 97.5% were prescribed by medical prescribers (GPs). This study showed that the prescribing trends varied over the study period, with the IPPs/independent physiotherapy prescribers prescribing more medications compared to INPs in the 2013/2014 year. The limitations of the study were similar to this empirical study in the PhD and that by Deslandes and colleagues (2022), whereby specific data for IPPs were not available. Hence, this may not provide a very clear understanding of the IPPs' prescribing trend. Also, some of the IPPs used in the study by MacVicar and Paterson (2022) prescribed medications by using the GP10 form, which is supposed to be for GPs only, and this may have underestimated the actual number of prescribed items by IPPs. In addition, the study was conducted in primary care settings in Scotland, which may not represent the overall prescribing of IPPs across the UK. In other countries across the world, Grant and colleagues (2023) conducted a recent study in Nova Scotia, which was the only study that examined the adoption of independent pharmacist prescribing practices in Canada. This study used secondary database analysis of prescribing data of IPPs from April 2017 to March 2020 across different healthcare settings. The findings showed a significant increase (p < 0.001) in the average of prescribed items by pharmacist prescribers (n= 1182) over the three years, which were 24.6 items in 2018, 26.3 items in 2019, and 32.5 in 2020. Patients with multiple health conditions and older patients were the most frequent consumers of their services. The study highlighted the growing role of pharmacists as prescribers in primary care, particularly in the management of patients' medication and improving their access to appropriate treatment. However, this study did not determine the therapeutic areas of prescribing by IPPs. In New Zealand Raghunandan and colleagues (2021b) conducted a study that aimed to understand the trends, scope, and scale of prescribing by NMPs in secondary care between 2016 and 2020. They utilised data from national prescription databases, which indicated that supplementary pharmacist prescribing increased from 1% in 2016 to 9% in 2019. The study emphasised that although supplementary pharmacist prescribing has increased over time, their number and prescribing volume could have been utilised further to overcome the medical practitioners' shortage and improve patients' access to treatment, particularly for chronic conditions' management in primary care.

4.7.3. Prescribing by supplementary prescribers

It was found that supplementary prescribers prescribed the least number of items and their rate of prescribing of medicines was relatively steady over the study period. Despite the study conducted by Guillaume and colleagues (2008), which was highlighted in Section 4.1.2, no other studies have investigated the prescribing of pharmacists as supplementary

prescribers. This could be due to the introduction of NMIPs in Great Britain in 2006, as many supplementary prescribers re-qualified as NMIPs (GPhC 2013). In addition, supplementary prescribing courses have not been available since 2009, and non-medical independent prescribing courses are the only available option to qualify as a prescriber (GPhC 2013). These may indicate that the number of supplementary prescribers has not changed or decreased over time, which may explain their consistent rate of medicine prescribing.

4.7.4. Prescribing by community nurse prescribers

In this study, only about 0.07% of items were prescribed by community nurse prescribers. Their prescribing trend of medicines decreased over time from April 2011 to March 2018. This decrease could be related to the fact that the formulary (the NPF 2015-2017) they use to prescribe medicines from is outdated as it has not been changed since 1998 (Courtenay 2018). Furthermore, community nurse prescribers used to prescribe dressings frequently. The 'centralised dressing schemes' was established in many health care settings, meaning that dressings are no longer needed to be prescribed by community nurse prescribers (Courtenay 2018).

The reduction in the number of community nurse prescribers who are actively prescribing is also reported in the literature. Courtenay and colleagues (2012) conducted a survey of NMPs across one strategic health care authority in England. They revealed that approximately one third of the community nurse prescribers who participated in the study were not using their prescribing rights. Similarly, Drennan and colleagues (2014) explored the prescribing activities of nurse prescribers in primary care settings in England from 2006 to 2010. They concluded that there was a decrease in the number of active community nurse prescribers over the study period. The study defined active prescribers as those who prescribed medicines at least two times per year.

4.7.5. Study limitation

Although this study has achieved its aim and objectives, it has several limitations. Firstly, during the time of the PhD it was only possible to obtain data from the CASPA software system for seven years. Secondly, the CASPA system was designed for financial reimbursement purposes for community pharmacies, which means that holding investigations at the level of patients or prescribers, such as stopping or changing patients' medications, as well as clinical safety issues or other prescribing activities, was not possible. In addition, this system only captures prescriptions that were dispensed in community pharmacies and submitted for reimbursement. Prescriptions issued by prescribers in Wales that were not dispensed nor submitted for pricing were not captured by the system. Moreover, as identified by the AWTTC, a very small number of prescriptions on the CASPA system may have been

prescribed by NMPs in hospital outpatient clinics or by GPs using NMIPs' prescription pads (Deslandes 2018). Finally, the professions of NMIPs as either pharmacist, nurse, physiotherapist, or others were not identified in the prescriptions and, consequently, in the CASPA system. In addition, the data obtained from the NHS Wales Shared Services Partnership, Primary Care Services Department was limited to information related to NMIPs in primary care in each HB in Wales. This meant it lacked information related to supplementary prescribers and community nurse prescribers. However, these limitations have not prevented the study from achieving its aim and objectives. Nevertheless, since September 2019, new changes have been implemented in the CASPA database, allowing for the identification of the NMIPs' professions and capturing their prescribing data across both GP practices and community pharmacies (Parsloe et al. 2023; Alshakmobarak et al. 2024).

The limitation of the retrospective ITS design is considered the most significant in this study because of the lack of researcher control over an intervention that has already occurred. In addition, unknown confounding variables, which are outside of the researcher's control, may have happened at the same time of the intervention and this leads to the difficulty of establishing causal effects (Ramsay et al. 2003). A randomised controlled trial design is considered the gold standard design to make a more reliable evaluation of the impact of an intervention (Campbell et al. 2000; Victora et al. 2004; Bonell et al. 2009), particularly within a healthcare field (Eccles et al. 2003). However, a randomised controlled trial approach, which requires the presence of a control group, was not appropriate for this study since the intervention was applied at a national level that lacks the availability of a control group. Moreover, it was not feasible to conduct a prospective evaluation of the intervention since primary care clusters had already been implemented in Wales. Therefore, a retrospective design was considered the best approach to conduct this study. In addition, the ITS analysis has the strength of evaluating data at the whole population level (Bernal et al. 2016), which allowed the researcher to evaluate the utilisation of NMIPs in primary care across all of Wales. This opposes the use of other methodological designs that can be conducted at one specific HB or healthcare authority, such as the survey carried out by Courtenay and colleagues (2012). Therefore, the results of this study can be considered representative of the whole NMIPs' role within primary care in Wales.

4.7.6. Future studies

This study has provided insights and empirical findings on the prescribing pattern of medicines by NMPs and the most common therapeutic areas of prescribing by NMIPs over time in primary care in Wales. It provides an opportunity for further studies to be undertaken regarding the utilisation of NMIPs in Wales, as well as in the UK in general. This study revealed that the uptake of NMIPs' role is inconsistent across the seven HBs. Due to the lack of

supporting evidence regarding this matter, further studies are needed to investigate the inconsistency in the uptake of using NMIPs across HBs in Wales. Such studies could provide information regarding the development of NMIPs' role across different HBs in terms of the challenges and enablers of the implementation of this role. It could also help in sharing ideas and strategies between HBs of this role over the study time. This might be done by conducting qualitative studies with IPPs to explore the role of IPPs in primary care settings in Wales and obtain more in-depth information about its implementation. In addition, the new changes in the CASPA system could provide an opportunity for researchers to specifically focus on the prescribing volume and trend of IPPs to determine their exact development and areas of prescribing.

4.8. Conclusion

Over the study period, the percentage of items prescribed by NMIPs increased compared to items prescribed by all HCPs in primary care in Wales and dispensed in community pharmacies. The majority of NMPs in primary care in Wales were nurses, the number of which increased steadily over the study period. In contrast, the number of IPPs saw a much greater increase over time. The trend of medicines prescribed by supplementary prescribers was steady, while the rate of medicines prescribed by community nurse prescribers decreased over the study period.

The trends of the medicines prescribed by NMIPs increased in the majority of HBs and within different therapeutic areas, particularly since the introduction of primary care clusters. This could be explained by the large increase in the number of NMIPs, particularly IPPs. The high influx of NMIPs could be related to the implementation of the WG plan (Welsh Government 2015) and the introduction of primary care clusters to improve primary care services and relieve pressure on GPs in Wales. BCUHB had recruited the highest number of NMIPs compared to other HBs, which may explain their high rate of medicines prescribed by NMIPs compared to other HBs. The therapeutic areas that NMIPs prescribed the most were in cardiovascular, infection, pain, and respiratory conditions.

The findings of this study also provided valuable information about the utilisation of NMIPs across HBs before and after the implementation of primary care clusters in Wales. It revealed that the prescribing volume by NMIPs had significantly increased after the introduction of primary care clusters in five out of the seven HBs in Wales. Although the study design was considered the best approach to conduct this study by the researcher, it has not established the exact causal effect. As a result, it cannot be determined if the observed differences in prescribing by NMIPs in primary care over the study time frame were due to the intervention, confounding factors, or caused by both. The findings of this study provide clear evidence that the utilisation of NMIPs is still inconsistent across the seven HBs in primary care

in Wales. This provides an opportunity to share learning between BCUHB, which was an early adopter, with other HBs. It also provides a starting point for further studies to investigate the inconsistency in the uptake of using NMIPs across different HBs in Wales. This study may have indicated some shift in prescribing from medical prescribers to NMIPs in primary care in Wales that may help to reduce medical prescribing workload over the study period. As a result, the implementation of primary care clusters in Wales seems to have helped the WG to reduce the increased pressure on GPs.

The findings of this study may suggest that with the increase of NMIPs' number, as well as their prescribing volume over time, their skills may have been well recognised in the primary care sector in Wales. Therefore, their role may help in improving the skill-mix across different therapeutic areas and reducing the pressure on GPs. This aligns with the main reasons for the implementation of NMPs in the UK, as outlined in the second Crown Report (DOH 1999). Future studies should focus on investigating the safety and quality of medicine prescribing by NMIPs compared to GPs, and the views and acceptability of NMIPs to their role as well as different HCPs' views and acceptability on the provided services by NMIPs.

4.9. Dissemination of the first study

The findings of the first study were disseminated at the Health Services Research & Pharmacy Practice (HSRPP) Conference (2019) in the form of two posters (Appendices 10 and 11). One of the posters (Appendix 10) has also been disseminated at the Postgraduate Research Day at the School of Pharmacy at Cardiff University in 2019. The findings of this PhD study were published in BMJ Open (Alghamdi 2020), as illustrated in Appendix 12.

5. Chapter 5 – IPPs' Views of Their Role as Prescribers in Primary Care
Settings in Wales

5.1. Introduction

This chapter includes the rationale, aim and objectives, results, discussion, and conclusion of a study that aimed to address the second objective of this PhD. It involved using a qualitative approach to explore the views of IPPs working within GP practices in Wales on their prescribing responsibilities and how their role is embedded in primary care.

5.2. Study Rationale

The evidence illustrated in the introduction and literature review chapters (Chapters 1 and 2, respectively) indicated that IPPs have been working in all healthcare sectors in the UK and prescribing for a wide range of conditions since the implementation of their independent prescribing role (Tonna et al. 2010; Bowron et al. 2011; Bruhn et al. 2013; Twigg et al. 2013; Courtenay et al. 2017). As highlighted in Chapter One (Section 1.1.3), initially, IPPs in Wales were more secondary care based but with the WG primary care plan and the implementation of primary care clusters in 2015 (Welsh Government 2015), many pharmacists have trained to be IPs in primary care (Royal Pharmaceutical Society Wales 2015; Hodson 2018). As a result, as demonstrated in Chapter Four, the number of IPPs who were actively prescribing in primary care in Wales and their prescribing trends of medicines have increased in recent years. Their numbers increased from 16 to 68 between 2011 and 2018 (Chapter 4, Section 4.6.5.2), and it is expected to increase more in the coming years (Courtenay et al. 2017). Moreover, the findings of the first study indicated that the volume of prescribing of NMIPs, including IPPs, has also increased over the years. In addition, they were prescribing medications mostly for chronic conditions (such as cardiovascular and diabetes diseases, as well as antimicrobial medications (for acute conditions). However, the study didn't provide detailed information on how the IPPs were practising their prescribing role or their views regarding it.

At the time of this empirical study, no study had been conducted in Wales to investigate the role of IPPs in primary care. Limited research in other UK nations focused on exploring IPPs' services and their views regarding their role across different healthcare sectors (McCann et al. 2012a; Hill et al. 2013; Fisher et al. 2018). McCann and colleagues (2012a) conducted semi-structured interviews with IPPs (n= 11) in both primary and secondary care settings in Northern Ireland, which aimed to explore their views regarding their positions as IPs. The participants reported positive opinions regarding the independent pharmacist prescribing role, such as perceptions of improved patient outcomes, increased patient access to healthcare services and treatment, better utilisation of pharmacists' knowledge and skills, and reduced doctors' workload, particularly in GP practices. However, some negative views and challenges were reported, including their inability to manage complex conditions, lack of diagnostic skills,

and resistance to their role by some doctors, particularly older ones. The study conducted by Hill and colleagues (2013) also investigated the views of IPPs regarding their prescribing duties using semi-structured interviews. However, only five IPPs participated in the study who were providing their prescribing services at an addiction treatment facility in England. It was found that all IPPs in this study reported a high degree of satisfaction, but they believed they would be able to provide more services to patients. They also indicated that other HCPs were supportive to them and appreciated their services as IPs, which they considered an enabler to their prescribing role. In addition, they identified having access to patients' records as another enabler to practise safely. Fisher and colleagues (2018) used a mixed-methods approach that involved using qualitative methods (both focus groups and semi-structured interviews; n= 25), followed by a quantitative approach (questionnaire; n= 170 and response rate was high= 62%) to investigate the views of hospital IPPs in Scotland on the factors that supported their role. The study identified that both structural support, such as accessing patient records within hospitals, and personal aspects (e.g., confidence and experience) were essential for effective prescribing. The study highlighted that most hospital IPPs felt adequately supported. However, this study was conducted in secondary care settings, which may not highlight the same findings in terms of IPPs' views on their role in the primary care sector. The literature has also identified some of the challenges that affected the initial implementation and practice of IPPs, such as a delay in the delivery of their prescription pads, funding issues that delayed their services as prescribers, and high workload (Latter et al. 2012; Maddox et al. 2016). However, none of these studies investigated the views of IPPs who were working in primary care settings in Wales. Therefore, the findings of these studies may not reflect IPPs' opinions on this role in this UK nation, particularly with the WG plan for developing healthcare services in this sector (Welsh Government 2015). As there are no specific details on how independent prescribing is used by pharmacists in primary care in Wales, this study aimed to explore the views of IPPs on their practice as IPs working in GP practices in Wales.

5.3. Aim and Objectives

The aim of this study was to describe the role of IPPs working within GP practices in Wales and to explore their views on how they are embedded in primary care. The objectives were:

- To describe the role of IPPs within GP practices in Wales and how it has changed over time.
- To identify the IPPs' professional responsibilities and areas of prescribing.
- To investigate their satisfaction and the perceived impact related to their services.
- To explore their views of the enablers and challenges related to their role.
- To investigate feedback that they have received on their prescribing duties.

5.4. Methodology

5.4.1. Overview

As the study aimed to describe the pharmacist prescribers' role and explore their views on it, a qualitative approach was chosen. As explained in the Methodology Chapter (Chapter 3), qualitative methods, such as focus groups or interviews, were considered appropriate since they help to provide a thorough understanding of a phenomenon and allow the researcher to investigate and understand the views and perceptions of the study participants in-depth (Bowling 2014). Quantitative methods were not considered appropriate as it was unknown what concepts should be measured, as there is limited research in this area. In addition, quantitative methods, such as a survey would not investigate the participants' views and perceptions comprehensively compared to qualitative approaches (Green and Thorogood 2018). The focus group approach was considered the ideal option for conducting this study due to its advantages, which were discussed in the Methodology Chapter (Chapter 3). Not only would focus groups collect data in an efficient time and cost-effective approach (Flick 2018), but the participants can also support each other to remember certain events and feelings that can help to provide in-depth information about the discussed topic. Other options that were considered to conduct this study were interviews, as well as a combination of both focus groups and interviews. As illustrated in Chapter Three, interviews are the most common method in qualitative research that involves a comprehensive exchange of information between the researcher and the participant (Green and Thorogood 2018). Semi-structured one-to-one interviews were considered either via the telephone or face-to-face. Due to some practical issues in conducting focus groups, such as being unable or unwilling to do a focus group by some participants, some researchers combine both methods (focus groups and interviews) (Lambert and Loiselle 2008). This increases the level of engagement by allowing participants to take part in the methods most convenient and suitable to the individual (Lambert and Loiselle 2008). A limitation associated with using focus groups and interviews in a single study might be related to the complexity of combining data from both approaches due to the variation in the dynamics and forms of data yielded from each method (Lambert and Loiselle 2008). However, proper planning by the researcher in terms of using the same coding technique in both approaches would help overcome this challenge and increase the trustworthiness and rigour of the study's methods and findings (Lambert and Loiselle 2008).

5.4.2. Ethical considerations

Ethical approval was obtained from the Cardiff School of Pharmacy and Pharmaceutical Sciences Research Ethics Committee at Cardiff University (Ethics Approval Notice (EAN) ref (1819-16) (Appendix 13). The study was deemed to be a service evaluation

(as outlined in Chapter 3, Section 3.11.1), and therefore NHS REC approval was not required (HRA 2017; HRA 2019; NHS Research and Development Forum 2021). Approval from the Research and Development Office at HBs to conduct such a study was not necessarily as the interviews were not held at NHS premises or involved the use of NHS resources. Moreover, the interviews were conducted outside of the participants' working hours.

5.4.3. Sampling criteria

The study's population was those IPPs who were working in GP practices in Wales and using their prescribing qualification. The first study of this PhD (Chapter 4) identified a low number of IPPs in primary care (68 IPPs). Ideally, a census of all members of the study population (Daniel 2012) would be used and all IPPs working in GP practices in Wales would be invited to participate in the study, with the aim of recruiting between 9 and 17 participants that hopefully would be enough for saturation to be reached (Hennink and Kaiser 2022). However, as there was no definitive list available of all IPPs working in primary care in Wales, a lot of work was undertaken by the researcher to explore how to identify IPPs in GP practices. This was challenging and involved meetings and discussions with two of the experts in the field, known to the supervisors, to determine the most efficient manner to identify IPPs in primary care and distribute the study information to relevant individuals.

The first expert is a pharmacist and at the time of the study was National Primary Care Manager, and Medicines Safety Programme Lead at 1000 Lives Improvement (the national improvement service for NHS Wales) and also acted as a facilitator at the Pharmacists in Practice: All Wales Community of Practice (PIPCOP) events in Wales. The PIPCOP events aimed to provide support to clinical pharmacists (including prescribers) and pharmacy technicians, as well as to develop the roles of pharmacy primary care clusters (NHS Wales 2018). It also provided an opportunity to share experiences, ideas, and best practices, as well as create a network as a community of practice. PIPCOP meetings usually occurred every three or four months and due to logistical issues, there were separate South and North Wales events (NHS Wales 2018). This expert confirmed that there was no list available of IPPs working in primary care and there was no list of IPPs who attend the PIPCOP events on a regular basis. As such, the use of PIPCOP as a sole avenue to access all IPPs in primary care was not possible and other avenues were investigated.

The second expert was a Lead Prescribing Advisor at CTHB, and primary care pharmacist, who had been seconded to HEIW, to lead on the training of pharmacists in primary care settings. It was thought that HEIW may have a record of primary care IPPs in Wales, however, this expert stated that there did not seem to be such a list of individuals.

From the meetings with these key experts, it became evident that there was no available list or direct contact approach with IPPs. Therefore, after taking the experts' and PhD

supervisors' opinions, a number of approaches was needed to ensure that as many IPPs as possible would be invited to participate in the study. These approaches were to contact:

- all individuals (whether they were IPs or not) at the PIPCOP events to identify IPPs (through the PIPCOP facilitator),
- local primary care cluster pharmacist leads (through contacts of the supervisors),
- directors of independent pharmacist prescribing courses (through contacts of the supervisors), and
- pharmacist leads in each HB in Wales,

to ask if they would be willing to act as gatekeepers (Figure 40). Gatekeepers are the individuals within organisations who have access or the ability to contact, as well as to ensure easy and smooth sharing of the study information to the study's potential participants (Bryman 2016).

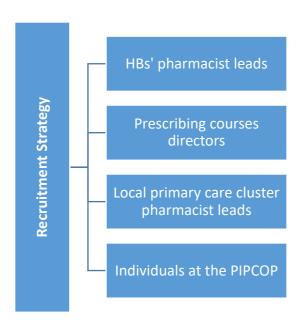


Figure 40 An overview of the gatekeepers used to recruitment participants for this study.

5.4.4. Recruitment strategy

An invitation letter (Appendix 14) was developed to recruit participants for this study. This letter included some background information, the aim of this study and information about the research team, as illustrated in the Methodology Chapter (Section 3.8.2). To try to increase the response rate for this study and to demonstrate the importance of the research, the Chief Pharmaceutical Officer for Wales (Andrew Evans) agreed to co-sign it (Appendix 14) (Kiezebrink 2009). In addition, a participant information sheet (Appendix 15) and two participant consent forms (one for a focus group and the second for a semi-structured interview to complete either one of them according to the respondent's choice of the type of

study that they would like to take participate in) (Appendix 16) were developed according to the HRA guidance (NHS Health Research Authority 2019). A demographic information sheet (Appendix 17) was also developed for the participants to complete in order to assist in organising focus groups or interviews and to maximise the homogeneity of each focus group (such as within the same HB or therapeutic area) (Krueger 1998). Every participant was offered a £25 Amazon voucher at the end of the focus group or interview as a gesture of showing respect for their time and their contribution to the study, and this information was stated in the invitation letter (Appendix 14) and participant information sheet (Appendix 15).

The demographic information sheet was available via a website link using Google Forms and included the participant's contact details, some background information about them, including the HB that they work within, and how long they had been an IP and whether they would like to participate in a focus group or interview. This sheet was developed to allow the researcher to understand how similar or diverse the different categories of participants were and to create focus groups to maximise homogeneity, which would allow participants to feel comfortable in talking and expressing their feelings (Krueger 1998).

The invitation letter was sent by the gatekeepers via email to each potential participant with the invitation letter, participant information sheet, consent forms and demographic data website link. Gatekeepers were asked to send the information to all known IPPs working in GP practices. The potential participants were asked to contact the researcher within 2 weeks and to complete, sign and send back the appropriate consent form or to bring it with them to the focus group / interview. To increase the recruitment rate, potential participants who did not respond to the invitation email after two weeks were sent a reminder email by the gatekeepers (Appendix 18).

Ideally, up to 9 to 17 IPPs would be recruited, as around this number has been shown to usually reach data saturation (Hennink and Kaiser 2022). From the data in Chapter Four, there were 68 IPPs, and therefore a strategy was developed to manage the number of respondents and choose who would be interviewed if more than a third of IPPs responded wanting to take part (a third was chosen as it was approximately 20-23 IPPs (n=20/68), which is near to the target number. This strategy would ensure the diversity of the sample size and ensure that not all participants were from only one HB. It was decided that quota sampling would be employed based on the HB that the potential participants were working within to ensure a proportional representation from each HB across Wales. Quota sampling is selecting individuals according to specific characteristics in order to fill a quota proportional to populations (Flick 2018). Table 16 illustrates the percentages of the IPPs in each HB in primary care in Wales based on the first PhD study. Therefore, quota sampling was to be applied to avoid selection bias. For instance, for each participant recruited from PTHB, 6 to 7 participants were going to be recruited from BCUHB based on percentages presented in Table 16 (1:7).

Table 16 The percentages of the IPPs in each HB in primary care in Wales

НВ	% Of the IPPs in primary care	Anticipated quota range (third of IPPs in HB)	
BCUHB	27%	6-7	
ABMUHB	19%	4-5	
CVUHB	18%	4-5	
СТМИНВ	12%	3	
HDUHB	11%	2-3	
ABUHB	10%	2-3	
PTHB	4%	1	

However, if the response to participate in the study was less than 1/3, quota sampling would not be needed, and a convenience sampling strategy would be applied to optimise the number of IPPs recruited to the study. This recruitment of participants would continue to help to reach theoretical saturation, that is until there is no new information added by the participants (Krueger 1998).

5.4.5. Data collection

Based on the limited literature on IPPs in primary care, there is no focus group/interview schedule to be used to conduct this study. Therefore, a focus group/interview schedule needed to be developed, based upon the advice provided by the researcher's supervisors, who have been involved in independent pharmacist prescribing since 2007, as well as expert opinions to ensure that relevant issues were discussed. Experts used to help develop the interview schedule were the Lead Prescribing Advisor at CTMUHB and an experienced IPP who was also a Practice Based Clinical Pharmacist at ABUHB and seconded to HEIW since 2015. All these experts identified areas that needed to be explored in the focus group/interview schedule. The guide (appendix 19) was reviewed extensively by all experts to ensure that the right questions were asked. Examples of the experts' suggestions were to include a question about the participants' opinion regarding working in more than one GP practice, to explore the participants' views about current indemnity insurance and protection, and the support they have received. This guide included questions about the satisfaction of participants about their role, their responsibilities and area of practice, the impact, and perceived benefits of their role on other HCPs, patients, and themselves, and their views of the challenges and enablers related to their role as prescribers. The final draft interview schedule was piloted with an INP with experience in GP practices, before starting the study to

ensure that the participants understood the questions and for the researcher to gain experience of interviewing. The guide was clear and well understood, therefore no changes were made to it. As it was piloted on a nurse, this interview was not included in the analysis

Data were collected between July 2019 and October 2019. Participants identified if they wanted an interview (30-45 minutes) or attend a focus group (60-90 minutes). The latter was proposed to be held at one of the PIPCOP events where a number of IPPs meet. The other option was to arrange a focus group at a meeting area or a conference room in a HB or a hotel, in North Wales, South West Wales, and South East Wales, depending on the number of potential participants and their location. Semi-structured interviews were conducted via the telephone or face-to-face. The focus groups and semi-structured interviews were audio-recorded, transcribed ad verbatim via a university approved transcription service. Each transcript was de-identified, so all identifiable information was removed, and each participant was allocated a participant code in chronological order (e.g., IPP1).

5.4.6. Data analysis

Based on the advantages of the thematic analysis method that were illustrated in the Methodology Chapter (Chapter 3, Section 3.10), both approaches, including deductive (to identify key information related to the objectives of the study or covered within the interview schedule) and inductive (potential new knowledge emerging from the data), were used to identify themes within the data (Braun and Clarke 2006). The six steps of the thematic analysis process; including data familiarisation, generating initial codes, searching for themes, reviewing themes, defining and naming themes, and producing the report; were demonstrated in detail in Chapter Three (Section 3.10). To ensure the trustworthiness of the data, as indicated in Chapter Three (Section 3.7.2), the researcher gained familiarity with the investigated topic by extensively engaging with the relevant key experts in the field (see Sections 5.4.3 and 5.4.5) and research supervisors, as well as conducting a pilot interview. This was prior to commencing the data collection in order to understand the topic, minimise biases and maintain the credibility of the questions asked (Bryman 2016).

5.5. Results

Although face to face focus groups were deemed to be the most suitable qualitative method to collect data for this study, only three respondents agreed to participate in a focus group. Unfortunately, as they were from different HBs and living far from each other, it was not practical to hold one. Therefore, all data were collected by using semi-structured interviews. A total of 12 IPPs participated in the study; all interviews were undertaken by telephone at the request of the participants due to geographical spread or in accordance with their personal desires. The length of the interviews ranged from 23 to 78 minutes, with an average length of 46 minutes. Interviews were conducted between the 12th of July 2019 and the 21st of October 2019. Saturation was achieved as no new information was added by the last two participants.

5.5.1. Demographic data

Participants' demographic data are presented in Table 17. There were seven females and five males, and their ages ranged from 30 to 46 years. IPPs from six out of the seven HBs in Wales participated. Nine of the participants were employed by HBs and three by GP practices. The years of experience as an IPP in primary care ranged from one year to 13 years. Four participants used to work as IPPs in secondary care settings (hospitals) before they moved to GP practices.

Table 17 Demographic data of the participants

IPP	Main clinical area of practice	Employed by	НВ	Year(s) of experience as a pharmacist	Year(s) of experience as an IPP	Year(s) of experience as an IPP in primary care	Duration of the interviews (minutes)
1	Sleep management	НВ	HB 1	18	3.5	3.5	78
2	Anticoagulation	GP practice	HB 4	10	2	2	39
3	Respiratory	НВ	HB 3	14	8	2	40
4	Type 2 diabetes	GP practice	HB 2	8	2	2	40
5	Type 2 diabetes	НВ	HB 4	17	3	2	44
6	Respiratory	НВ	HB 5	7	4	4	47
7	Hypertension	НВ	HB 1	15	1	1	54
8	Stroke prevention in atrial fibrillation	НВ	HB 2	12	2	2	35
9	Hypertension and diabetes	НВ	HB 1	16	8	1	33
10	Asthma	НВ	HB 6	4.5	1.5	1.5	45
11	Hypertension, hyperlipidaemia, and type 2 diabetes	НВ	HB 1	15	10	5	48
12	Polypharmacy, coronary heart disease, and substance misuse	GP practice	HB 4	23	13	13	52

NB. Each HB name was coded with a number to protect the participants by de-identifying their personal information.

5.5.2. Themes

Three main themes were identified from the data by deductive analysis (Figure 41). All themes have sub-themes, which are presented below in more detail. These sub-themes were identified via the use of deductive thematic analysis, except for the confidence of IPPs and awareness and acceptance of the role sub-themes that were identified using an inductive approach. A colour-coded example of an extract from an interview transcript is presented in Appendix 20 to illustrate the thematic analysis approach. In addition, examples of how quotes were coded, and final sub-themes and themes identified are presented in Appendix 21.

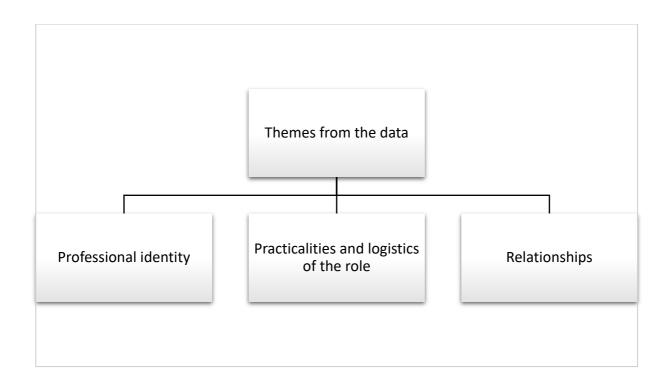


Figure 41 Themes of GP practice IPPs' interviews.

5.5.2.1. Professional identity

This theme has six sub-themes that are related to the professional identity of IPPs, which are presented in Figure 42.

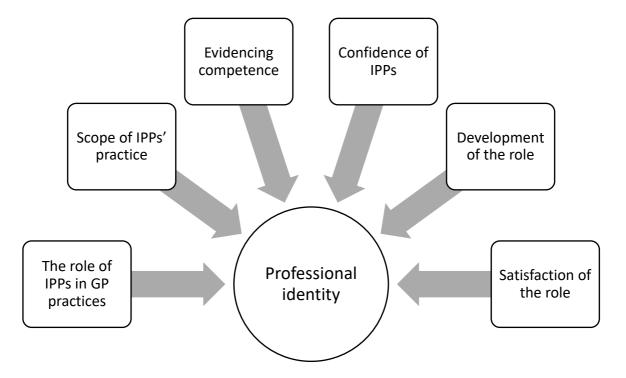


Figure 42 Sub-themes within the professional identity theme.

5.5.2.1.1. The role of IPPs in GP practices

The role of participants as IPPs and their responsibilities included running clinics, dealing with clinical posts, reviewing all the prescribing processes, and doing some clinical administrative roles within GP practices.

In terms of the clinic role, all participants reported that they ran clinics only within specific therapeutic areas (mainly chronic conditions). Most participants indicated that GPs usually see patients first to make the diagnosis for their conditions and may initiate new medications. Thereafter, IPPs follow up these patients regularly by managing their medical conditions and current medications, starting them on new medications, and providing them with self-care advice. Only one participant was seeing newly presented patients and diagnosed them with chronic conditions within their scope of practice of hypertension and hyperlipidaemia.

The IPPs' role within these clinics involved an annual review of patients' medications. It included reauthorising the prescribing of medications, changing medications or doses, or deprescribing medicines when necessary, depending on the patient's condition. The latter involved either discontinuing unnecessary medications or decreasing doses, particularly for pain management, multiple comorbidities, and substance misuse.

'...to help patients on long term hypnotics and anxiolytics, to help reduce them down and stop' IPP1.

All participants stated that they ran their clinics face-to-face, but some of the annual reviews of patients' medications were conducted via telephone. Most participants reported that they were using certain clinical assessment skills during their consultation time with their patients depending on their scope of practice; examples included blood pressure monitoring, auscultation of lungs and heart, or reviewing and requesting certain patient blood tests. However, a few participants believed that independent prescribing courses across different universities were not providing pharmacists with adequate and standardised clinical assessment skills, which initially prevented them from practising their prescribing role.

Another role, as identified by many participants, was dealing with clinical posts, which included letters from hospitals with recommendations for the patient's prescriptions, acute medication requests by other clinicians, and hospital discharge letters, as well as responding to medication enquiries raised by patients or other HCPs. They identified that this role helped to improve patient safety by preventing any medication discrepancies, such as duplications or interactions that could harm the patients. This was mainly related to hospital discharge letters, which they reviewed alongside the patient's current prescribed medications within the GP system. Some IPPs were also issuing prescriptions according to other clinicians' advice or

request to help take some of the GP's workload off them.

'I do use my prescribing qualification every day in issuing lots of other medications ... We'll get a letter into the GP practice from urology, saying ... on Cilocin [Ciprofloxacin], so I'll ... issue a prescription for that ... as long as I'm happy with doing that ... so, I've not made the decision to assess the patient ... but I'm facilitating a prescription, so helping out with the GP's workload ... I'm issuing on the advice of the urologist' IPP3

Some participants were involved in reviewing all the prescribing processes within GP practices. This involved feeding back to HCPs on issues related to their prescribing of medications, which they believed helped in maintaining safety and solving prescribing issues that GPs may lack the time to do so. It also included reviewing repeat prescribing, for example, one participant helped in introducing a new repeat prescribing system, which helped to improve the practice's process and ultimately patients' safety.

'I've done a lot of work with implementing a new repeat prescribing system, so improving patient safety and making it a more efficient repeat prescribing system ... where all the patients that come to see me have been screened by myself beforehand.' IPP4

Clinical administrative roles were also identified by a few participants, which included medicine management, prescribing advisory within the HB, and medicines safety duties. For example, the medicine management role involved discussing and supporting patients with their medications, and the prescribing of other HCPs by providing advice and teaching sessions to them.

5.5.2.1.2. Scope of IPPs' practice

Most participants explained that the original scope of practice when completing their independent prescribing programme was often chosen by the HB or GP practice based upon the needs of the organisation. This would either be an area with a high number of patients (e.g., atrial fibrillation) or an area where no-one was leading on it. For example, one participant explained their HB chose their scope of practice to be within pain management and medication misuse due to the lack of an expert within this field.

'The reason why ... the deprescribing of hypnotics to begin with was because this was a national prescribing indicator set by the All Wales... and it was an area where most practices have failed to achieve to reduce the number of hypnotics and anxiolytics prescribed.' IPP1

Likewise when developing their scope of practice, once qualified, that tended to be in areas which were causing 'pressure' on the GP practice or cluster. Whether their original or extended scope of practice, most were related to chronic conditions; examples include type 2 diabetes, hypertension, thyroid conditions, lipid management, asthma, chronic obstructive pulmonary disease, pain management, and atrial fibrillation. In order for the IPP role to be beneficial and effective, participants also believed that their scope of practice should depend on GP practice needs. However, this meant for those IPPs in a cluster role, that they could have a different scope of practice in different GP practices, as each GP practice had different needs. For example, some participants were running acute minor condition clinics in one GP practice, and an anticoagulation clinic in another GP practice. They highlighted the variety of clinics that those IPPs were running compared to IPPs employed by GP practices who mainly focused on just one area.

'I also then run clinics which are around minor illness, so on-the-day complaints, and that could be anything from sore throats to urinary tract infections.' IPP6

While the scope of practice of most participants was related to chronic conditions, many reported inappropriate referral of patients with acute conditions to them, particularly by receptionists. They stressed that there was a need to educate other HCPs and receptionists to understand the scope of what IPPs can prescribe and their capabilities. They felt frustrated to be unable to prescribe for acute conditions and help those patients, but they believed it was important to keep working within their scope and competence to maintain patient safety. A few participants were only prescribing for simple newly presented acute conditions within their scope or from their previous background experiences in community pharmacy, such as uncomplicated urinary tract infections (UTIs). Some participants stressed the need to do more training for other minor illnesses, such as upper respiratory tract infections, and otitis media as it would be beneficial for many practices that they work in.

Some participants felt their scope of practice was restrictive and they had the capability to prescribe other things, based upon their previous experience, such as in a community pharmacy or hospital. They felt this was a barrier to using their independent prescribing qualification, and believed this would change over time as the role of the IPP in a GP practice was in its infancy.

5.5.2.1.3. Evidencing competence

Some participants identified the independent prescribing qualification certificate as the most important evidence of their competence. Most participants added that they also documented the role-playing and shadowing of their DSMPs and other experienced

colleagues, in addition to when they were being observed themselves.

All the participants stated that they were keeping evidence of their progression and any developments related to their scope of practice by regularly updating a portfolio of their CPD learning, courses, and training to document the newly gained clinical knowledge and patient assessment skills. Examples provided included learning through reading articles in journals (e.g., The Pharmaceutical Journal), reading and documenting The Medicines and Healthcare products Regulatory Agency (MHRA) warnings and various guidelines, documenting completed courses and tutorials, and reflections.

'... I think obviously reflection and I think the GPhC requirements for revalidation now are all as pertinent to independent prescribing as they are to, to any other area of practice. I think you need to reflect and CPD is really important.' IPP8

After qualifying as an IPP, a few participants indicated that they also obtained and evidenced post-graduate diplomas either in their scope of practice or more broadly involving many therapeutic areas that they may come across during their IPPs' role. These courses were thorough, and participants believed having a postgraduate degree within their scope of practice allowed them to be experts in the field.

'The therapeutic diploma from [University Name] expanded my scope of practice a lot. It was very intensive, very detailed and covered all sorts of areas that I hadn't really worked in before.' IPP12

Participants believed that the range of activities outlined above helped to ensure they practised safely within their scope of practice and that they had the required knowledge and skills before they started their independent prescribing role or practising in a new/extended scope of practice. Some participants indicated that they developed a portfolio that includes their evidence of competence, such as certificates of completing courses or shadowing hours by their DSMPs, and asked their GP leads to sign them since it was not reviewed by an external body. They highlighted that there was no formal process, guideline, or standard practice about how IPPs should document their CPD or provide evidence of their competence. This was a barrier to their role as it was also not clear to them how to develop their scope of practice in new areas as they lacked the required details to ensure IPPs' competence.

'It would be nice to have like ways of recording in a portfolio and signing stuff off more efficiently. So, make that standard across the board so ... if you want to do hypertension management, here's the rest of the criteria that you need to meet. IPP4

5.5.2.1.4. Confidence of IPPs

The majority of participants indicated their high confidence in their prescribing role and only a few highlighted that they are lacking confidence. There were some aspects that had an impact on their confidence. One aspect was related to the independent prescribing course, which some participants believed had helped in building their confidence before they started their prescribing role. They indicated that the course was comprehensive and involved DSMP's clinical supervision and support, and many clinical scenarios that helped them to be prepared for their prescribing role. Previous patient-facing roles for some participants were another factor that provided them with confidence. These participants were either working as pharmacists in community pharmacies or already as IPPs in secondary care settings before moving to GP practices.

'I was already qualified when I came into this role, so it made it a bit easier for me. I was already a qualified prescriber.' IPP3

Getting more experience with this role also assisted most participants in building their confidence to do more clinical duties. Likewise, CPD and increasing knowledge through relevant courses and training sessions also assisted. Many participants believed that the support of other HCPs, such as GP Leads, GPs, or their DSMPs, helped improve their confidence to do their independent prescribing role, particularly at the beginning.

'I've always had the support of my colleagues, so being able to have a review regarding patients, just while you become more confident.' IPP4

A few individuals reported a lack of confidence to do the role due to various reasons, including being more concerned with patients' safety, the lack of appropriate skills, and the lack of other HCPs' support, which they believed were barriers to their independent prescribing role.

5.5.2.1.5. Development of the role

All participants stated that their role as an IPP had developed over time in GP practices. Most participants developed more clinical assessment skills. Also, many IPPs indicated that their working days and the number of clinics that they were running have increased over time. They started practising in a very narrow scope of practice within one therapeutic area and then expanded to other clinical conditions. Many believed that the development of their scope of practice occurred naturally as it extended to therapeutic areas that were related to their original scope of practice.

'It's been very channelled to sleep and hypnotics and then developing an interest in pain. And then with the pain ... I've expanded my formulary to include the management of depression and anxiety, which co-exist with the pain problems.' IPP1

Participants employed by GP practices tended to develop their scope of practice from a personal perspective. They identified their lack of knowledge and skills in areas where patients presented with complex medical conditions and multiple comorbidities. Then, they were self-motivated to develop their role within these areas and provided a clear development plan to their employers to get their approval. In contrast, participants who were employed by HBs were directed to extend their scope of practice based on need. This was either to overcome the increased demand in a specific clinical area or as a result of a shortage of GPs within their HB. A few participants employed by HBs explained that due to the lack of GPs, they extended their scope of practice to include acute conditions, for example, minor illness conditions, such as conjunctivitis, sore throat, and hay fever. However, one participant stressed that it was difficult to prescribe within the acute scope of practice due to inadequate training in clinical assessment skills related to these conditions. This participant added that most of the acute conditions within the GP practice were complicated and not straightforward to manage, which required a GP intervention.

Some participants believed that the development of the role was related to an increase in their number (as IPPs) over time. They highlighted that this role became more popular in recent years as it was utilised and embedded further in GP practices. Other drivers to their development were the recognition of the usefulness of IPPs' role, their capabilities to do the role, their high quality of care, and public and stakeholder understanding and acceptance. They believed that this improved the reputation of the IPPs compared to their previous pharmacist role, which mainly incorporated dispensing.

Some participants compared the IPPs' roles within hospital and primary care. They commented that in hospitals IPPs usually only prescribe within a very specific scope of practice. In contrast, within GP practices there was the opportunity to develop competence in many therapeutic areas, allowing them to use their independent prescribing skills more effectively and frequently, and be more recognised by the public, other HCPs, and relevant stakeholders.

'I think it [primary care] is just given us a better platform to be able to use the prescribing skills better ... which ... I think will make independent prescribers a bit more, a bit more prominent' IPP8.

Some challenges that were related to the development of the participants' independent

prescribing role within GP practices were highlighted. The unavailability of appropriate courses and training and the lack of their HBs and GP practices guidance in finding them was a barrier to developing the clinical assessment skills and knowledge of some participants. The process of expanding the scope of practice was long and complicated as it involved obtaining approval from various channels. A plan or set of guidance to support and direct them on how to expand their scope of practice was also lacking. The lack of time due to the high workload of some participants also prevented them from developing their scope of practice as they were involved in prescribing duties alongside their other non-prescribing responsibilities, such as repeat prescribing.

5.5.2.1.6. Satisfaction of the role

The positive impact of the role on patients, other HCPs, and themselves as IPPs played an important role in their satisfaction. In terms of the impact on patients, many participants were highly satisfied due to patients' positive impressions when their medical conditions improved, which they felt was rewarding as this role helped them to make a difference. They believed that the role helped them to build a good relationship with patients and patients were happy to see them again. The role also provided a positive impact on other HCPs, particularly GPs, by relieving pressures on them and being a part of the clinical primary care team. Therefore, they felt satisfied as they believed their role was important within the GP practice team

'I enjoy it because there's health benefit to the people, I work with ... I can see it benefits people in terms of, you know, ... reducing their risks and the risks they have by what we're prescribing.' IPP12

Concerning the impact of the role on themselves as IPPs, all participants stated that they were satisfied as it involved a more patient-facing focus and clinical responsibilities, compared to their previous role. In addition, it allowed them to prescribe autonomously, which highly increased their job satisfaction. The role also increased their job satisfaction by providing them with a great opportunity to effectively use and develop their clinical skills and knowledge, with additional remuneration. They indicated that this allowed them to fit easily within the team and develop good relationships with other HCPs. Some participants also highlighted that the IPPs' role helped in developing the actual pharmacy profession by improving its image within the healthcare system. Most participants were satisfied with the role since it was related to managing chronic conditions, which involved a lot of medications that IPPs had more expertise in, compared to other HCPs.

Some participants expressed their dissatisfaction with some aspects of their independent prescribing role. A few participants were dissatisfied with the low number of

independent prescribing sessions allocated by their HBs, which were only two sessions per week (each session for a half day). One participant believed that HBs reduced their independent prescribing sessions as they did not value the IPPs' role or see it as being cost effective compared to the services provided by IPPs.

'I don't see perhaps ... there being more sessions that the IPs are providing on a weekly basis because of the funding route of them. ... the IP is probably helping the practice, but the health board is paying for the pharmacist ... it's a business decision, I guess, from the health board, is that a good use of money or not?' IPP1

Another issue that some participants were dissatisfied with was related to the high workload. They stressed that their role involved clinical responsibilities that were time-consuming, alongside their other duties (e.g., handling repeat prescribing, dispensing, or some administrative responsibilities), which increased pressure on them. A few participants believed that their GP practices were not appreciating their prescribing role by having them carry out these other responsibilities that could have been handled better by admin staff or technicians. A few added that their independent prescribing role was not valued fairly as the remuneration that they received was not appropriate for the services and benefits that they provide to patients and practices.

5.5.2.2. Practicalities and logistics of the role

This theme is divided into four sub-themes that are related to the practicalities and logistics associated with their role as IPPs. These sub-themes are presented in Figure 43.

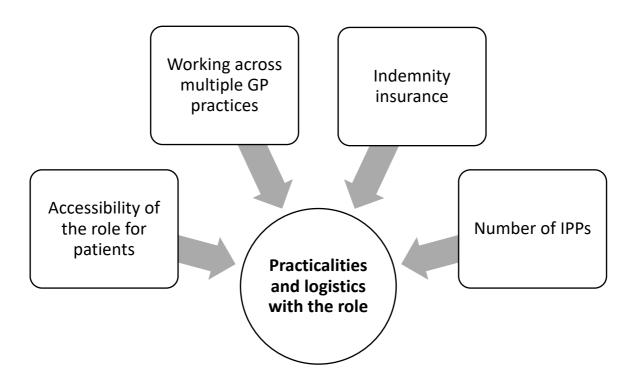


Figure 43 Sub-themes within the practicalities and logistics with the role theme

5.5.2.2.1. Accessibility of the role for patients

The booking system for patients to see their IPPs varied between participants and GP practices, which depended on their scope of practice and GP practice process. Some participants tended to choose their patients through their GP practices' system. Those participants stated that they usually went through the repeat prescribing list, identified relevant patients for their scope of practice, and saw whether they were due for a medication review or needed medication changes or adjustments. Then, they either autonomously or through the approval of GP leads arranged with the receptionists to make appointments for those patients. Those participants added that their ability to choose their patients helped them to utilise their time effectively since they prioritised according to the needs of their patients. However, some acknowledged that identifying relevant patients through this approach can be time-consuming and that pharmacy technicians may be appropriate to undertake such searches in the future. Patients are also occasionally referred to them by doctors, nurses, or receptionists. In contrast, some other participants indicated that they were only seeing patients referred by doctors or nurses since they understood their role and had a good work relationship with them.

In addition to what was presented earlier (Section 5.1.2.1.2), the referral of patients through receptionists or GPs initially resulted in inappropriate patient appointments. It took

these professionals a long time to understand the nature of patients to be seen by IPPs. Some participants added that they had to ask receptionists to obtain their approval before confirming the appointments with patients.

'... reception staff will ask me first before booking them in, so they're not just sort of getting booked in with me unless I've asked them too really.' IPP2

Some GP practices wrote letters to their patients who required medical review to book in with their GPs or IPPs. Participants explained that the majority of patients preferred to see their GPs instead of IPPs as they usually did not understand the IPP role or had many medical issues.

'I don't tend to get many patients booking in with me because ... if they're given a choice, they'd rather see their own GP because perhaps they can kill two birds with one stone and see their GP about something else ... and they're not really too sure what a pharmacists can do.' IPP3

Most participants identified that they were only seeing a small number of patients per day due to their other responsibilities. They indicated that the low number of patients allowed them to provide appropriate consultations and prescribe safely. They stressed that they would prefer to see more patients and could do this only if these other responsibilities were reduced or not included within their workloads.

'I've got too much work. Whether I should either have fewer appointments or fewer administrative tasks, I don't really feel strong which way round that should be ... there's too much for me to do in one day.' IPP12

The duration of appointments was also highlighted by participants. While most were providing long appointment times with an average of 20 minutes, some participants identified that it depended on their scope of practice, which varied across GP practices. For example, it was longer for some patients with complex conditions (almost 30 minutes), around 20 minutes for most patients with certain conditions (e.g., anticoagulants clinics), and shorter for medication review appointments (almost 15 minutes). They believed they provided enough time to do a comprehensive review, build relationships with patients, and allow patients to ask questions related to their medications and medical conditions. In contrast, a few participants were only providing 10-minute appointments as the volume of patients they were seeing, the workload associated with it, and their other responsibilities, were high. They believed the duration of these appointments was not enough as some patients had a lot of medications and needed at least 20 minutes, which they highlighted as a barrier to their role.

Another barrier to the independent prescribing role that was identified by a few

participants was the lack of an appropriate consultation room in the GP practice. They stressed that this has prevented patients from accessing their prescribing services as all consultation rooms were occupied by GPs; they believed this was out of the GP practice's control.

5.5.2.2.2. Working across multiple GP practices

Most participants were employed by HBs as cluster IPPs and performed their independent prescribing role in more than one GP practice. The number of GP practices they were working for varied between two and seven. Their working time in each GP practice also varied as some of them worked a full day every week in each GP practice, while others worked half a day in each GP practice. This seemed to be dependent upon the number of GP practices they covered, as their working time decreased in each practice as the number of practices increased. A few participants were employed by both the HB and a GP practice within the same HB. Some of those participants worked two days for their GP practice and three days for their HB to cover three other GP practices. One participant worked only one day for the GP practice and four days for the HB, covering six other GP practices. This was either on a weekly or every two week basis. Only three participants were employed solely by GP practices. These participants were performing their independent prescribing role on a daily basis. Two of them worked full days and one participant worked half days.

Some participants indicated that working across multi-GP practices provided them with variety. It allowed them to learn from different HCPs and be exposed to different kinds of practices, improve their relationships, and share different experiences and knowledge. They believed that their role helped to provide a positive influence across different GP practices on the prescribing by GPs and INPs. It also helped in providing services to as many patients as possible as they were not limited to only one practice. In contrast, some participants indicated a lack of time and continuity of practice when working within more than one, which were challenges to their independent prescribing role. They identified that GP practices were different in terms of their processes, such as the booking system, and logistical IT issues that required more time to understand. Continuity of practice was a major issue for them as their patients, if they had any enquiries regarding their conditions or needed a follow-up, were not able to find them easily after their appointments. It also had an impact on the scope of practice of IPPs as one participant highlighted the inability to develop it to include insulin prescribing for diabetic patients as it required regular monitoring.

'... the patient may not be able to see me the next day or the day after, because I'm only there maybe once a week or once a fortnight' IPP6.

Although some participants believed that working as IPs across multi-GP practices provided them with good relationships with other HCPs, a few participants highlighted the

difficulty in building relationships with other professionals in each GP practice as a barrier. They added that they were not able to keep regular contact with them due to being there for only a day or less per week.

'I guess the relationships aren't as good as they could be if I was just based in one practice every day.' IPP3.

5.5.2.2.3. Indemnity insurance

One of the major barriers identified by most participants was indemnity insurance for their IPP practice. A few participants identified the difficulty in sorting out their indemnity insurance at the beginning of their role as a barrier. In addition, a lack of clarity about indemnity and what IPPs were allowed to prescribe was another barrier to most participants. This was despite the fact that all participants had been told by their employers (HBs or GP practices) that they were fully insured, provided they were prescribing within their scope of practice. However, most participants indicated that they would like to have more information and clarification about their indemnity insurance to prescribe effectively. Some indicated that due to the lack of clarity with their indemnity insurance, particularly with the development of their scope of practice over time and its variation across different GP practices, their prescribing rate decreased. They felt frustrated and cautious since they were worried about prescribing for conditions out of their original scope of practice although they felt confident to do so, particularly for patients with multiple comorbidities. As a result, they asked GPs to prescribe for such conditions.

'I'm more likely to prescribe less cos I'm worried about whether or not I'm indemnified to do it.' IPP2.

A few participants divulged that although indemnity insurance changed in 2018 to be through the Welsh Risk Pool, it was still not clear due to the lack of information. Therefore, most participants were paying for their own indemnity insurance to ensure more protection for their IPP practice and avoid issues and conflicts with HBs and GP practices.

'I'm paying a lot of money at the moment as, as extra indemnity.' IPP3.

5.5.2.2.4. Number of IPPs

Although the number of IPPs was increasing over time, most participants indicated that there were still insufficient numbers within the GP practice. They added that there was only one IPP in a GP practice or none. In addition, IPPs usually work in multiple GP practices within different therapeutic areas as their number was inadequate. This has increased the pressure

on them, which they believed was a barrier. In contrast, a few participants believed that the current number of IPPs was reasonable within a GP cluster as they had different scopes of practice and met regularly to discuss clinical conditions.

To avoid being isolated, most participants highlighted the need for more IPPs to directly support each other and develop their role, particularly for IPPs who were working in one GP practice. A few indicated that recruiting more IPPs depended on GP practices as some were willing to train more and others were not.

'I think it's different everywhere I work at the moment, because ... some surgeries seem to have grasped the opportunity and are trying to get as many paths as they can, and then others ... are a little bit slower to take up the opportunity.' IPP5

5.5.2.3. Relationships

This theme has five sub-themes that were related to the relationships of IPPs within their role, as presented in Figure 44.

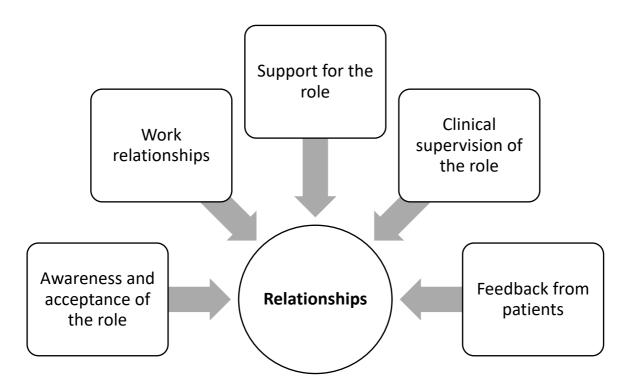


Figure 44 Sub-themes within the relationships of IPPs' theme.

5.5.2.3.1. Awareness and acceptance of the role

The lack of independent prescribing role awareness by patients and other HCPs was highlighted by many participants regardless of being either employed by HBs or GP practices. There was a lack of clarity of the role as some participants identified scepticism from GPs, patients, and others about their impact, capabilities, and types of services that they could provide. For example, some IPPs were asked by other HCPs or patients to provide prescriptions for medical conditions that were out of their scope of practice, as they thought IPPs were capable of doing that. Another example was related to patient's perception, whereby they believed IPPs were 'chemists' who would only discuss their medications. They added that this usually occurred when receptionists call patients to make an appointment with them without explaining their role and the reason for seeing an IPP beforehand. The participants felt uncomfortable about these issues, particularly when they started their independent prescribing role. Some participants were also dissatisfied with the lack of national guidance or a clear job description on how IPPs' should be working. They believed that such guidance could help IPPs and others to understand their role. However, they believed this has changed over time due to the positive impact they have had on their patients. They stressed the importance of increasing the public, patients, and other HCPs' understanding and awareness of the role by advertising it. This would also allow patients to consider them as a useful option to seek advice regarding their health issues, instead of going to their GPs. Only one participant identified that the independent prescribing role was advertised as posters were displayed within the GP practice.

'We have got in the surgery posters on display who I am, what my role is, and they are told before they book with me as well that I'm a pharmacist.' IPP10

While most participants indicated that their independent prescribing role was generally accepted, a few felt that some GPs did not initially accept their role as they were not open to having them in their practice. They believed this might be related to their lack of understanding. As a result, they highlighted the need to promote their independent prescribing role by WG to increase HCPs and public acceptability.

5.5.2.3.2. Work relationships

The participants highlighted their work relationships with other HCPs and patients. They had a lot of contact with GPs, nurses, other HCPs, and patients, which most believed resulted in building good relationships with them. This relationship developed over time by getting more experience as an IPP. They added that good relationships with other IPs,

including GPs, helped to facilitate patients' referral to them and vice versa. They also felt respected and important within the multidisciplinary team, which fostered a team ethic and improved patients' access to efficient and safe services. They felt that having different professionals within the team who have different skill sets helped to encourage learning from each other and sharing experiences. In contrast, a few participants indicated that it was challenging to build relationships with other HCPs at the beginning of their role due to the lack of recognition, which has changed as they provided their independent prescribing services. In addition, some participants who were employed by their HBs to work in a GP cluster believed that their relationships with other HCPs were still limited since they were working in many GP practices, which they identified as a barrier.

Many participants believed that the benefits of their role to other HCPs contributed to having a good relationship with them. They indicated that the role helped other HCPs, particularly GPs, to markedly decrease their workloads by sharing some of their duties, such as running clinics, medication reviews, and managing hospital discharge letters. This helped GPs by relieving some pressure on them, allowing them more time to deal with their other duties, and freeing up more appointments for complex medical conditions. Some participants also indicated that they were responding to GPs and other HCPs' enquiries about patients or their medications, such as drug interactions, which GPs usually had no experience with. They were also responding to medication enquires raised by HCPs from hospitals as they were a point of contact between primary care (GP practices) and secondary care settings (hospitals). They added that other HCPs' feedback on their role was highly positive since IPPs helped them within areas that they felt inexperienced and IPPs were experts within their scope of practice. This allowed them to see many complicated conditions within their scope of practice, which led to an appreciation of their role, particularly by GPs as they felt IPPs complemented them. They believed that this reduced referral of patients to hospitals that GPs were unable to manage as they referred those patients to IPPs within their scope of practice.

"They now don't send that patient to secondary care ... they now refer the patient to myself for diagnosis and assessment.' IPP6

The feedback of other HCPs to the participants was obtained ad hoc and not gathered in a formal manner. Most participants stressed that feedback should be gathered in a more formal way in order to identify any areas for improvement. Only one participant identified that there was formal feedback by the GP practice team that was conducted through online questionnaires, which was highly positive.

'As a team, where I work, we've sent out a smart survey to all the GP practices who have a pharmacist working there prescribing and the feedback we've had from them has been very positive with them expressing

that the pharmacist has meant that they can ... some GP capacity because of the pharmacist being able to see a patient instead of them. And they also value their knowledge that the pharmacists have.' IPP11

5.5.2.3.3. Support for the role

The participants' views regarding the support of their independent prescribing role from different parties were described in the interviews. Many participants indicated that the support from HBs involved their commitment to fund their independent prescribing sessions per week. Support of HBs or GP practices by allowing most participants to choose their main scope of practice was another facilitator that encouraged them to obtain the independent prescribing qualification. As identified by most participants, the support of HBs and GP practices was also evident whilst undertaking the independent prescribing course and further training to develop their skills during the working week. However, a few participants highlighted that HBs allowed many of their employed pharmacists to undertake these courses and training, compared to pharmacists who were employed by GP practices who were less supportive as there was no replacement for them to backfill their duties during their training. Nevertheless, a participant who was employed by a teaching GP practice emphasised they received high support:

'... when I first went into the role, it was just type 2 diabetes that I did ... So, cos my practice is a teaching practice, I've had a lot of support in terms of tutorials, and I've been given time to go on courses, role play and stuff like that to expand in- so the latest one I did was mental health, so anxiety and depression. So, I've had numerous tutorials and time spent on that.' IPP4

Support from other HCPs, including their DSMPs, GP leads, GPs, and nurses, was also identified by most participants, which they believed facilitated their role. Their support involved providing IPPs with advice and responses to their enquiries regarding their patients' conditions, particularly by DSMPs during the same clinic time either via the telephone or by going to their offices. Some identified that their GP leads supported their transition from other sectors to GP practices.

'I think almost like a buddy system to start off with is if you get paired up with a GP lead ... that you can go and ask any questions. I think that would make the transition into GP surgery as an IP much more smooth.' IPP5

In contrast, a few participants expressed a lack of support by other HCPs as they felt 'self-reliant', particularly at the beginning of the role. They indicated that might be related to the lack of time as other HCPs were very busy with their responsibilities. In addition, most participants lacked communication with other IPPs either within the same HB or other HBs

due to their low numbers and lack of time, therefore, they lacked the support of each other. Some believed that this could lead to feeling isolated and vulnerable, which they felt was a barrier.

5.5.2.3.4. Clinical supervision of the role

The clinical supervision of IPPs was mainly related to the participants' mentoring by DSMPs. Although most participants indicated that they easily found DSMPs to train them, a few reported that it was difficult to find a DSMP.

'I know there's lots of, of colleagues ... would like to do the course, but it's providing the tutor, somebody to tutor them.' IPP3

Most participants highlighted that they had a positive experience with DSMPs during their independent prescribing training. DSMPs also allowed IPPs to shadow them, and they also shadowed IPPs to ensure their competence in the role. Some participants added that they still had regular meetings with them after they became IPPs to maintain their competence, particularly at the beginning of their role, and to develop their scope of practice. They believed this provided them with the required clinical supervision and ongoing guidance.

Many participants identified the need for formal and structured clinical supervision on a regular basis to ensure accountability, revalidation, and appraisal, such as GPs and other HCPs. Only one participant who was working in a teaching GP practice had yearly appraisals, as well as being audited monthly to monitor their prescribing practice. A few participants also stated that they regularly audit themselves by collecting consultations in which there were prescribing issues and reflecting on it, as this was a requirement of their employers (HBs) to improve their patient care.

'There's actually no formal clinical supervision ... for us as independent prescribers. It's quite vague.' IPP11

5.5.2.3.5. Feedback from patients

All participants stated that their patients reported very positive feedback and were highly satisfied with their role due to the many benefits offered to them. For example, it provided quicker and easier access to treatment, as IPPs were more flexible compared to GPs, and longer appointments to discuss their conditions and medications in detail. In addition, patients felt more aware of their conditions and medications, as they had more time to ask questions, and were involved more in making decisions about their management plan. This led to positive changes in their patient's conditions and improved safety and quality of care. It also helped in building a good relationship with patients who sought their advice again.

"...they tend to just come and see me about that problem because we've still got a good rapport and relationship with them...". IPP4

The feedback provided by patients was obtained informally as it was provided verbally to most IPPs after consultations. Only a few participants collected patient feedback through questionnaires. Therefore, all participants believed that the current patients' feedback was not enough and there was a need to obtain more feedback to help in developing the role. This was to understand their patients' exact opinions, which could provide constructive feedback.

'Yeah, all the feedback I've had has been good, but I suppose they wouldn't necessarily feed it if it was bad to me ... because if they thought I was rubbish, they probably wouldn't say, but if you gave them a questionnaire, then they would.' IPP3

5.5.3. Summary of the findings

The summary of the findings of the three themes is as follows:

- The participants' IPP role was mainly related to chronic conditions within therapeutic areas of high demand in primary care and a few of them extended their scope of practice to include minor acute conditions.
- The IPPs' role has developed over time with having more experience and support from their HBs and GP practices. This support helped to increase their confidence and expanded their main scope of practice to relevant clinical areas.
- All participants were satisfied with their IPP role as they recognised the positive impact of their role and its benefits to patients, other HCPs, as well as for themselves.
- However, there were some challenges related to the IPPs' role that many participants highlighted, which were as follows:
 - There was a lack of a national guideline, plan, or framework to guide IPPs when they start their prescribing role. In addition, the process of expanding their scope of practice was long, difficult, and lacked guidance in finding courses and training.
 - High workload due to independent prescribing responsibility and other timeconsuming duties.
 - There was a lack of continuity and work relationships when working across multi-GP practices.
 - The funding provided for the role in terms of its remuneration and development by undertaking training and courses for the role was still inadequate.
 - The indemnity insurance was not clear, which made them uncomfortable to prescribe medications, particularly in the expanded scopes of practice.

- They lacked support from other IPPs as their numbers were still low, and a few stressed the need for more support from other HCPs.
- There was a need to promote the IPPs' role to increase the public, patients, and other HCPs' understanding, awareness, and acceptance of this role.
- There was a need for more clinical supervision and guidelines for the role.

5.6. Discussion

The role of IPPs has expanded in the last two decades and they play a vital role across many settings of healthcare across England, Scotland, and Wales (GPhC 2019). IPPs practise their independent prescribing for any condition within their personal clinical competence and scope of practice. This empirical study explored the views of IPPs on their role as IPs working in GP practices in Wales. This section will discuss the findings in relation to the literature and will highlight the strengths, limitations, and recommendations of the study.

Based on the findings of this study, the roles of IPPs within GP practices in Wales are mainly related to managing patients' chronic conditions and related medications. Most run clinics to manage and monitor patients' conditions, as well as regularly review their medications. Their role also included addressing questions posed by patients and other HCPs, particularly about medications. This is consistent with the literature that highlighted the role of pharmacists in running clinics to manage patients with chronic conditions. For example, Bruhn and colleagues (2013) reviewed the role of pharmacists in managing chronic pain in primary care in England and Scotland as a pharmacist-led clinic role. The trial focused on the effectiveness of pharmacists in reviewing patients' medications by using telephone services in six GP practices. Pharmacists improved the Chronic Pain Grade (CPG), and this proved the benefits of their role to patients with chronic pain. Other studies that were conducted by Bowron and colleagues (2011), Gerard and colleagues (2012), and Hill (2014) have also shown the ability and effectiveness of IPPs in running clinics to manage patients with chronic conditions that were reported by the IPPs' who participated in these studies, such as type 2 diabetes, hypertension, rheumatology, hyperlipidaemia, pain control, and addiction management. Each study proved that IPPs have the skills and competence to provide healthcare services to their patients and improve their access to treatment, which is consistent with the aim of introducing this role in 2006 in the UK (in 2007 in Wales) (DOH 2006). Bowron and colleagues (2011) used a retrospective data analysis of the metabolic targets and weight of patients managed by only one IPP in secondary care settings in England, compared to those managed by a doctor. Gerard and colleagues (2012) and Hill's (2014) studies collected data based on the views of their participants in primary care settings in England and Scotland, respectively, which were not showing the actual effectiveness of IPPs in the management of their patient's conditions. As a result, further research should be conducted to examine the ability and effectiveness of IPPs. All of the identified studies above in the literature were conducted in the UK but not in Wales. Additionally, all of these studies were based in secondary care settings, except Gerard and colleagues' (2012) study which was conducted in GP practices. Only a few participants in this study expanded their scope of practice to include

acute medical conditions. Those participants were employed by their HBs, and it seems like these HBs were using the IPPs' services to overcome the shortage of GPs in these areas following the WG Plan (Welsh Government 2015). In the study conducted by Tonna and colleagues (2010), they identified that IPPs were being incorporated into chronic patient care alongside their acute medical conditions' scope (prescribing of antimicrobials), thereby leading to their expanding role in health care. Although this study was conducted in secondary care settings, it may indicate the capability of IPPs to also run acute condition clinics for their patients. However, it must be acknowledged that this study was published in 2010 when independent prescribing was in its infancy. IPPs may have the capability to provide a highly beneficial service in acute conditions, and this needs more focus from HBs and GP practices to encourage IPPs to develop their scope of practice. There is also a need for further research that aims to investigate the scope of IPPs' practice in primary care across all of Wales and the UK in general to understand their common therapeutic areas of prescribing within this sector.

This empirical PhD study observed the shift in the role of IPPs as experience was gained, whereby there was a natural progression from their original single therapeutic area to multiple areas of expertise, particularly chronic medical conditions, such as pain and sleep management, to managing several other conditions, such as depression. The IPPs in this study indicated that primary care settings allowed IPPs to run a wider range of clinics, which made their role highly flexible and varied when compared with IPPs' role in secondary care settings. With IPPs working in various clinics across primary care, they indicated that their skills have been put to effective use. Moreover, their scope of practice expanded significantly with their incorporation into GP practices compared to the IPPs' role in secondary care. Additionally, their role as IPPs across GP practices provided more exposure to patients and other HCPs also working in these settings, than working as IPPs in secondary care. This was consistent with the GPhC report (2016) which indicated that the extension of the scope of IPPs was influenced by the variety and difficulty of medical conditions in GP practices that encouraged IPPs to extend their scope of practice to cope with it.

The perceived feedback from other HCPs and patients on the IPPs' role was positive as stated by the participants of this study. They believed that this positive feedback was due to the benefits that their independent prescribing role provided to other HCPs, patients, and GP practices. Most participants believed that their role helped GPs to reduce their workload relating to the management of patients' conditions. There have been increased workloads on GPs owing to staff shortages (Smith 2018). As GPs were overworked, the role of IPPs was one of the solutions to overcome this issue in primary care in Wales. The findings demonstrate that IPPs have been able to develop their practice to address chronic conditions, medication reviews, and run various clinics. As a result, the pressure on GPs was believed to be reduced, which enabled them to divert their focus onto their other duties. This has been reported in the

study conducted by McCann and colleagues (2012a), which indicated that the IPPs' role allowed GPs to spend more time with complex patient cases out of the IPPs' scope of practice. Alshehri and colleagues (2023) conducted a recent study exploring the role of IPPs (n= 13) in GP practice in England using semi-structured interviews as presented in the Literature Review Chapter (Chapter 2, Section 1.2.5). Most participants in this study highlighted that their prescribing role was also highly recognised and appreciated by other HCPs, particularly GPs. Some participants from the general public in the MacLure and colleagues (2013) study in Northern Ireland, as well as GPs in the McCann and colleagues (2012a) study in Scotland, believed that IPPs were able to provide high-quality care to their patients within their clinical area of practice. Moreover, the reported perceived benefits by GPs in McCann and colleagues' (2012a) study of the role were the reduced waiting time across GP practices. Similar findings have also been reported by the participants in this PhD study.

This study also indicated that IPPs improved other HCPs' knowledge, particularly about medications, that allowed them to educate their patients. This has helped to improve working within the multidisciplinary team, as well as sharing knowledge between team members. All these benefits have been reported in the literature by Stewart and colleagues (2011), McCann and colleagues (2012b), and Hill (2014). Moreover, this study noted that their IPP role in GP practices enabled them to build a better rapport with their patients and helped to improve their patients' care. In addition, the role helped IPPs to use the skills that they already have more effectively. This is consistent with the study conducted by Courtenay and colleagues (2017), in which participants felt that their skills were put to better use and the quality of care had improved (Courtenay et al. 2017).

Other findings from this PhD study include that their role as IPPs has helped to improve the general public understanding of their role. This had a positive impact on IPPs as it helped to improve the image of the pharmacy profession and increased job satisfaction. The literature also highlighted job satisfaction and the development of the pharmacy profession as benefits of the role. Alshehri and colleagues (2023) revealed that most IPP participants were highly satisfied with this role within GP practices. Similarly, Stewart and colleagues (2019) surveyed the pharmacy workforce in Scottish GP practices (n= 393; response rate= 83%) and found that 69% of them were IPPs (almost two-thirds of them were currently prescribing). Most participants reported a high level of job satisfaction, highlighting their role in the management of chronic conditions and medication reviews. They also believed this has contributed to improving patient outcomes and alleviating GP workloads.

Additionally, there has been improved communication between primary and secondary care settings as IPPs handle medication queries and discharge letters from hospitals. This is in line with the literature since pharmacists have a vital role in preventing or reducing medication discrepancy during the transmission of care to primary care after being discharged

from hospitals (Johnson 2015). As reported in the WHO report (WHO 2019), between 25% to 80% of discharged patients from hospitals had medication discrepancies. This role that pharmacists, particularly IPPs, can provide may have a beneficial impact on reducing this discrepancy including evaluating the appropriateness of using medications for their patients, communicating with other HCPs regarding their patients' medications, and updating their patients' medical record information (Mantzourani et al. 2014; Johnson 2015). Moreover, as reported by some IPPs in this study, their role may have provided a positive cost-effective impact on their GP practices compared to other HCPs. This was because they had more knowledge of medications compared to other HCPs, which enabled them to prescribe medicines more efficiently and only when required. This finding contrasts with the results of Latter and colleagues' (2012) paper that showed the cost of prescribed medications by IPPs was rated inappropriate and considered high. However, in that study, data were collected from only nine primary and secondary healthcare settings in the UK and the exact locations of data collection were not transparent, which may make the findings ungeneralisable across the UK.

The participants in this empirical PhD study reported some enablers to their prescribing role. Initially, the availability of prescribing courses across Wales and initial funding by the HBs and WG allowed many pharmacists to undertake the role. This was followed by continued funding from their HBs and the WG, as well as support and a good relationship with GPs and DSMPs. Those participants highlighted that this continued support enabled them to expand their scope of practice. This was consistent with the findings of a national survey conducted in Wales which elaborated on numerous factors that were essential for successfully implementing and continually developing non-medical prescribing. These included organisational procedures (such as funding), visible outcome benefits, strong management, clear demarcation of roles, support of HCPs, and strategic fit between IPPs and existing service provision (Courtenay et al. 2018). As indicated in this study, the WG and HBs were providing continuous funding and support for the IPPs' role due to its visible benefits, which are considered parts of the organisational procedures that were identified in Courtenay and colleagues' study (2018). Self-motivation, previous experience, and appreciation of their prescribing services were found in this study, which allowed IPPs to be capable of managing many therapeutic areas in their role. With improved public recognition and understanding of IPPs, as reported by some participants in this study, the public may have started considering IPPs for the management of their ailments and not only GPs. This serves as positive feedback for IPPs and stakeholders as it indicates stronger potential for the future of IPPs in GP practices. Additionally, IPPs have gained recognition and positive feedback from other HCPs and patients concerning their roles in managing chronic conditions. Positive patient feedback and satisfaction served as a strong enabler to the role of IPPs, which has also been reported in the study conducted by Stewart and colleagues (2011) that obtained patients' feedback across primary care settings in the UK. IPPs who were part of the Royal Pharmaceutical Society of Great Britain invited their patients to report their views and experiences. Results indicated that patients had positive feedback and felt as safe with their pharmacists as they did with their GPs (Stewart et al. 2011). Moreover, patients were supportive of the role of IPPs, and they were satisfied with the communication, services, and appointment timings. However, the findings of this study may not represent the whole population's views since the response rate was low. The paper was also published in 2011 which is over 10 years ago, and so patient views may have changed during this time. A more recent scoping review conducted by Famiyeh and McCarthy 2017, highlighted similar findings regarding the patients' opinion of the prescribing role of pharmacists. More recent studies also highlighted the same enablers to their role (Fisher et al. 2018; Graham-Clarke et al. 2021; Graham-Clarke et al. 2022). However, with the development of this role in primary care in Wales (Welsh Government 2015), future research should focus on exploring their views and opinions on IPPs' services in this sector.

Some challenges were also reported by the participants in the study. The most reported challenges were a lack of clarity and framework in developing their scope of practice and indemnity insurance. In terms of the development of IPPs' scope of practice, some participants highlighted the lack of guidance and support from GP practice and HBs as the main issue that prevented them from expanding their role further. Those participants emphasised the need for a national guideline for the role and its development to avoid confusion related to expanding their scope of practice. However, this issue has been addressed by the recent report published by the RPS in 2022 (RPS 2022), which provided guidance to IPPs to expand their prescribing scope of practice as highlighted in detail in Chapter One (Section 1.3.4). A few participants also reported a lack of support from some GP practices for training courses throughout the work hours of pharmacist prescribers. This has also been observed by Weiss and Sutton (2009), although this study was undertaken just after the establishment of independent prescribing. The issue of indemnity insurance restricted IPPs from prescribing certain medicines although they felt competent to do that, as reported by many participants. Many of the participants in this empirical study paid for their own indemnity insurance, even though they were insured by their employers (HBs or GP practices). This was due to the lack of clarity about what they can and cannot prescribe within their workplace insurance. There is no study available in the literature that observed this issue to the IPPs' role. At the time of initial writing, the Welsh Risk Pool (which is a part of the NHS Wales Shared Service Partnership Legal and Risk services that provides all Trusts and Health Authorities to obtain indemnity against risk) was reviewing their cover for all Trusts and Health Authorities, including their employees such as IPPs in GP practices (NHS Wales Shared Services Partnership 2019), which aimed to resolve this issue. This was followed by changes

in the GMPI scheme in 2019 (NHS Wales 2019), which provided indemnity insurance to all medical staff, including IPPs, in GP practice as indicated in the Introduction Chapter (Chapter 1, Section 1.3.6).

The findings also identified some other challenges to the participants' role as IPPs. However, these challenges were only reported by a few participants. Issues of obtaining prescription pads and prescribing numbers were highlighted as initial challenges for a few participants who were employed by HBs as they worked in more than one GP practice. Additionally, a few IPPs who were employed by HBs lacked continuity of work and relationships as they were working across multi-GP practices. The literature did not identify such challenges to the role, which may indicate the need for more research to further investigate this matter. A few IPPs also indicated that some GPs and other HCPs expected them to conduct all GP's responsibilities since they were unaware of their scope of practice, which may require improving other HCPs' and patients' understanding and awareness of the role, particularly before IPPs start practising. The lack of doctors' and patients' awareness and understanding of the role was only reported in two studies in the UK (Weiss and Sutton 2009; McCann et al. 2012b) and one study in Canada (Perepelkin 2011), which may be considered outdated. Many IPPs in a recent study conducted by Alshehri and colleagues (2023) also highlighted a lack of understanding as a major challenge although their role has increased patients' access to healthcare services and enhanced their quality of care. A few IPPs expressed that some patients would still like to see a GP for a further consultation due to the lack of confidence and understanding of their role and capability. As a result, there is a need for a new study aiming to explore the public, patients, and HCPs' awareness and understanding of the role. Additionally, IPPs reported not being compensated enough for their prescribing services. The lack of appropriate remuneration for IPPs' services in GP practices was not reported in the literature, as this challenge was only identified in a few studies in secondary healthcare settings in Canada (Isenor et al. 2018; Waite et al. 2018), Australia (Vracar and Bajorek 2008), and Scotland (Tonna et al. 2014). Although the WG provided continued funding for the role over the years, as highlighted in Chapter One (Sections 1.1.4, 1.2, and 1.3.2), more financial support might be needed in order to increase the utilisation of this role in GP practices. A few IPPs found it difficult to obtain doctors as mentors at the start, as well as a need for more clinical supervision for the role. This has been also noted in the study conducted by McCann and colleagues (2012b), which identified a lack of mentor support for some IPPs, which was serving as a barrier to their role (McCann et al. 2012b). However, the new changes in the NMIPs' Competency Framework in 2019 allow HCPs, other than doctors, who are IPs and have met the criteria; known as DPPs (Chapter 1, Section 1.3.4), to mentor pharmacists during their training to overcome this issue. Nevertheless, the literature lacked a study exploring the role of DPPs and their impact on pharmacists. Finally, a high

workload was identified by a few participants, which was related more to the high levels of paperwork that they had to do during their prescribing role. The studies that highlighted this challenge were related to IPPs' role in secondary care settings in England (Bourne et al. 2016; Hindi et al. 2019; Graham-Clarke et al. 2022), which indicates the necessity of conducting further research to explore this issue in primary care.

5.6.1. Strengths and limitations of the study

Interestingly, during the data analysis of this study, only one theme was identified from the inductive approach. This may reflect the time and effort in developing the interview schedule by the researcher with the supervisors and experts working in the field.

This study collected data using a qualitative method. Although this study aimed to also conduct focus groups to collect data, it was difficult to arrange due to the inability to find suitable opportunities for participants to be in the same place at the same time. This may be related to the small study population distributed across Wales, and being busy with work and other life responsibilities, which were known as one of the barriers to conducting focus groups (Green and Thorogood 2018). However, semi-structured interviews, with twelve IPPs, were conducted. Although the number of interviews may seem low, it may represent 15 to 18% (12/68) of the study population who were using their prescribing qualification. In addition, saturation was reached as no new information was added over the last two participants, which indicates that there was no need to conduct more interviews (Krueger 1998). The qualitative approach provided detailed and deep information about a phenomenon (Bowling 2014), allowing the aim of this study, which was to explore the views of IPPs regarding their role in GP practices in Wales, to be met. The semi-structured interviews were conducted over the telephone, which lacks face-to-face communication that could help in building a rapport with participants to obtain more details (Flick 2018). This may lead to telephone interviews being shorter compared to face-to-face interviews. However, this does not seem to have been an issue with interviews lasting between 39 and 74 minutes. As highlighted in Chapter Three (Section 3.7.3.3), the virtual interview approach might be a suitable alternative to the telephone method as it may help improve the rapport with participants (Sah et al. 2020). However, virtual interviews became common practice over the last four years (Sah et al. 2020), which was after this study was conducted.

5.6.2. Recommendations

As this study is the first in Wales to explore the views of IPPs in GP practices, the findings that were fed back to the relevant stakeholders might have informed the development of this role. It identified some challenges at the time of the study to the role of IPPs, such as the indemnity issue, insufficient funding support, and lack of a policy or framework to guide

IPPs on how to extend their scope of practice. Additionally, IPPs need to receive ongoing feedback from other HCPs to continually improve their quality of care in primary care settings and encourage HCPs to support them more. Therefore, future work should focus on exploring the views of the other HCPs who work with IPPs regarding their role as prescribers. This might be done by conducting a qualitative study with other HCPs about the role of IPPs in GP practices to have in-depth and detailed information.

5.7. Conclusion

The study explored the role of IPPs working within GP practices in Wales. IPPs were interviewed using a semi-structured interview approach. Using data collected from 12 IPPs, three themes were identified in relation to their role as an IPP. The findings identified IPPs' professional identity, relationship, and practicalities and logistics related to their role. The role of IPPs has changed to include more therapeutic areas since its initial implementation, which included running clinics, reviewing patient medication, and responding to queries of patients and other HCPs. The IPPs in this study identified that their role expanded within the primary care sector by getting more clinical exposure to patients, which enabled them to improve their clinical expertise compared to the IPPs' role in secondary care settings. The participants in this study also believed that GPs and other HCPs in their work area have benefited from the incorporation of their services in primary care settings since it may have helped to reduce their workloads. This study served to address the gap in research relating to IPPs' role in Wales. IPPs in this study identified the feedback of other HCPs on their role as beneficial to them. As such, the next study aimed to explore the views of other HCPs who work with IPPs regarding their role as prescribers.

6. Chapter 6 – An Exploration of The Independent Prescribing Role of Community Pharmacists in Wales

6.1. Introduction

This study aims to address the third objective in this PhD, which is to explore the views of community IPPs, and HB community pharmacy leads (CPLs) regarding the role of IPPs within a community pharmacy setting. This chapter presents the rationale, aim and objectives, methodology, results, discussion, and conclusion of this study.

6.2. Study rationale

Given the increasing pressure and demands on healthcare services in Wales (Local Government Association 2018), the WG acknowledged the positive impact of IPPs on patient outcomes in primary care (Mansell 2015; Famiyeh and McCarthy 2017; National Assembly for Wales 2017; Welsh Government 2018) and emphasised the importance of utilising their skills within community pharmacy (Welsh Pharmaceutical Committee 2019). Therefore, since the time of the last empirical study (Chapter 5), a strategy was developed by the Welsh Pharmaceutical Committee in 2019 for expanding the role of IPPs in community pharmacies. This strategy, as identified in Chapter One (Section 1.2) entitled 'Pharmacy: Delivering a Healthier Wales', included the vision to include at least one community IPP in each community pharmacy by 2030 aiming to improve local healthcare services and alleviate the pressure on GP practices (Primary Care 2018; Welsh Pharmaceutical Committee 2019). The WG financially supported the training of pharmacists to qualify as IPPs, which was directed through HEIW, and commissioned their services (Community Pharmacy Wales 2019; Slawther 2019). For the first few cohorts of community pharmacists undertaking the course, there was no national guidance or specific scope of practice for community pharmacists. However, some HBs chose the scope of practice for their IPPs, such as contraception in CVUHB and UTIs in CTUHB (Hodson 2019). In other UK nations (as highlighted in Chapter One, Section 1.3.2), Scotland implemented this role within this sector in 2020 (NHS National Services Scotland 2023). England started in 2023 to explore the Independent Prescribing Pathfinders to all ICBs aiming at introducing it in 2026 (NHS England 2023). However, Northern Ireland has not implemented or planned to adopt this role in community pharmacies yet.

At the time of the PhD, the role of IPPs in community pharmacy in Wales was very much in its infancy, as such there was a lack of research available on this development. To help realise the goals of the 2030 Welsh Pharmaceutical Committee's vision (2019), additional research is necessary to understand the enablers and challenges to its implementation, the views of community IPPs on their extended role and training, as well as the views of the HB community pharmacy leads (CPLs) regarding this role. There are seven CPLs in Wales (one in each HB). Their role involves the development, implementation, and monitoring of plans, strategies, and pharmaceutical services of community pharmacies within their HB. They are

therefore responsible for the strategy for IPPs within community pharmacies in their HB, which includes making decisions regarding the role, identifying opportunities for IPPs, commissioning their services, and supporting and facilitating their embedding in community pharmacies. Therefore, their views would be valuable.

At the time of this empirical study, research illustrated how IPPs working in various settings, such as primary care settings, are providing a wide range of prescribing services to their patients (Weeks et al. 2016). As indicated in the previous chapter (Chapter 5, Section 5.2) most of this evidence is within secondary care, although some are based in primary care, including the studies in this PhD (Chapters 4 and 5), which were conducted in GP practices. The research identified some challenges to the role of IPPs including inadequate funding, restricted access to patient's medical records, and limited opportunities to develop their role (Hill et al. 2014; Bourne et al. 2016). However, they also reported positive outcomes, such as increased job satisfaction after they started prescribing (Hill et al. 2014). At the time of writing, no research was identified about the role of IPPs within community pharmacy settings in the UK or worldwide, except for two studies that were conducted in Canada (Guirguis et al. 2014; Mansell et al. 2014). Guirguis and colleagues (2014) used semi-structured interviews with pharmacists (n= 38, of which 13 IPPs) to explore the incorporation of their services across different settings in Alberta. The findings revealed that community IPPs' scope of practice was very limited to conditions such as oral contraception and they were focusing on selling medications rather than applying a holistic patient management approach as in hospitals. Similarly, Mansell and colleagues (2014), using a questionnaire approach (n= 125), indicated the limited scope of IPPs' practice in community pharmacies related to managing some minor ailments conditions. They identified that patients had better and quicker access to treatment, their symptoms improved, and they were not concerned with medications' side effects with the management of their conditions by pharmacist prescribers. Nevertheless, the limited scope of IPPs in this sector in Canada may not present the same findings in Wales. Therefore, it is unknown if similar or new outcomes and challenges may be revealed that need to be addressed to develop the role further.

6.3. Aim and Objectives

The aim of this study was to explore the views of community IPPs, and HB CPLs regarding the role of IPPs working within the community pharmacy setting. The objectives of this study were:

- To explore the current role of community IPPs.
- To investigate the views, experiences, and satisfaction of community IPPs regarding their prescribing role and the training associated with it.

- To investigate the views of CPLs on the role of community IPPs and how the role is being utilised and developed in practice.
- To identify the enablers and challenges to the role of community IPPs and its development.
- To explore the perceived impact of community IPPs' role on them, workforce, patients, and other HCPs.

6.4. Methodology

6.4.1. Overview

Since this PhD study aimed to investigate the views of community IPPs and HB CPLs regarding the role of IPPs within community pharmacy settings, a qualitative methodology was deemed to be suitable. Based on the discussion in the Methodology Chapter (Chapter 3, Section 3.7), qualitative research methodology was used to conduct this study as it aims to understand the views and experiences of participants. This method could address the 'what', 'where', 'who', and 'when' questions, as well as understanding the world from the viewpoint of subjects, to understand the meaning of people's experiences (Bowling 2014). Semi-structured one to one interviews were used to conduct this study. Interviews were held utilising open questions within an interview schedule, to keep the discussion within the topic of investigation. In the interview schedule appropriate prompts were provided to collect as much in-depth information as possible from the study participants (Creswell and Creswell 2018).

6.4.2. Ethical considerations

Ethical approval was obtained from the Cardiff School of Pharmacy and Pharmaceutical Sciences Research Ethics Committee at Cardiff University for both the community IPPs, and CPLs at the seven HBs. For the community IPPs' interviews, the HB Research and Development Offices were not required to approve the study as the potential participants were not employed by them. However, as the HB CPLs are employed by HBs, the Research and Development Offices at the seven HBs were approached to obtain their approval. These Research and Development Offices focus on the capability and capacity to conduct studies within their HBs (Welsh Government 2020); five HBs assessed and approved the study. These HBs registered this study as a service evaluation that didn't require NHS ethical approval, as per the HRA decision online tool (Chapter 3, Section 3.8.1) (HRA 2017; HRA 2019; NHS Research and Development Forum 2021). The other two HBs didn't respond to requests by the researcher, which may be related to the COVID-19 pandemic that started during the time of this study.

6.4.3. Sampling criteria

The inclusion criteria for this study were community IPPs who had obtained their prescribing qualification, irrespective of whether they were using the qualification in practice, and the CPLs in each of the seven HBs. Purposive sampling was used since it enables the researcher to select participants (community IPPs) who are the most informed about the area of investigation and met the inclusion criteria (Krueger 1998). This study aimed to use a census approach to recruit all the CPLs in the seven HBs. The recruitment strategy involved

the use of gatekeepers to help identify potential participants who met the study characteristics.

6.4.4. Recruitment strategy

In North Wales, the CPL of BCUHB, who was known to the research team, was leading the development of the pharmacist's role within primary care (both GP practice and community pharmacy based). At the time of the study, this CPL was leading some of the WG's work on the pharmacists' independent prescribing services in the community pharmacy sector. Therefore, this CPL was considered appropriate to be a gatekeeper to assist with recruitment. As there was no available list of IPPs who work in community pharmacies in Wales, this CPL, along with the course leaders of the independent prescribing courses, who were all known to the research team, were asked to act as gatekeepers and approach potential participants. The CPL who helped to recruit community IPPs also acted as a gatekeeper to approach the remaining HB CPLs. Those gatekeepers were used as they would be able to identify and have the contact information of an appropriate selection of IPPs who work in community pharmacies in Wales. All gatekeepers for both studies were emailed a copy of the letter inviting participation (Appendix 22), participant information sheet (Appendix 23), and consent form (Appendix 24) and asked to forward onto potential participants. A reminder email (Appendix 25) was sent out two weeks after the initial contact. All interested individuals were asked to contact the study lead, Saeed Alghamdi, to express an interest in taking part. Interviews were conducted at a suitable date and time for the participants. The participants were asked to complete and sign the participant consent form before conducting the interview. Relevant contact details were obtained to organise the interview.

6.4.5. Data collection

The interested individuals were asked to participate in a one-to-one interview. This was anticipated to last between 30 and 45 minutes, at a time and date appropriate to them, either face-to-face or over the telephone, dependent on location and what was most convenient for them. Face-to-face interviews were conducted at a mutually agreed location, such as a quiet room close to or within their workplaces. The interviews were audio recorded and transcribed ad verbatim immediately after the interview by a university approved transcription service. Once quality was assured by the researcher the data were de-identified by removing all participant identifiable information to ensure that no individual could be identified from the data. The consent forms were signed electronically and returned via email. All electronic materials contained personally identifiable information (including the electronically signed consent forms), and interview transcripts were stored on a university password protected computer, which were kept secure until the end of this PhD plus five years according to the Cardiff University policy of data retention (Cardiff University 2020).

An interview schedule was developed from information in the literature and stakeholder involvement (Appendix 26). The community IPPs' interviews were conducted first followed by the CPLs study. The interview schedule of the community pharmacy IPPs' study was developed under the supervision of the researcher's supervisors, with the help of the HB CPL who was acting as a gatekeeper. This aimed to ensure that the questions asked were understood by the participants and appropriate to the aim of the study. This interview schedule was not piloted as it was extensively reviewed by the researcher, supervisors, and the CPL to ensure the appropriateness and wording of the asked questions. The interview schedule of the CPLs study was developed based on the findings of the community IPPs' study, which was also reviewed extensively by the researcher and the PhD supervisors. Both interview schedules involved questions about the scope of practice of community IPPs and its development, their views on the prescribing courses and training experience, the impact of the role, the enablers and barriers to the role, and the vision for all community pharmacies to have an IPP by 2030. Community IPPs were also asked about their motivation to obtain their prescribing qualification and utilising it. They were also asked about the usefulness of the independent prescribing university course content on a scale of 1 to 10 score where 1 was the lowest and 10 was the highest score. This type of question was used since it allows for a comparison between the provided opinions by the participants compared to just a simple yes or no answer. CPLs were also asked about the available and future strategic plans for the role in HBs, as well as their strategies to implement the 2030 vision.

6.4.6. Data analysis

Transcripts were analysed through both deductive and inductive thematic analysis. Detailed information regarding the thematic analysis process was presented in Chapter Three (Section 3.10). The same thematic analysis approach and involvement of the researcher's supervisors utilised in Chapter 5 (Section 5.4.6) were also employed in this study. This was to ensure the consistency of the research process and maintain the trustworthiness of the findings.

6.5. Results

A total number of thirteen community IPPs from four HBs were interviewed, of which five had already started practising as prescribers. In addition, out of the five HBs, where Research and Development Office approval was obtained, two CPLs responded and participated in this study. The length of the IPPs' interviews ranged from 33 minutes to one hour and 4 minutes, nine interviews were conducted via telephone and four face-to-face. Table 18 presents a summary of the community IPPs' details and the type and duration of interviews. The first community pharmacy lead (CPL1) was interviewed face-to-face with an interview duration of 58 minutes (HB 1), while the length of the second community lead's (CPL2) interview was 55 minutes and conducted via telephone (HB 2).

Table 18 Demographic information of the community IPPs who participated in this study.

IPP	Scope of practice	Time since being qualified as IP	Prescribing status	НВ	Type of interview	Interview length
1	Otitis media, ENT, respiratory, skin & minor ailments	8 months	Prescribing	HB 2	Telephone	42 minutes
2	Otitis media and externa, UTIs & sinusitis	2 months	Not prescribing yet	НВ 3	Telephone	33 minutes
3	Sexual Health	3 months	Not prescribing yet	HB 3	Face-to- face	49 minutes
4	Asthma & COPD	5 months	Not prescribing yet	HB 3	Telephone	1 hour & 4 minutes
5	UTIs, shingles & sore throat	4 months	Not prescribing yet	НВ 3	Face-to- face	1 hour & 2 minutes
6	UTIs, ENT, sore throats & Otitis media and externa	1 month	Not prescribing yet	HB 4	Face-to- face	47 minutes
7	Minor ailments	1 week	Not prescribing yet	HB 2	Telephone	41 minutes
8	Pain management & addiction to prescribed medications	5 months	Prescribing	нв з	Face-to- face	42 minutes
9	Minor ailments & Hypertension	8 months	Prescribing	HB 2	Telephone	36 minutes
10	Respiratory conditions, hypertension & minor ailments	1 month	Not prescribing yet	HB 2	Telephone	1 hour & 2 minutes
11	Minor ailments	3 years	Prescribing	HB 1	Telephone	27 minutes
12	Respiratory conditions	4 years	Prescribing	HB 4	Telephone	46 minutes
13	Sexual Health	2 months	Not prescribing yet	HB 2	Telephone	1 hour & 1 minute

NB. HBs' names were coded with numbers to de-identify the participants' personal information.

6.5.1. Themes

The analysis of the community pharmacy IPPs and CPLs interviews was conducted and presented separately as follows:

6.5.1.1. Themes of the community pharmacy IPPs' interviews

Three themes were identified from the data via the use of both deductive and inductive thematic analysis (no new themes were identified by the inductive approach). These themes have sub-themes as illustrated in Figure 45, detailed information on these themes and their sub-themes are presented in the following sections. As IPPs who had already started to provide a prescribing service were still very much at the beginning of their journey in the community pharmacy sector, very similar themes were identified from their data compared with data obtained from IPPs who had yet to start. As such, the themes generated from both groups are presented together to avoid repetition in the findings. However, any difference in opinion between those who were practising and those who were still waiting to practise, is indicated in the text within the relevant themes. Appendix 27 presents a colour-coding of a portion of the transcript that was obtained from an interview illustrating the thematic analysis approach, while Appendix 28 shows the employed approach to identify and arrange the final sub-themes and themes with examples of quotes and used codes.

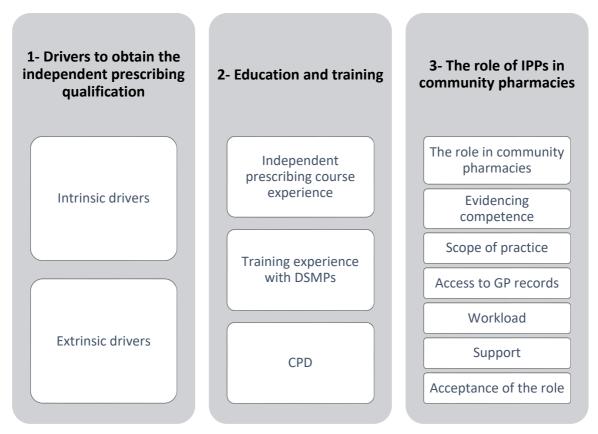


Figure 45 Themes and sub-themes of the community pharmacy IPPs thematic analysis.

6.5.1.1.1. Drivers to obtain the independent prescribing qualification in community pharmacies

Both intrinsic and extrinsic drivers were identified that encouraged pharmacists in community pharmacies to train and qualify as IPs.

6.5.1.1.1.1. Intrinsic drivers

The intrinsic drivers for pharmacists to obtain this qualification stemmed from personal interests. Some expressed that they were inspired by other colleagues who had become IPPs, as well as identifying it as a new career challenge, doing something different than their previous role. Most IPPs identified that they desired to do a clinical role and felt it would be more useful. They also believed that this new role would help improve their profession by developing their knowledge and skills, which could lead to more job satisfaction.

'We need to move away from being checkers. At the moment we're just checking machines, aren't we? We just stand and check all day and get wheeled out onto the counter for a consultation if someone wants to buy Viagra, which is very sad.' IPP9

A few participants who own their community pharmacies qualified as IPPs due to financial benefits that may help keep their businesses solvent.

'It's my own business and I got to run the business efficiently, ethically, and financially profitable. So, training as an IP seemed the next logical step.' IPP6

6.5.1.1.1.2. Extrinsic drivers

There were extrinsic factors that encouraged some participants to do this role. A few participants indicated that a change in the way that community pharmacies are remunerated from more traditional services (e.g., dispensing) to clinical services, including independent prescribing, drove them to undertake the training.

'Also, our remuneration has been reduced in the dispensary and ... that they were wanting to see more community pharmacists working in a clinical setting within the community pharmacy.' IPP5

Another major driver was the funding and support from HBs across Wales for the majority of participants to undertake the independent prescribing course and the new Welsh Pharmaceutical Committee (2019) vision. Some participants believed it was better to start their training as IPs instead of following their colleagues later. The opinions of most

participants about this goal were positive since they believed that the WG and HBs are determined to achieve it due to the positive impact that this role would provide. This included providing more patient access to treatment, relieving pressure on GPs, and improving their pharmacy profession.

6.5.1.1.2. Education and training

This theme illustrates the participants' experiences of their independent prescribing education and training. Three subthemes were identified, which are their experience of the independent prescribing course, their training experience with DSMPs, and their CPD.

6.5.1.1.2.1. Independent prescribing course experience

This sub-theme highlights the participants' experience of the taught part of the independent prescribing course. The participants evaluated the usefulness of the content of the independent prescribing university course on a scale of 1 to 10 (1 was the lowest and 10 was the highest score). Most participants evaluated the course as 10, while a few IPPs gave it 7 or 8 (the average rate was 8.9). This indicated that most participants had an overall positive view of the course; they felt it was useful and comprehensive.

'[It] did help me to have a better understanding of the evidence base guidelines, and the various types of international guidelines as well as ... NICE and SIGN and BTS guidelines.' IPP10

It was explored why the participants gave such a score, which was mainly related to the useful parts of the course. This included workshops that aimed to develop their physical assessment (e.g., taking blood pressure, vital signs, and listening to chest and cardiac sounds) and consultation skills including history taking, writing a prescription, and communication skills. Some participants felt that the course changed their perspective as pharmacists to be more clinical and thorough with patients and helped to increase their confidence in decision-making and responding to symptoms.

'I'd say they had demonstration rooms with dummy patients, so I felt that we were covering more of the physical aspects. Even though it was unrelated to my personal prescribing, it was good to see the use of different equipment and diagnostic tools for the various ailments, so that if I would broaden my prescribing practice, it won't be so foreign to me.' IPP13

The course also involved legalities around confidentiality, auditing, and responsibilities that they needed to fulfil. Some IPPs explained these helped them to know their boundaries as IPs in community pharmacies by practising only within their competence and understanding

their accountability and limitations.

'It gave you tools of you needed and you could apply it to whatever role you were doing ... even things I hadn't thought about like all the consent aspect of it ... when I first went into the course I thought I was going to be one of these ones who would be happy to write a prescription for anything, I'm an easy going pharmacist and ... it did kind of frighten ... I will be more careful ... because of the consequences.' IPP8

Some participants expressed negative opinion about certain aspects of the course. Their experience was stressful as the volume of material and coursework were high over a short time, alongside their full-time work and family responsibilities.

'I think you kind of have to view it that it's going to be intensive 6 months, it's going to put a big strain because you are trying to balance many many things going on.' IPP3.

A few participants expressed concern that their independent prescribing course involved other HCPs, which resulted in reduced content of physical assessment skills and an increase in pharmacology-based learning. They felt that was a duplication of their pharmacy degree. As a result, those pharmacists would have preferred a course more targeted toward their clinical needs.

'Back to basics just because nurses were on the course, it was like an assumption that that wasn't necessary so even the basic things like, how to do a chest examination ... take a blood pressure, there were things that I then after that learned on the job rather than on the course' IPP12.

On the other hand, some participants who attended the independent prescribing course with only pharmacists highlighted that it involved a high content of assessment skills. However, pharmacists within the course were from different healthcare sectors (GP practices, hospitals, and community pharmacies) with varied scopes of practice. They felt that the course did not therefore cover all of their requirements as it was difficult to provide generic clinical assessment materials or separate clinical study days, such as sexual health.

Other negative comments on course content were the irrelevant lectures, the complexity of the university IT platform, the few materials on the Objective Structured Clinical Examinations (OSCEs), and the need for more real or simulated patient contact to increase their confidence and experience.

6.5.1.1.2.2. Training experience with DSMPs

Most participants completed the practical part of the independent prescribing course (90 hours of practice training) in GP practices; a few also spent some days in hospitals. The majority believed that this training was the most beneficial part of their course. The overall experience with their DSMPs, was positive, allowing them to gain a lot of knowledge and skills. For example, their training with GPs helped them to understand their consultation approach and communication skills. In addition, GPs shadowed them during consultations and provided them with feedback on areas that needed to improve, which they believed increased their confidence and prepared them to do the role.

'It's been good training with the GP ... So sometimes the GP would agree with me [during consultations] sometimes he wouldn't.' IPP5

Some other beneficial aspects of IPPs' training with GPs included helping them to practise and improve their clinical assessment skills (such as the use of an otoscope to diagnose ear infections), gaining more knowledge on ethical aspects, and sharing experiences with medical students. Moreover, training with local GPs developed IPPs' relationships with them as many were still in contact after the course finished to discuss clinical queries, which resulted in increased communication between GP practices and community pharmacies.

A few participants explained that GPs were seeing a lot of patients with medical conditions out of their scope of practice, for example, patients with mental health or cardiovascular conditions. Even though these were not in their scope of practice, the experience allowed them to learn how the GPs approached the consultations and the way they interacted with patients.

To undertake the independent prescribing course, each participant had to find their own DSMP. It was easy for some IPPs to find a local DSMP (GP) as they already had a good relationship with them. A few participants indicated that GPs were willing to train them without financial benefits. This was mainly due to the previous positive experience of GPs with those participants who would provide their services within the same locality. The scope of practice of two other participants, which was related to sexual health, helped to easily find DSMPs since a HB had a department for this field that was willing to facilitate their training. In contrast, some other IPPs had great difficulty in obtaining DSMPs, due to the pressure on GPs to train other medical students and IP HCPs. They pointed out that they did not previously have a relationship with GPs, which made it challenging, and felt more support was needed to avoid that potential risk in the future.

'It was hard, I contacted multiple GP surgeries, and it was really difficult to find anybody who had any free time to train us ... It would be nice to know if there are surgeries who, doctors who are interested in doing it in the first place because I just sort of rang round all the surgeries and blindly not really knowing if anybody would be interested so it would be nice to know if there was some sort of list ... because I wasted hours doing that. IPP7

Some participants did not spend all of their training time with GPs and trained with ANPs and INPs. These participants completed 60 hours of their training with GPs and 30 hours with ANPs or INPs, directed by their independent prescribing course provider. They felt these practitioners had similar experiences with the independent prescribing course and training, therefore, they understood the challenges of training as an IP more than a GP. ANPs and INPs provided them with increased exposure to relevant patients as they were specialists within the same area of clinical practice, which they believed was beneficial. They also provided IPPs with different styles of consultations, more clinical assessment skills, more knowledge within the same scope of practice, and support.

'Advanced practitioners were more my kind of scope so I could learn a lot more about all the different ailments and what to look for.' IPP7

Mixed feelings were provided by the participants about the possibility of being tutors (DPPs) in the future and training new IPPs. Some participants stated that they would not be tutors since they lacked the medical experience and depth of knowledge that doctors have built over a long time with a wider scope of practice. Therefore, they stressed that the GPhC should not approve this change in tutoring. In contrast, some IPPs believed that once they obtain more knowledge, experience, and confidence, they would be willing to undertake this role. They added that this would be a good alternative to address the high demand for DSMPs.

6.5.1.1.2.3. CPD

This sub-theme relates to the CPD completed by participants after the independent prescribing course. Although most IPPs felt comfortable with the topics that they covered during their initial training, they indicated that there were always many gaps in their clinical knowledge and skills that they needed to develop further. The participants who had started their independent prescribing role identified that they read guidelines, completed online and face-to-face courses, obtained diplomas, attended learning sessions in GP practices, and did further training and shadowing of other expert professionals. They highlighted that this helped to expand their independent prescribing scope of practice and proved their competence in community pharmacies. A few of those participants indicated that it was easy for them to undertake such courses, training, and sessions in GP practices as they used to work in these settings or still had a good relationship with them. However, most of these courses were self-

funded as there was no financial support provided by their HBs. In addition, there was no clear clinical supervision for their original and new independent prescribing scope of practice. On the other hand, one participant who had yet to start their independent prescribing role acknowledged the need to have a plan for CPD that involved arrangements with relevant individuals.

'I'd have to think about how to do that systematically and sit down with the GP and formulate a plan. For example, if I'm going to do dermatology, wound care maybe going on further courses and speaking to people in secondary care.' IPP5

An example of the CPD that most participants completed was related to minor illness conditions that they commonly see in a community pharmacy. Some participants highlighted that their HB directed and funded them to take courses related to these conditions in order to develop their scope of practice and had a positive opinion of them. Some participants felt that these courses were well-structured, interactive, broad, and clinically intensive, and were directed by experienced HCPs with acute illnesses. In addition, these courses focused on many aspects, such as major red flags of acute clinical conditions and differential diagnosis, which a few participants believed were very useful since the independent prescribing course did not focus on these components. Moreover, these courses involved a lot of clinical assessment skills that were provided by a variety of expert HCPs, which involved using some diagnostic tools.

'It [The minor illness course] was excellent ... It was sort of designed by nurses and we had a respiratory OSCE exam. So that made us learn how to do a respiratory exam from start to finish ... classical examination and we had speakers coming to talk to us about acutely ill children, migraine, dermatology nurse ... a paramedic.' IPP9

However, a few individuals had a negative view of these courses, including that they involved a lot of material over a short time, there were a few repetitions from the independent prescribing course, no assessment involved, and no end-of-course certificate that could prove their competence. One IPP believed that there was a need for a standardised minor illness course that is incorporated within the independent prescribing course to ensure consistency of prescribing practice.

6.5.1.1.3. The role of IPPs in community pharmacies

This theme provides detailed information on aspects related to the role of IPPs in community pharmacies. It consists of seven sub-themes, which are the role in community

pharmacies, scope of practice, evidencing competence, access to GP records, support, workload, and acceptance of the role.

6.5.1.1.3.1. The role in community pharmacies

The participants who had already started their independent prescribing services in community pharmacies highlighted some aspects regarding its implementation. Most of those participants identified setbacks in the initiation of their role. One reason for this was a delay in the commissioning of their independent prescribing role by their HBs, including funding for their services and indemnity insurance. A few IPPs added that their current remuneration was still low compared to their previous pharmacist role, which they felt was unfair:

'There's a massive amount of risk associated with this, for very little finance reward ... if they're doing £150 per ten patients that's £15 per patient, well we get £28 for doing an MUR which doesn't go up any medical, legal responsibility really or accountability because you're only recommended things to people.' IPP10

Other reasons were more logistical, such as inadequate pharmacy workforce in the community pharmacy, obtaining prescription pads, waiting to be registered with the GPhC, and a lack of an IT system to be able to access their patients' records. There was also difficulty in understanding their exact role at the beginning. Therefore, some IPPs were practising in a GP practice a few days a week to maintain their skills until they started the independent prescribing role in a community pharmacy (a few were still working in both community pharmacies and GP practices). The implementation was also slow, as indicated by the participants who had commenced their prescribing position. A few of those participants added that they were doing a lot of checking of their consultation approach and prescription writing when they started the role to avoid issues, which became easier and quicker as their confidence grew over time.

'... when I first qualified and I'd spend about 20 minutes looking at the same thing over and over again.' IPP8

Being qualified as an IPP in GP practices before was an enabler to a few participants who started their role that helped implement their independent prescribing services in community pharmacies with more confidence. Another enabler for a few other IPPs was the availability of consultation rooms, which they felt were necessary to see their patients in a private and quiet space. In contrast, a few IPPs who own their community pharmacies highlighted that there was no available consultation room within their community pharmacies as there was no space for it, which prevented implementation.

The other eight IPPs identified challenges that prevented them utilising their prescribing qualification. Some indicated that there was a lack of funding from their HBs to remunerate their independent prescribing role and invest in more staff to handle their regular pharmacy duties. They added that they still lacked information on the exact number of independent prescribing sessions and stressed the need for a national model for that. A few of those participants were granted funding from their HBs to only do 24 independent prescribing sessions with no specified time as a transition phase in either a community pharmacy or GP practice to maintain their independent prescribing skills. The process of implementation was seen to be complex by the participants who had not yet started. A few highlighted that they could not obtain indemnity insurance, which was required by their HBs to commission their services. They indicated that it involved a lot of time-consuming paperwork when completing insurance company forms and was very expensive with no financial support from their HBs. In addition, obtaining access to GP records was a requirement by the insurance company, which they also lacked.

'An IP ... is going to include waiting for your certificate, waiting for IP to be stuck onto your annotation on the GPHC register and having indemnity insurance.' IPP3

Although most participants were positive about the Welsh Pharmaceutical Committee's vision (2019), as indicated earlier in Section 6.1.1.3.1.3, some highlighted the challenges to achieving it. First, there was a need to have a clear plan for its implementation. This included a plan for promoting the role to the public to increase their understanding and awareness, as well as change public behaviour when they seek medical help to include pharmacists and not just GPs. They also believed the role needed to be promoted to pharmacists as the number of IPPs was still low. A few IPPs indicated that the number of higher education institutions providing independent prescribing courses was still too low and there was a need to involve more schools to offer more courses. There was also a need to have standardised courses and training to ensure full understanding and competence of the pharmacists to be IPs. Some participants indicated that the use of expert IPPs as DSMPs (DPPs) to train pharmacists as IPs was another requirement to be able to achieve this vision due to the current challenges in finding DSMPs. Another aspect was related to granting IPPs access to patients' records on a national level to allow them to practise their prescribing role effectively and avoid any issues or delays.

'Many [changes needed to achieve the goals of the vision], cultural, financial, IT infrastructure ... there will have to be a cultural change which empowers the patient to see the practitioner they want. Once that is there, you've got a

better chance of seeing a shift in the way people choose to access the NHS.' IPP6

The prescribing and dispensing of medications in the same community pharmacy were highlighted by IPPs who had started their independent prescribing role. They identified that these two processes were separated to ensure patients' safety. When they write a prescription, they hand it to the patient who then has the choice to collect the medication(s) from their community pharmacies or take it elsewhere. If the patient decided to collect it from the same community pharmacy, then the patient would take the prescription to a technician to dispense it and subsequently be checked by another pharmacist. They added that this proved the importance of having a second pharmacist. One IPP indicated that they were already separating the processes of prescribing and dispensing before doing this independent prescribing role:

'We're already prescribing in minor illnesses in the community pharmacy so I can prescribe ... for conjunctivitis and haemorrhoids and ... it gives you an idea when we're talking about separating the dispensing ... the prescribing aspect, we're already doing it anyway.' IPP7

As the independent prescribing role was in its infancy, the majority of participants saw patients via a walk-in service. These patients were identified either within the pharmacy or via GP practices referring some patients to them. Some IPPs believed this approach may need to change, as it could become unmanageable as the service grows. Only one participant applied a booking system to see patients referred by a GP.

'At the moment, we have tried to make it into a walk-in service. I think as this goes further, we need to look at providing some kind of appointment service ... we are conducting 15-to-20-minute consultations, I think it is getting to the stage it will become impossible.' IPP1

The impact of the role on patients, other HCPs, and themselves as IPPs was also emphasised by participants who had started their role. All participants believed their independent prescribing role had many benefits for their patients. For example, it increased patient access to appropriate treatment within their locality, provided quicker access than GPs, improved their quality of care, and enhanced their healthcare experience. They added that their community pharmacies are open every weekday and serve patients in the late or early hours of the same day. In addition, quick access to their independent prescribing services could help in preventing the progression of illnesses and identifying serious conditions much earlier to quickly direct them to the most appropriate clinical facilities.

'So, patients are going to be able to be seen by a highly qualified health professional closer to their home without having to travel to ... seeing a GP and ... a lot of the working population are just unable to take the time off to see the GP, so we've got longer working hours.' IPP1

Regarding the impact of their role on other HCPs, IPPs, who had started, emphasised that their role helped to handle a lot of acute conditions. This minimised the number of patients being referred to their GP. They added that their role might help to relieve current pressure on primary care and secondary care. In addition, it may help to free GPs' time, which will provide them with more appointments to see other patients.

'It's certainly increased capacity ... the bulk of the GP surgeries where I've worked, it means that GPs have been able to focus more on complex cases, freeing up their time, freeing up nursing time.' IPP10

The impact of the role on themselves was related to their profession and business. Most IPPs identified that the role helped to increase their job satisfaction as it allowed them to use and develop their clinical knowledge and skills more effectively. It also provided them with more clinical duties and patient contact, which they felt was rewarding. In terms of the impact on the business, participants who own their community pharmacy indicated that this role helped to increase their staff capacity and provide them with more support and advice. It also improved their business by increasing the range of services and income, as well as keeping up with other community pharmacies.

'From a business point of view would bring further people forward to think, well perhaps this independent pharmacy they're using this new model and ... I'm going to go there for my prescriptions as well.' IPP12

6.5.1.1.3.2. Evidencing competence

This sub-theme is related to the way that community pharmacy IPPs provide evidence of their competence. Some participants indicated that there was no clear guidance or plan that they could use to evidence their competence. They believed that it is very important to have such guidance with the increase in their prescribing responsibilities and scope of practice. However, most participants stated that they were evidencing their competencies by keeping a clinical logbook of their CPD that involved building up a portfolio of certificates of completion from relevant courses, documentation of their shadowing, guidelines read, reflections on their practice, feedback from patients, other pharmacists, or GPs, and clinical information from meeting with other colleagues. A few participants who had not started their independent

prescribing role indicated that they would approach their line managers for further guidance and support on that. Only one participant, who had not started practising, identified the use of the RPS framework as a potential approach to evidence the competence.

'I think I might use RPS faculty one to keep some evidence because you can keep them on there for a bit longer ... and you can link it into your CPD.' IPP2

6.5.1.1.3.3. Scope of practice

The scope of practice of all participants is presented above in Table 18 (Section 6.5). The focus of most of the participants was acute minor illnesses, mainly infections, such as UTIs, eye and ear infections, and respiratory infections. A few IPPs' scope of practice was related to both acute minor illnesses and some chronic conditions (e.g., hypertension). Those participants indicated that their independent prescribing services e related to chronic conditions were usually conducted in GP practices a few days per week. Another few participants identified that their scope of practice was only related to chronic conditions, such as asthma and COPD as they chose their own scope of practice.

'My specific scope was asthma reviews ... so I always been interested in asthma and COPD. Asthma and COPD was my thing ... so I tried narrowing to become an expert in it and I thought it was useful.' IPP4

The scope of most participants, (acute minor illness conditions) was directed and chosen by their HBs. They highlighted that their HBs identified therapeutic areas of high demand and pressure with local GP practices to ensure their independent prescribing role would have a positive impact. The HBs subsequently funded their independent prescribing courses and training.

'It was sort of decided upon by the local health board as this was ... seemed to be a necessity in the area where I work.' IPP13

The participants who had started their independent prescribing role indicated that they identified the most frequently presented medical conditions and wished to expand their scope of practice within these areas.

'You know we're seeing an awful lot of people doing dermatology and wound care and that's one aspect I'd like to look into ...' IPP5.

The IPPs, particularly those who had not started, expressed their willingness to develop their scope of practice with time. They added that they would prefer to expand it in

clinical areas related to their main scope of practice. However, many IPPs emphasised the potential lack of funding as a barrier in terms of paying for courses, training, and other staff to backfill their duties during their learning time.

'I think again it might just come down to finances ... So, I had to have cover for the days that I wasn't present at the pharmacy.' IPP13

6.5.1.1.3.4. Access to GP records

The lack of access to GP records was a major issue for most IPPs. Most participants expressed that they would prescribe blindly, and their independent prescribing role would not be safe without access to their patients' GP records. They believed that it is essential to obtain their patient's medical information, including medical history, medication history, and blood tests before they make any changes to their medications. A few IPPs were doing their role without having access to patient's records, as they could take a medical history from their patients or call their GPs for information. They highlighted that it was time-consuming to obtain this information, and patients may not provide all the relevant information. This prevented or limited some participants from providing their independent prescribing services in community pharmacies. An example of the necessity of getting access to GP records is:

'I haven't got access to medical records ... like blood tests to check kidney function ... So, I wouldn't feel happy to see someone with hypertension and not have any access to their blood results and start changing their doses. It's just not safe.' IPP9

Some reasons were suggested as to why access to GP records was problematic. This included the lack of understanding of their role by HBs and GP practices, the issue of confidentiality and handling of patients' information, IT issues in terms of obtaining software (different GP practices were using different software), and GPs being very protective of their patients' records.

'They [GPs] hold that [patients' records] very dear to them ... the GPs feel it is their GP records not the patients' health records.' IPP1

In contrast, one IPP believed that some GPs were aware of the benefits of this role to themselves and their patients, therefore, they were less protective of patients' records. However, this participant indicated that the process of obtaining the GP practice consent to access their patients' medical records was complex and time-consuming.

The good relationship between IPPs in community pharmacies and GP practices played an important role in obtaining access to their patients' records. Some participants

acknowledged that this relationship developed during their independent prescribing training within GP practices, which helped them to understand their role and its benefits.

'I trained with the local GP practice here, which ... I'd had a really excellent relationship with ... I was just like an extended arm of the practice, although I was separate, it made no difference because I had full read access to their notes as well that made everything synchronised.' IPP10

6.5.1.1.3.5. Workload

The increased workload of IPPs in community pharmacies was stressed by most participants, as they still needed to carry out their previous work alongside their new prescribing duties. They felt under huge pressure and needed to work harder even at times outside of their working hours. Those participants indicated that this was difficult to cope with due to the large time commitment.

'I would do 4 or 5 IP consultations a day but that is on top of our other workload so medication reviews, smoking cessation, morning after pill services.' IPP1.

The importance of increasing the number of staff in community pharmacies, such as hiring a second pharmacist, accuracy-checking technicians (ACT), and pharmacy technician, to relieve some of their previous duties was emphasised by most participants. However, the finances related to hiring more staff were an issue as there was a need for more funding support.

'If I was to book a locum, not many locums want to work a half day, you'd have to book a locum in for a full day, so I'd get £150 for a morning session but it's going to cost me £200 to get a locum in.' IPP10

6.5.1.1.3.6. Support

Some participants identified a lack of appropriate support, as there would only be one IPP in a community pharmacy, and they were not working alongside a GP. They believed there was a need to build a professional network, particularly during their prescribing course, to overcome this issue.

'We do not have a fellow medical profession next door to us ... So, that is the scary bit about being a community Pharmacist IP is that ... you haven't got anyone next door to you to knock on the door and ask for a second opinion.' IPP1

There was a lack of support by community pharmacies, as identified by a few IPPs, in terms of allowing them to do the independent prescribing training and further training. They felt that their community pharmacies were concerned that they might move to other sectors, such as GP practices or hospitals. The lack of support from HBs also prevented some IPPs from starting their independent prescribing role since HBs did not address the barriers associated with its implementation.

'The reality is that IP community has not kicked off ... the health board need to be involved ... and I don't know if the people at the health board level have that real understanding of how the local issues work.' IPP5

6.5.1.1.3.7. Acceptance of the role

This sub-theme presents the acceptance of the public, patients, and GPs of the IPPs' role in community pharmacy. Most participants believed there was a general acceptance of their independent prescribing role. Patients were very positive about the role due to the benefits that it provided to them. However, a few participants who still had not started their independent prescribing role felt that the public views might be an issue in terms of accepting their ability to assess their conditions and the comparison of their services with GPs. Those participants felt that since IPPs do not have the same qualifications as GPs, they may have a perception that community IPPs would not provide them with appropriate services. They added that the public, in general, does not like changes, which may negatively impact their acceptance of the role. Therefore, those participants stressed the need for increasing public awareness and understanding of this role. While GPs in general were also positive with the role, there was some negativity by a few GPs as identified by a few participants:

'I have had one or two GPs be a bit negative about it ... We could provide a threat to the GP as they are seen as the kind of key stone in healthcare, primary care ... [this role] will not be directly accountable to a GP and ... they are very protective of their own profession.' IPP1

6.5.1.2. A summary of the community pharmacy IPPs' results

A summary of the results is as follows:

- The drivers to qualify as IPPs were intrinsic or extrinsic, or both, which has increased their job satisfaction.
- All participants believed that the 2030 Welsh Pharmaceutical Committee's vision (2019) was great for the role. However, to achieve this there was a need to have a clear plan for

its implementation, promote the role to the public, other HCPs and pharmacists; increase the number of independent prescribing courses, include expert IPPs in the trainer list, provide them with access to patients' records to prescribe safely, and provide more funding to ensure its sustainability.

- The independent prescribing course and training with DSMPs were useful to participants, but there was a need for more clinical content to be directed to their needs and support in finding DSMPs.
- The scope of practice of most participants in community pharmacies was mainly related to acute conditions, particularly infections.
- There was a lack of support for a few IPPs from community pharmacies and HBs.
- Most participants identified the high workload as an issue as they were still fulfilling their previous duties, which highlighted the need for more staff in community pharmacies.

6.5.1.3. Themes of the community pharmacy leads' interviews

Three themes were identified from the data; two were identified via the use of deductive thematic analysis (national strategy and local implementation and strategies), and only one theme by inductive analysis (clinical governance) (Figure 46). These themes are presented in the following sections in detail with supporting quotes. Appendix 29 provides a colour-coded example of a portion of the transcript that was retrieved from an interview to illustrate the thematic analysis approach. Appendix 30 highlights the thematic process utilised to identify and arrange the final sub-themes and themes, including examples of quotes and used codes.

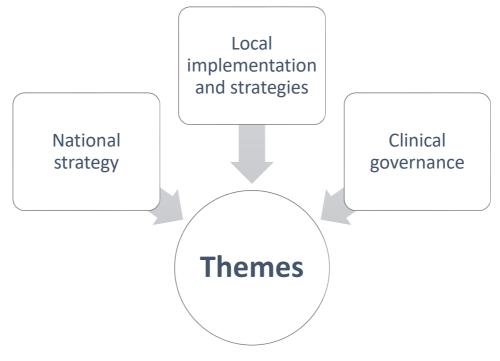


Figure 46 Themes of the community pharmacy leads interviews.

6.5.1.3.1. National strategy

This theme presents the data related to the national strategy for the role of IPPs in community pharmacies in Wales, outlined in the Pharmaceutical Committee's vision 'Pharmacy: Delivering a Healthier Wales (Welsh Pharmaceutical Committee 2019). Both CPLs believed that its aim, of having at least one IPP in each community pharmacy in Wales, was 'great', since it represented the future of the pharmacy profession.

'Great ... If we don't take on prescribing, then we're dead.' CPL1

Both CPLs believed that the vision could help in expanding the IPPs' role further since their services might already have a positive impact on patients and other HCPs. They also believed that IPPs in community pharmacies might have taken some of the workload from GP practices who were under pressure. In addition, it might help to manage patients' conditions and their medications more effectively and increase access to appropriate treatment. This allowed patients to see the right HCP at the right time. It also helped in building relationships between GP practices and community pharmacies, which would improve overall patient care. The IPP role also had a positive impact on the pharmacist's profession in general as it allowed them to fully use their clinical skills rather than solely being involved with dispensing and the supply of medicines. Both CPLs explained that these benefits were the reasons for introducing this role in community pharmacies, which also were stated in the vision.

"... supposedly the [IPPs] expert in drugs aren't they, so, really a prescribing qualification seems to me, in order to allow us to manage medicines more efficiently and effectively, seems to be the way forward." CPL1

Both CPLs believed it was an ambitious vision and was associated with some challenges. There was no clear implementation plan provided to the HBs. One CPL commented:

'How do we ensure that pharmacies are integrated into the NHS primary care offering rather than sitting on the outside of it? ...I think they really need to be recognised as true NHS providers, and maybe brought into the primary care offering in a more collaborative way.' CPL2

Another challenge was the need for more promotion of the role. One CPL highlighted the importance of developing a strategy to promote the role among pharmacists in order to train more as IPs. The second CPL believed that it was essential to promote the role to the public and other HCPs to increase their awareness and understanding of the IPPs' capabilities

in providing this role and have their ongoing support.

'I think we probably need a strategy for engaging with those pharmacists that are a little more cautious about a change of direction in their role. So how do we engage with those individuals that are broadly comfortable with the traditional community pharmacy role? How do we encourage and enthuse them to become IPs? I think that's one challenge.' CPL2

The final challenge that was highlighted by both participants was the funding provided by the WG. Whilst this funding was appreciated, it was perceived to be inadequate in the long term. Both CPLs highlighted that they were commissioning this role from the funding provided by the WG. Therefore, they emphasised that a change to the pharmacy contract was needed to ensure sufficient payment was given to reflect the workload undertaken. It was acknowledged that pharmacists are doing their independent prescribing role alongside other responsibilities, such as dispensing and other enhanced services (e.g. smoking secession). Therefore, there needs to be greater investment in staff and premises, for example, a second pharmacist or ACT. The participants also explained that the inadequate funding from WG was a barrier to increasing the number of IPPs in community pharmacies. Although they knew of many pharmacists who would like to be qualified as IPPs, they explained that the money only allowed them to train a few pharmacists every two years, and ideally, if more funding was available, they would train pharmacists annually.

'I think unless we can change the way in which this service is funded long term, we're never really going to be able to get the maximum benefit out of it. So, for example, we have 23 pharmacies in [HB]; we probably couldn't afford to have more than three or four of those provide an acute independent prescribing service in the way that we already have, because it would just spend too much of our allocated budget.' CPL2

One of the aspects that was associated with achieving the vision was the education and training of pharmacists to undertake the independent prescribing role. Both CPLs highlighted that HBs supported pharmacists to do the course at the most convenient location of their choice, as the courses were available in different areas across Wales. They also discussed the feedback that they received from pharmacists who had undertaken the course, with one CPL explaining that this was the only feedback they could use since they hadn't undertaken the course themselves. Both CPLs had received positive feedback on the course in general; the IPPs gained further knowledge, skills, and confidence to prescribe within their therapeutic area. IPPs explained that their consultation skills and general advice had changed to provide more holistic care. However, one CPL highlighted the need for more content on

therapeutics since some IPPs reported that as a negative aspect.

'The negative feedback I've had is about maybe a lack of therapeutic advancement within the IP [independent prescribing] course itself. And I know ... that's not what the IP course is necessarily designed to do, but if we could do something about that, I think it would be helpful.' CPL2

The feedback of IPPs on their training experience with their DSMPs was also reported to CPLs, which was deemed to be positive in terms of the knowledge and skills gained from them. However, some IPPs, in preparation for the course, reported difficulty in finding DSMPs, particularly within their local areas. Both CPLs believed this reflected how some pharmacists did not have an established relationship with local doctors. They highlighted that they would support their pharmacists to find DSMPs from different sectors if they were not able to identify one. However, one CPL added that they would prefer to allocate DSMPs from GP practices to train IPPs in order to build the relationship between these settings and community pharmacies and be familiar with the nature of their patients. Another reason for the difficulty in finding DSMPs was related to capacity issues, with the high demand for their training services by all different HCPs. Both CPLs added that the legislation is changing to allow IPPs to be DSMPs (DPPs), which could help to overcome this issue but would still not replace the knowledge base that a GP provides to them.

'We have got involved where no DSMP is readily available, so for example we've identified a hospital doctor that can act as a DSMP ... It's not the best option for us, because it doesn't help to build relationships with the local GP practice, and the kind of patient group that they'll be seeing in hospital is very different from the patient group they'll be seeing in the community ... I know it's not just pharmacists that face this challenge ... we certainly had feedback from our local midwives that they find it very challenging to identify DSMPs, because GP time is limited.' CPL2

The funding for DSMPs to train IPPs was another challenge within the participants' HBs. They indicated that some GPs who had a good relationship with the IPP trained them without receiving remuneration. These GP practices were hugely supportive of the whole process because they recognised the positive impact of IPPs within the primary care sector. Whereas DSMPs who trained other IPPs, particularly from the new cohort, received remuneration from the HB, which they had not accounted for within their budget. They believed there was a need for a national solution to help provide the necessary training to all HCPs who are going to be qualified as IPs.

'To identify DSMPs ... to support IPs is perhaps challenging. There may be needs to be a national programme of high-quality DSMPs that are funded for the skills that they pass on.' CPL2

Another important aspect of this vision was IPPs accessing patient information to effectively do their role. Both CPLs identified that access to patient records was lacking as some GP practices were concerned with the General Data Protection Regulation (GDPR) requirements of information sharing and the financial consequences associated with it if it was not managed appropriately. Once some GP practices understood the benefit of IPPs having access to the records, they were supportive and facilitated this initiative. The CPLs once again highlighted the need for national involvement to resolve this issue. Another challenge identified by CPL1 with accessing records was the provision of appropriate software and hardware (computers or laptops) to be able to access GP practices' patient records from community pharmacies.

'It's convincing the practices that it's in their interest to share the information with these IPs so that they can actually contribute to the care of their patients ... it took a lot of our time early on, to crack that one. We were a bit lucky, because ... we were choosing practices that the health board was running at the time, so it was within our gift to share the information. So were the data holders, so we could do that.' CPL1

6.5.1.3.2. Local implementation and strategies

This theme identified the local implementation and strategies associated with implementing the role of IPPs in community pharmacies within the HBs. Both CPLs indicated that the process of implementation was slow and not well understood since it was still in its infancy. Therefore, it was challenging to design a clear plan. In addition, they highlighted the need for a strategy or framework for its implementation that involved cooperation between different stakeholders in primary care in Wales. This was to allow IPPs to immediately start their role and avoid delay once they complete their training.

'I think there probably does need to be a little bit more joined-up work between the university and the GPhC and the health board, and shared services, so that we can put processes in place so that as soon as someone qualifies, there's a clear pathway to getting that person - the information they need to become a prescriber and getting that person a prescription pad.' CPL2

One of the strategies that the HBs of these CPLs considered related to the remuneration for IPP services as national guidance was lacking. Therefore, they developed Service Level Agreements (SLAs) or used other HBs' methods to inform their approach to remuneration. The similarity between approaches both CPLs identified was providing remuneration for a limited range of IPPs' services per week. However, the remuneration methods were still different between these HBs. It was calculated based on the number of independent prescribing sessions in one HB, whereas it was determined by the number of consultations in the other HB. Both CPLs acknowledged that IPPs were always looking for more remuneration, but they used these approaches to make sure it was manageable within the HB capacity and budget.

'The other issues were, we didn't have a clue how much to pay for the service, right. So, we had to develop our own SLAs [Service Level Agreements] ... working with other health boards, because, you know, we wanted to have a similar cost structure ... There was a lot of debate about that. So that took a long time to put together.' CPL1

Another local strategy that was highlighted by both participants was related to choosing the scope of practice of IPPs. Both HBs decided that the IPPs' scope of practice would be within therapeutic areas of high demand and pressure. They highlighted that this helped in obtaining funding from WG. Some examples of the scope of practice were provided by both CPLs, including infection and opioid management. One CPL identified that the infection scope was chosen for new IPPs since there was a successful model of infection management implemented by an IPP in a community pharmacy within their HB. This model was associated with treating short-term uncomplicated acute infections that many GP practices were seeing regularly and included ear infections, UTIs, skin infections, and sore throats. All these could be managed by IPPs in community pharmacies instead of the patient seeing a GP. The opioid management scope of practice was needed by a HB to reduce the use of opioids for pain management and optimise patients' medicine withdrawal, which helped in minimising patient harm with these medications. Although both CPLs indicated that the scope of practice of their IPPs was dictated by them, one CPL identified that the HB was less prescriptive on the scope of practice of the second cohort of IPPs. They believed that going forward, the scope should be more related to the development of their pharmacists' skills and knowledge within their preferred therapeutic areas.

'Opioids are a huge issue for the whole of the country as well, so we directed him to get his training and scope of practice in those areas ... to work with the practices to actually withdraw medicines, weren't necessarily needed by patients.' CPL1

The HBs' strategy of choosing pharmacists to do this independent prescribing role was another local aspect that was identified by both CPLs. They indicated that it was directed by their HBs as a service-led development to use the specific IPPs' knowledge and skills in community pharmacies near GP practices that were under pressure and were willing to use their services. This involved a discussion between GP practices and the HB to identify clinical areas where IPPs could provide a positive impact and relieve pressure on GPs, without duplicating services. Thereafter, they identified pharmacists who would be willing and enthusiastic to be trained as IPPs to deliver their independent prescribing services on a robust and regular basis to provide them with ongoing financial support. This was because there was growing concern amongst pharmacy owners and HBs that when pharmacists qualified as IPPs they became employable by other sectors and therefore those individuals, and the money invested, would be lost.

'We looked at areas where our practices were struggling ... where there were service issues, where we had patients who weren't very happy with the level of services that we were giving from our practices. So, we picked practices within those geographical areas. The practices that we tend to pick would be those ones who really engage with us on delivery of enhanced services ... and really having the right person there, who could be developed as an IP really ... Another issue was ... out of the seven we trained, three of them left to become IPs in practices.' CPL1

Logistical challenges to the implementation of IPPs' role in this sector were highlighted by participants. One of the challenges was related to the difficult process of obtaining prescription pads for IPPs, which caused a delay in the implementation of the role. Both CPLs identified the challenge of funding equipment, such as laptops, software, and clinical assessment tools (such as otoscopes), from their budget as another issue. Therefore, they had to split the funding for this equipment with community pharmacies or GP practices. The final logistical issue was associated with the determination of the number of sessions for IPPs in community pharmacies, which was not clear since the demand for their services was still unknown.

6.5.1.3.3. Clinical governance

There were some aspects related to clinical governance identified within the interviews; these were ongoing education and training, patient involvement, and risk management. In relation to ongoing education, one of the CPLs identified that there was no professional guidance for the IPPs to extend their scope of practice. Such guidance was felt

to be helpful to both the IPP and the HB. The same CPL raised a concern as to how to commission a new IPP scope of practice. Another area related to ongoing training and education was the IPP CPD. One CPL believed that IPPs would self-direct their learning needs and development. Both CPLs indicated that they provide support to new IPPs to encourage them to continually develop their skills and knowledge. One CPL explained that IPPs identified the need for taking some courses, such as the minor illness course. This CPL added that the HB commissioned these courses to those current and newly qualified IPPs as it was very useful to their role. In addition to courses, another suggestion was ongoing peer support, such as establishing a forum for them, to help in the ongoing development of their knowledge and avoid being isolated in community pharmacies.

'They will ring and ask us for say minor illness training, which we are very happy to provide for them, so we are providing a three-day course for that. We are going to commission another course next year, out of next year's monies for that ... That gives them a chance to speak to their peers which is really important.' CPL1

Another clinical governance aspect was related to risk management in terms of accessing patients' GP records to practise their independent prescribing role safely. Although IPPs had only a 'read' access to all patients' information, such as laboratory results, medical and medication history, and allergy status; both CPLs highlighted the importance of providing IPPs with a 'read' and 'write' access to ensure that they were doing their clinical role, including prescribing medications, safely. They believed that this would help in preventing medication errors and interactions. Moreover, the ability to have a 'write' access was stressed to ensure that other HCPs who are providing healthcare services to patients, or if IPPs themselves are seeing the same patient again, have all the relevant information to make an informed decision on patient care.

'Ideally write access is important, because we have had instances where patients have attended the pharmacy, they've had a consultation, maybe they don't like the outcome of that consultation and they've gone straight to the GP practice. Well, by having the ability to write to the records, when that person sits down in front of the GP, the GP can go, 'Ah, I can see you've been to see the pharmacist, and the pharmacist examined you and said this. I'm completely in agreement with what they've said, you don't need to see me anymore.' CPL2

The final aspect of Clinical Governance was regarding patients' feedback. They identified that the feedback from patients was very positive on the role of IPPs in community

pharmacies as it provided them with safe and effective services that they valued which, as CPLs, had exceeded their expectations.

'The feedback from patients is phenomenal ... that is meeting the needs of that local population. So yeah, we've, you know, we've not had any safety issues, the pharmacist has been comfortable, they've been - as far as we are aware, they've been managing things appropriately without clinical risk. We think it's been a, you know, a good use of funding.' CPL2

6.5.1.4. A summary of the community pharmacy leads' results

The summary of the findings is as follows:

- Both CPLs were supportive of the vision for primary care, including IPPs in community pharmacies and felt it represents the future of the pharmacy profession. They believed it had a positive impact, but the service could be expanded further.
- There were some challenges related to the 2030 Welsh Pharmaceutical Committee's vision (2019). There was no clear plan provided to the HBs to implement the role, a lack of access to patient records, the need to promote the role, and the inadequate funding for remuneration of their services and training of more pharmacists. CPLs felt that some of these challenges should have been addressed on a national basis to ease its implementation.
- Some local HB challenges were the process of obtaining prescription pads, funding equipment, and determination of the independent prescribing session number for IPPs in community pharmacies.
- HBs usually chose the scope of practice of IPPs within therapeutic areas of high demand and pressure on GP practices and that pharmacists were keen to train as an IPP.
- CPLs reported that the independent prescribing course and DSMPs training experience of IPPs was positive. However, they felt that more therapeutic content was required.
- Some aspects related to clinical governance were highlighted by CPLs, in terms of:
 - the lack of professional guidance for IPPs to extend their scope of practice and continue their ongoing education and training,
 - positive feedback received from patients on this role, and
 - risk management as IPPs were limited to 'read' access to patients' GP records, which might impact their prescribing safety.

6.6. Discussion

This study aimed to explore the views and experiences of community IPPs on their new role as IPs in community pharmacies, as well as the views of CPLs. The findings provided positive feedback on the independent prescribing service, the prescribing course and further training, identified enablers and challenges for their role, and the future of the role in community pharmacies.

The findings of this study and two more recent studies (Mantzourani et al. 2023; Parsloe et al. 2023) revealed that the role of community IPPs in Wales is mainly related to managing patients with acute minor conditions, such as UTIs, respiratory infections, and sexual health conditions. Mantzourani and colleagues (2023), as identified in the literature review in Chapter Two (Section 1.2.5), carried out thirteen interviews with nine IPPs and four commissioners in community pharmacy settings in Wales to explore their views on their role as part of the pilot module of the IPS. The participants believed that the role of IPPs was convenient for patients, they had a good experience, and it increased patients' access to medical care. Parsloe and colleagues (2023) conducted a study at Cardiff University, which aimed to analyse the prescribing of IPPs in community pharmacies in Wales retrospectively from September 2019 to September 2022 using the CASPA system (N.B. the CASPA system. as highlighted in Section 4.7.5, was developed in 2019 to include prescribing data specifically from community pharmacy IPPs). The focus on acute conditions differs from hospital and GP practices, where chronic conditions have been reported to be the focus of IPPs (Hinchliffe 2015; Bourne et al. 2016; Courtenay et al. 2017; Alshehri et al. 2023). The variation in their scope of practice may suggest that IPPs have the skills and knowledge to provide healthcare services to patients across all sectors within different therapeutic areas. This, in turn, may help to improve patients' access to treatment and relieve some of the increased pressure on all healthcare settings, which is in line with the aim of introducing this role (Welsh Pharmaceutical Committee 2019). In other UK nations, studies were lacking in the literature exploring the role of IPPs in the community pharmacy sector. Worldwide, only two studies examined this role in community pharmacies, which also indicated the management of IPPs of acute conditions within this sector with a limited scope of practice compared to Wales as indicated earlier in Section 6.2 (Guirguis et al. 2014; Mansell and colleagues 2014).

The findings of this empirical PhD study also identified some drivers that allowed pharmacists to train as IPs. The major driver was the encouragement and availability of financial support from their HBs (Welsh Pharmaceutical Committee 2019). The financial support included payment for their independent prescribing course and DSMPs' (which have now changed to DPPs) fees by the HBs or WG, and for day release to undertake the training and backfill staff to cover their duties. Most participants were encouraged by their HBs to be

trained as community IPPs to overcome the increasing pressure on primary care services. In contrast, some of the community IPPs who participated in this study indicated that they personally wanted to be trained as IPPs to develop their profession. These findings were similar to a survey conducted by the GPhC in 2016 on IPPs who reported that they had obtained the prescribing qualification to personally improve their clinical skills, and the services provided to their patients (GPhC 2016), although this study was conducted in England a few years ago. Mantzourani and colleagues (2023) also pointed out the IPPs' satisfaction and enthusiasm with their role as IPPs in this sector in Wales. Other studies in the UK or other countries, as highlighted in the literature review (Chapter 2), provided similar results in terms of pharmacists' enthusiasm and drivers to be trained as IPs and carry out this role within community pharmacies (Tonna et al. 2010; Hoti et al. 2013; McIntosh et al. 2011; Hanna et al. 2014; Faruquee et al. 2018; Raghunandan et al. 2021a; Ibrahim et al. 2022; Kauser et al. 2022; Ghabour et al. 2023b).

Both community IPPs and CPLs indicated that feedback on the independent prescribing courses and training of community IPPs was positive and that they provided them with the skills and knowledge to do their prescribing role. However, they identified that there is a need for more focus on clinical examination skills for community IPPs to manage their patients more effectively, such as using a stethoscope and taking blood pressure manually. This finding is illustrated in the literature as many studies found that there is a need to develop the clinical examination skills of IPPs in the UK and other countries (Weeks et al. 2010; Hoti et al. 2013; Pojskic et al. 2014; GPhC 2016; Schindel et al. 2019; Kauser et al. 2022). Such a study was conducted by Schindel and colleagues (2019), which revealed that pharmacists needed additional training on clinical examination skills since most of the study participants (pharmacists with a prescribing qualification) lacked confidence in this skill. However, this study was conducted in Canada whereby the training of IPPs, including examination skills, is different from the UK. It is also important to note that different prescribing programmes in the UK also have different content on patient assessment skills. Some programmes cover only a few patient assessment skills while others offer a wide range of skills. The community IPPs and CPLs who participated in this study also identified that the independent prescribing courses should focus more on enhancing community IPPs' confidence and competence in consultation and patient's monitoring skills.

All participants in this empirical PhD study reported the positive impact of the DSMPs during their training as IPs. However, some community IPPs mentioned the difficulty in finding a DMSP to train them. Nevertheless, CPLs indicated that they usually support pharmacists to find DSMPs if they cannot find one themselves. The systematic review conducted by Noblet and colleagues (2017) also reported these difficulties with NMIPs, explaining the lack of DSMPs' time to train them and the lack of appropriate remuneration were contributory factors.

The GPhC also highlighted this issue in their report, which suggested allowing other nonmedical professionals who are NMPs to train IPPs to overcome this issue (GPhC 2016). A discussion paper conducted by the GPhC in 2016 aimed to obtain feedback from key stakeholders (prescribers, supervisors, pharmacy professionals, trainees, patients, public, education organisations, representative bodies, and health services organisations) across the UK on the extension of the supervision of IPPs in training to other IPs via the use of both online and hard copy questionnaires. They received 576 responses with 88% from individuals who were from the pharmacy profession, working across different healthcare sectors. Most of the participants (76%) agreed to extend the right of IPPs' supervision during their training to include experienced NMIPs, while 79.5% of the participants were in favour of extending the supervision to experienced IPPs, and only 67% to other IPs. Many respondents who were in favour of IPPs being supervised by experienced IPPs identified some reasons for making this selection, which were that they have been involved in significant training in pharmacology and therapeutics, they should understand the responsibilities and requirements of the supervisory role since they have successfully completed the same independent prescribing training, and they would probably have more time to train IPPs than medical mentors. However, a few participants were in favour of only medical professionals who could mentor pharmacists as IPs. Those participants identified some reasons for expressing this view, which were that the medical mentors have more broad clinical experience, as well as more training in patient examination, diagnosis, consultation, and evaluation. They also indicated that the medical professionals' training of pharmacists as IPs would provide external credibility to it and will ensure the safety of IPPs' practice. This is consistent with the views of some community IPPs and a CPL in this empirical PhD study who felt that the mentors needed to be doctors to obtain as many clinical skills from them as possible, while other participants felt that a multidisciplinary approach should be encouraged in the teaching institutions. In 2019, the regulations changed (as indicated in Chapter 1 Section 1.2.4) allowing for DPPs (other HCPs who meet the criteria) to train pharmacists as IPPs and provide them with workplace-based supervision (Royal Pharmaceutical Society 2019).

The impact of the community IPPs' role on themselves as well as other HCPs and patients was also illustrated by IPPs and CPLs in this study. The findings revealed that the role of community IPPs improved their job satisfaction. All participants, including IPPs who were not using their prescribing qualification at the time of the study, reported that the prescribing qualification enhanced their job satisfaction as it improved their knowledge, skills, and confidence. IPPs who started felt that the role had provided them with more clinical responsibilities, such as running clinics and assessing patients' medical conditions within their scope of practice. Furthermore, the findings indicated that IPPs considered their role as the most beneficial change in their pharmacy profession because it was a more patient-facing role

that helped to appropriately use their skills, which in turn may have improved patients' access to healthcare services and treatment. This was also reported in the study conducted by Mantzourani and colleagues (2023) in community pharmacies in Wales. In another study conducted by Hindi and colleagues (2019), it was found that all pharmacists in England undertaking independent prescribing also reported an increase in their job satisfaction. This empirical PhD study also highlighted the participants' views in terms of the impact of their role on other HCPs. Most participants believed that their prescribing services may have reduced other HCPs, particularly GPs, workload and provided them with more time to handle complex cases in their healthcare settings. Hindi and colleagues (2019) also reported similar findings, however, their study was conducted using questionnaires with a low response rate (5% response rate; 20 IPPs participated). This may not represent the perception of all IPPs in England, and the findings may lack a more detailed explanation by using questionnaires compared to qualitative research. Moreover, the participants of this study were working in GP practices, which may provide different findings in comparison to IPPs working in community pharmacies. Similar findings were published in a report in 2015 by NHS Wales, which indicated that the role of IPPs helped to free medical professionals' time and minimised hospital admissions rate (NHS Wales 2015). However, this report focused on the role of IPPs in secondary care settings. This is consistent with a study conducted by Mann and colleagues (2022) in England that evaluated the role of IPPs in GP practices. The results from the evaluation also indicated that patients had longer appointments with IPPs compared to GPs as they provided them with more information regarding their health conditions. The benefits of the role to patients were also reported in this study since it was perceived to provide patients with quicker care and thereby improve their healthcare. This was supported by findings obtained from the larger study conducted by Hill and colleagues (2014) that involved the participation of medical prescribers, pharmacists, and patients in examining the role of IPPs in addiction treatment settings in England. Patients reported they felt able to make extra appointments easily and they were given more detailed information with more time when they attended their appointments with IPPs.

Clinical Governance was a theme within the CPLs' findings. Clinical Governance is defined by Scally and Donaldson (1998; p.62) as 'a system through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish'. It involves seven pillars, which are patient involvement and experience, risk management, clinical effectiveness, resource effectiveness, communication, learning effectiveness, and strategic effectiveness (Grey 2005). With respect to patient feedback, both CPLs believed it was positive regarding the independent prescribing role. Similar views were reported by patients in the study conducted by Alshehri and colleagues (2023) and Hill and colleagues

(2014) in England, where the IPPs managed chronic medical conditions. As there is no current research on patients' views of IPPs in community pharmacy, it would be useful to undertake such research.

Another aspect associated with clinical governance was related to risk management in terms of patient safety concerns due to the lack of access to patient GP records by IPPs. Community pharmacy IPPs reported this as a significant challenge that limited many from practising their independent prescribing role. This challenge was also highlighted in the GPhC policies for IPPs, which acknowledged the need to access patients' records to provide safe practice (GPhC 2019). George and colleagues (2006) also reported this challenge in a study conducted in Scotland that aimed to explore the views of community pharmacists on independent prescribing services. The results of the study indicated that most respondents affirmed the need to access patient records to be able to prescribe medications safely for them. Although the number of participants in this study was high, it is considered outdated since it was conducted 15 years ago, and the IPPs' role and policies may have developed a lot during this time, but this barrier still existed at the time of the PhD study. In a more recent study by Zhou and colleagues (2019), the lack of access to patient GP records was also identified, which limited IPPs to utilise their independent prescribing qualification. Although the reviewed papers were not focused on the role of IPPs in community pharmacies and it was conducted not only in the UK but also in Canada, the same challenges were reported. In Wales in 2019, all HCPs who are engaging in patient care in primary care in Wales, including community IPPs, were provided with access to patients' GP electronic records (Welsh Pharmaceutical Committee 2019). This helped to address this issue through the digital WGPR of patients (NHS Wales 2023). However, some community IPPs and both CPLs who participated in this study pointed out the need to also have a 'write' access and not to be limited to a 'read' access to all patients' records. This was to enable them to write their medical notes to avoid any discrepancy or missing information that could harm patients when treated by them again or by other HCPs. This issue was also emphasised by the IPP participants in the study by Mantzourani and colleagues (2023).

Both community IPPs and CPLs in this study identified the main challenge to implementing the community IPPs' role as inadequate funding associated with remuneration for running their prescribing services and ongoing CPD and training. The results are supported by findings gathered following a review of 64 papers by Zhou and colleagues (2019) that aimed to investigate the barriers affecting the implementation of IPPs' role. Insufficient funding was a major barrier found to preventing IPPs from utilising or developing their prescribing role. Both CPLs and many IPPs in this PhD study stated a lack of clarity regarding the exact remuneration and number of independent prescribing sessions permitted as there was no nationally agreed scheme, which resulted in different payment approaches across HBs.

However, the WG changed the Community Pharmacy Contractual Framework in 2022 to direct funding to clinical services in this sector across all of Wales, including PIPS as highlighted in Chapter One (Sections 1.2 and 1.3.2) (Welsh Government 2022). As a result, the number of IPPs in this sector and their prescribing volume increased over the years. The findings of Parsloe and colleagues (2023) showed that the number of items prescribed by IPPs increased by more than 500% between the first quarter of 2020 (Jan-March 2020) and the Jul-Sep 2022 quarter, which may be related to the change in the contract. The largest prescribed volume of items was in BCUHB (25%, of the total prescribed items n=11,041) and the largest number of prescribed items per 100,000 population was in CVUHB followed by BCUHB. This may show that HBs that have the highest number of populations, including BCUHB and CVUHB, utilised IPPs' services in community pharmacies more than the others. A limitation of this study was that the time period the data represented was only three years, which may be considered a short period to understand the actual impact of the service. The increase in the number of IPPs' consultations over time (between June 2020 to September 2022) in community pharmacies in Wales was identified in the study conducted by Al Hussain (2022) as highlighted in the Introduction Chapter (Chapter 1, Section 1.3.2). Similarly, the number of consultations increased between May 2022 and May 2023 as presented in data obtained from Choose Pharmacy by the WG (Hodson 2023). However, a limitation maybe the lack of documentation for all consultations where a medicine was not prescribed, resulting in the number of consultations being underestimated. These studies also show the increase in the utilisation of this role in community pharmacies in Wales. However, the commissioning of the independent prescribing services in terms of the exact number of prescribing sessions to be funded is still an ongoing issue that needs to be addressed as also highlighted in the recent study conducted by Mantzourani and colleagues (2023).

Although most participants in this empirical study identified that they were highly supported, a few highlighted a lack of support from other HCPs particularly when they started. Although old studies that investigated the implementation of this role in its infancy across different healthcare settings in the UK identified this challenge (George et al. 2006; McCann et al. 2011), most of the recent literature (as indicated in Chapter 2, Section 2.2.5) highlighted that HCPs were supportive of this role (Hill et al. 2013; Tinelli et al. 2013; Weiss et al. 2014; Weiss et al. 2015; Nabhani-Gebara et al. 2020; Mann et al. 2022; Alshehri et al. 2023). However, the recent study that also explored IPPs' services within the IPS in community pharmacies in Wales also reported the need for more support for this role, specifically from the wider pharmacy team to take some of their non-prescribing responsibilities and reduce the IPPs' workload (Mantzourani et al. 2023). This empirical PhD study also highlighted high workload as a challenge to IPPs' role within this sector, which may have limited the implementation of some community IPPs' role. The high workload issue was also reported in

many studies conducted across different sectors in the UK as illustrated in the literature review chapter (Chapter 2, Section 2.2.5) (Bourne et al. 2016; Graham-Clarke et al. 2021; Graham-Clarke et al. 2022; Kauser et al. 2022). Therefore, these ongoing challenges need to be addressed by relevant bodies, such as by hiring or upskilling other HCPs (e.g., pharmacist technicians or ACTs) to take some of the non-prescribing duties of IPPs to allow them to focus on their prescribing role. The findings of this PhD study also highlighted the lack of a structured model for community IPPs that could help implement this role and achieve its vision in the community pharmacy sector in Wales. This involved the lack of a clear strategy concerning the arrangement of workforce and funding to facilitate proper functioning and development of the role. Similar findings were reported in the study by Zhou and colleagues (2019), which aimed to investigate barriers related to the pharmacist prescribing role by reviewing research papers in the UK, Australia, and Canada. They found that there was limited support from health authorities causing a lack of a structured model and strategies to guide the implementation of IPPs, which may create a series of barriers regarding the training, prescribing services, and the availability of support from other staff for IPPs.

Public perception lacked the understanding of community IPPs' services as reported by some participants, which was another issue identified within this empirical PhD study. Limited literature has explored the public perception of IPPs' role across different sectors in Scotland (Stewart et al. 2009b; MacLure et al. 2013), with no study conducted within community pharmacy settings as highlighted in the second chapter (Chapter 2, Section 2.2.5). These studies indicated the public's positive perception and awareness about the role of IPPs, highlighting their abilities and knowledge in conducting healthcare services. These studies may be considered outdated and lack the public perception of this role within the community pharmacy sector. As this issue has been reported by IPPs in this PhD study, further research may need to focus on examining recent public perception and understanding of this role to help develop it further.

An enabler to the implementation of the community IPPs' role that this study revealed was the services in community pharmacies that are already in place, such as the CAS (NHS Wales 2020). This may have provided community pharmacists with the confidence to obtain an independent prescribing qualification since it is the next logical step in their pharmacy practice. Some IPPs believed that the independent prescribing role represented the next natural progression to their pharmacy profession, which aligns with the findings of the second study in this PhD (Chapter 5) and a small qualitative research study conducted by Stewart and colleagues (2009), although the latter was published over 10 years ago. The Welsh Pharmaceutical Committee 2030 vision for primary care, including community pharmacies, was another enabler for the community IPPs' role based on the findings of this study. The Community IPPs in this study were optimistic in general about this vision since it supported

their training to become IPPs and be more involved in clinical patient care (Royal Pharmaceutical Society 2019). However, some community IPPs and both CPLs who participated in this study indicated that it is an ambitious vision that needs to be supported financially by the WG to be achieved. They identified the lack of funding by the WG as a major barrier to achieving this vision.

6.6.1. Limitations of the study

This study aimed to explore the views and experiences of community IPPs on their role, as well as the views of CPLs. Saturation was reached in the interviews conducted with community IPPs since no new information was added in the last three interviews (Krueger 1998). However, only two CPLs, who represented two HBs out of the seven, participated in this study (approval was obtained from five HBs). Communication with the CPLs and data collection were conducted during the COVID-19 pandemic, which may have limited the response of other CPLs.

Another limitation of this study was that ten interviews (nine with community IPPs and one with a CPL) were conducted via the telephone, which lacked face-to-face communication. This may have led to minimising good rapport with participants to obtain more details (Flick 2018). However, five interviews were conducted face-to-face and resulted in similar findings and as much obtained data as the interviews conducted via the telephone. Since the role was still new in community pharmacies at the time of the study, many community IPPs who participated in this study were waiting to start their prescribing services, which will have led to them only predicting the effect that independent prescribing will have on their profession and medical care in general. Moreover, some collected data, such as the impact of the IPPs' role on other HCPs was only perceived by the participants rather than evidenced.

6.6.2. Recommendations

Since the role of IPPs in community pharmacies is still relatively recent, a new study may need to be conducted in the future to further investigate its utilisation and understand the implementation of the WG's strategy for achieving the Welsh Pharmaceutical Committee 2030 vision by HBs. This may be helpful because it will highlight what has changed over time and will likely involve more community IPPs as their numbers have increased with time. The findings of this study may help suggest future recommendations for the role of community IPPs to improve its implementation and ensure its continuity. WG funding may need to be increased to enable community IPPs to continue utilising their prescribing role, encourage other pharmacists to undertake the prescribing qualification, and allow IPPs to provide more independent prescribing sessions. More support to IPPs might be needed by hiring and upskilling some other community pharmacy staff, such as pharmacist technicians and ACTs.

These staff could potentially undertake some of the community IPPs' responsibilities (e.g., dispensing and final checking of prescriptions) so that they can practise their prescribing role to a greater extent. WG and HBs may need to provide more support in terms of identifying DPPs to train community IPPs and offer IPPs with 'write' access to patient GP records so that they can include their medical notes and improve patient safety. A review of the teaching content of the independent prescribing courses might also be required in order to be tailored to their needs within the community pharmacy sector across Wales and the UK.

6.7. Conclusion

This study has explored various aspects related to the role of community IPPs. It has revealed the perceived benefits of IPPs' role within community pharmacies and its positive impact on themselves, other HCPs, patients, and primary care. It has also highlighted the challenges that could limit its further development. It has pointed out, from the participants' point of view, the need for additional support from WG, HBs, and other HCPs. The implementation of a community IPP service in each community pharmacy will achieve the 2030 vision, which aims to reduce pressure on primary care and improve patient care and access to treatment. However, several concerns, mainly related to inadequate funding and training of more IPPs in community pharmacies and the practicality of the proposed plans may affect the possibility of achieving this vision. In this study, recommendations have been suggested to overcome these concerns. Since this study was conducted at the infancy of this role, a new study is needed to investigate the development of this role within this sector over more recent years and whether the 2030 vision is being achieved.

7. Chapter 7 - General Discussion

7.1. Introduction

This PhD aimed to explore the IPPs' role in terms of its implementation and development in primary care settings in Wales (both GP practices and community pharmacies). The three objectives were to 1) evaluate the change in the numbers of NMIPs; including IPPs, and their prescribing volume in primary care over time; 2) explore the views of IPPs in GP practices on their independent prescribing role, and 3) investigate the role of IPPs within community pharmacies in Wales from the views of IPPs and CPLs within this sector. These research objectives were successfully achieved throughout three empirical studies. The purpose of this final chapter is to integrate the key findings from all the empirical studies within the wider context of policy and practice within the UK and worldwide. It will also discuss the methodological considerations, future work, and conclusion of the PhD.

7.2. The implementation and development of IPPs' role in primary care in Wales

In the UK, the demand for IPPs has changed over the last decade, particularly in primary care. The number of IPPs has increased in this sector as their contribution to patient care and healthcare services became more recognised by the Governments of the UK nations. Embracing the potential of IPPs was needed to utilise their skills efficiently, improve patient healthcare services, ease access to treatment, and reduce doctors' workload. This aligned with the second Crown report (DOH 1999) and the implementation policy of IPPs and INPs in the UK entitled 'Improving patients' access to medicines ...' (DOH 2006). In Wales, as identified in the first empirical study of the PhD (Chapter 4, Section 4.6.5.2), the number of IPPs who were actively prescribing in GP practices had increased over the study time (n= 16 in April 2011; n= 68 in March 2018), particularly since 2015 following the implementation of GP clusters (n= 20 in March 2015). During this period, their prescribing volume had also highly increased. As highlighted in the Introduction Chapter (Section 1.3.1), recent figures for IPPs in GP practices in other nations in the UK showed a similar trend as their numbers have continued to rise over the years (Wickware 2021; Burns 2022; NHS Wales 2023). Additionally, the number of IPPs in community pharmacies in Wales has increased since the published strategy of the Welsh Pharmaceutical Committee in 2019 that aimed to develop their role within these settings (as indicated in Chapter 1, Section 1.3.2) (Welsh Pharmaceutical Committee 2019; Hodson 2023). However, there is no published literature on the number of IPPs in community pharmacies in other UK nations to compare with Wales. In addition, it was impossible to compare IPPs' number and their prescribing volume between Wales, and the UK in general, with other countries worldwide. This might be related to the differences in the healthcare structure between the UK and other countries. In the UK, public healthcare services are funded through the NHS and provided at no cost to patients (NHS inform 2024). In

addition, in some nations, including Wales, Scotland, and Northern Ireland, prescriptions are dispensed free of charge, while in England patients pay a defined amount of money for each item on a prescription (£9.90 per item) (NHS inform 2024). There are therefore databases available in the UK designed for community pharmacy reimbursement purposes from freely dispensed medication to patients, such as CASPA in Wales (NHS Wales Shared Services Partnership 2021). In addition, some other databases, such as the Choose Pharmacy in community pharmacies in Wales, were designed to provide reimbursement and document healthcare services (NHS Wales 2020). These databases usually provide secondary data that can be studied to understand the nature and development of IPPs' prescribing. Other countries around the world mostly depend on healthcare insurance companies; therefore, they may lack the availability of such databases, as identified in Chapter Two (Section 2.3).

The literature review (Chapter 2) highlighted that the practice and extent of the pharmacist's role as an IP differs worldwide. The UK, including Wales, appears to be more supportive of the IPPs' role in contrast to other countries. As a result, most pharmacists in the UK are practising their prescribing services as IPs compared to a lot of other countries in which their prescribing role is limited and mostly conducted collaboratively. The UK Governments have not only supported the development of the IPPs' role, but also provided financial assistance for pharmacists to complete the training programme. In contrast, pharmacists in most other areas of the world need to complete self-funded postgraduate clinical programmes (Chapter 2). In the UK, the RPS published a new policy in 2022, which provided guidance for IPPs to identify further areas of improvement and expand their expertise and scope of practice to use the utmost of their skills (RPS 2022). Many other new developments were implemented in the UK to ensure the development of the IPPs' role and increase their numbers compared to other countries around the world (Chapter 1, Section 1.3.4). One of these developments was related to a change in the practice-based learning standards of pharmacists during their independent prescribing training in which DMPs (DSMPs in Wales) changed to DPPs. This change allowed doctors or other non-medical professionals who meet the specific criteria to supervise them during the required time in practice (GPhC 2021). The aim was to increase the number of appropriate professionals who could qualify as DPPs to share their clinical experiences with pharmacists and other NMIPs, thus increasing the training capacity. The RPS developed a competency and supporting framework for DPPs that outlined the skills and knowledge a prescriber needed to have to be a DPP (RPS 2023). Another updated policy was related to the competency framework for all prescribing professionals (RPS 2021), which outlined the essential knowledge, skills, and manners to prescribe safely and effectively.

Although the number and prescribing volume of IPPs have increased over time in different UK nations, the percentage of pharmacists who were qualified as IPs across all healthcare settings in 2022 was the highest in Scotland (34%) and Wales (29%) compared to

England (22%) (Burns 2022). This may reflect the policies from the Scottish and Welsh Governments around the role of IPPs in helping to deliver their health strategies (Welsh Pharmaceutical Committee 2019; NHS National Services Scotland 2023). Wales has ambitious plans to develop this role in primary care, including the development of a vision to adopt at least one IPP's services within each community pharmacy by 2030 (Welsh Pharmaceutical Committee 2019). However, Scotland was the first to implement IPPs' services in community pharmacies and to change their Community Pharmacy Contractual Framework in 2020 (NHS National Services Scotland 2023). In England, relevant bodies are still looking for Independent Prescribing Pathfinder sites to help identify the role of IPPs in community pharmacies as they plan to fully adopt and commission their services from 2026 (NHS England 2023). It would be interesting to see the results of these pathfinder sites, which may open a new horizon for this role in community pharmacies across the UK in the future. Northern Ireland is still the only nation, at this time, that has not planned for such a role within community pharmacies.

As outlined previously, the development of IPPs' role in primary care in Wales was driven by the WG plans, policies, implementation of primary care clusters, and vision for this sector, to provide high quality healthcare services for patients within their locality (The National Assembly for Wales 2010; Welsh Government 2015; National Assembly for Wales 2017; Welsh Pharmaceutical Committee 2019). As a result, the number of IPPs and their prescribing volume have increased in GP practices (as identified in the first empirical study, Chapter 5) and community pharmacies over the recent years (Burns 2021; Al Hussain 2022; Wickware 2022; Hodson 2023; Alshakmobarak et al. 2024). Chapter One (Section 1.3.2) described how the WG provided continued funding over the years, which is currently managed by HEIW (Mantzourani et al. 2023). The WG also changed the Community Pharmacy Contractual Framework in 2022 to support this role further by directing funds to clinical services in community pharmacies (Welsh Government 2022). The new contract, in addition to the IPPs' role, included other clinical services in Wales that can be conducted by non-prescribing pharmacists under Patient Group Directions (PGDs), which became effective in June 2024 (Welsh Medicines Information Centre 2024). The PGDs are specific written nationwide instructions that allow certain registered HCPs to supply and administer some medications to particular groups of patients without the need for a prescription by a doctor (Community Pharmacy Wales 2023; Welsh Medicines Information Centre 2024). The PGDs services provided by non-prescribing pharmacists in community pharmacies in Wales include CAS, Sore Throat Test and Treat (STTT), and the treatment of simple UTIs. These additional services were designed to enhance patient access to treatment and reduce the burden on GPs and other HCPs (Community Pharmacy Wales 2023). This showed the WG's confidence and recognition of the skills and capabilities of pharmacists within primary care. The change

in the contract also included the PIPS in community pharmacies (as outlined in Chapter 1, Section 1.3.2) in order to be provided on a national level instead of being determined by HBs (Chapter 6) (Community Pharmacy Wales 2023b). The PIPS service specification includes conditions mostly related to common ailments and contraception management. The aim was to provide more easily accessible, timely, and appropriate healthcare services to patients. The new contract may have influenced the increase in the number of community pharmacists to train as IPs to maintain the same amount of funding, particularly if they own their community pharmacies. This might be related to the fact that the amount of funding has not changed within the new contract but is directed to clinical services rather than dispensing. The Welsh Pharmaceutical Committee's collaboration with RPS Wales has also set out short-term goals for 2025 in response to the WG to ensure achieving the vision for 2030 (Welsh Pharmaceutical Committee 2022). The percentage target was to achieve an IPP in 30% of community pharmacies in Wales by 2023 (Welsh Pharmaceutical Committee 2019). However, only 13% was achieved in 2022 (Wickware 2022) and almost 16.5% in 2023 (Hodson 2023). Since these percentages do not reflect the goal for this role, it would be interesting to explore the reasons for not achieving it. Although inadequate funding was highlighted as a major barrier to implementing this role worldwide, HEIW in Wales has funded independent prescribing courses for pharmacists across Wales. In addition, HEIW also aims to provide the opportunity for all pharmacists who are involved with a patient-facing role across all sectors to be trained as IPs (NHS Wales 2023). Therefore, new studies should focus on investigating other challenges to adopt this role in accordance with its vision.

The utilisation of IPPs' services in GP practices in Wales significantly varied across different HBs as identified in the first empirical study (Chapter 4). HBs (BCUHB and HDUHB) with higher population figures (NHS Wales 2017) and GP recruitment issues (Brennan 2017; Jessup 2017; Jones 2017; Welsh Government 2018b), which also have the largest geographical areas, had a larger number of IPPs. These HBs had a higher number of prescribed items by NMIPs, including IPPs, compared to other HBs. The findings were the same despite calculating the number of prescribed items per 100,000 population to eliminate the impact of population size. Therefore, the higher number of prescribed items by IPPs in some HBs compared to others may be related to the number of GPs per 100,000 population. The lower the number of GPs per 100,000 population, the higher the number of IPPs to overcome the high demand. For example, BCUHB had the highest number of IPPs (n=28) compared to PTHB (n=2). While the number of GPs per 100,000 population in BCUHB (n=6.1) was lower compared to PTHB (n=7.7). Similar findings were reported in the community pharmacy sector in Wales (BCUHB 2023; Alshakmobarak et al. 2024), in which high demand for IPPs' services was indicated within these HBs to alleviate the pressure on GP practices. This variation in the utilisation of IPPs amongst HBs needs to be studied further in future

research to investigate the actual factors related to it. Such a study may help in sharing effective practices between HBs to improve the healthcare system and overall patient care across Wales.

The support of the WG to IPPs in recent years was not limited to their role within the primary care sector. The WG commissioned the RPS to undertake a report on clinical hospital pharmacy entitled 'Prescribing Progress: Transforming Clinical Hospital Pharmacy in Wales for Enhanced Patient Care' (RPS 2023). One aspect of this report focused on developing a job plan that could support the development of the pharmacists' profession, including the prescribing role. This was to enhance IPPs' integration into multidisciplinary teams, improve the quality of patient care, optimise medication management, and improve healthcare efficiency in secondary care settings. It also emphasised the importance of maintaining active prescribing, CPD through increasing their access to education and training opportunities and using technology to support clinical services and decisions. New Standards for Competency Assurance of NMPs, including IPPs, were also published by HEIW (NHS Wales 2023). It aimed to ensure their competency by keeping them updated on clinical and professional developments, particularly on their prescribing role. These new standards guide them in engaging with CPD and maintaining a portfolio that records their learning activities and evidences their competence. It also stressed the importance of employers in ensuring NMPs' access to relevant education and training courses and conducting annual appraisals. This was to ensure the safety and efficiency of their clinical and prescribing practice.

In 2024, the WG also published updated guidance for employers, managers, and practitioners in NHS Wales on different aspects related to NMPs' role (Welsh Government 2024). This guidance provides information related to competence, medicines that can be prescribed, education and training requirements, supervision in training, CPD, and professional liability of NMPs. This may highlight the significant support of the WG and different pharmacy professional bodies, including the Welsh Pharmaceutical Committee and RPS Wales, to this role. The actions taken by the WG and pharmacy professional bodies in Wales have contributed to the further development of the independent prescribing role of pharmacists in Wales across all sectors. This emphasises the importance of the IPPs' role, its benefits, and recognition of their capabilities in this nation. Wales's experience with this role may help provide a learning opportunity for other countries to utilise pharmacists' skills and knowledge and develop the pharmacy profession.

7.3. The role of IPPs within primary care settings in Wales

As identified in this PhD, the role of IPPs in both GP practices (Chapter 5) and community pharmacies (Chapter 6) was related to seeing patients, prescribing medication when needed, and responding to medication enquires. IPPs in GP practices were also running

clinics to manage patients with mostly chronic conditions and dealing with discharge prescriptions issued by doctors in hospitals. The findings of the first empirical study (Chapter 4) indicated that the most commonly prescribed therapeutic groups of medications by NMIPs, including IPPs, in GP practices in Wales were infections, cardiovascular, respiratory, CNS, and pain conditions. As argued in Chapter Four, the literature highlighted that prescribing for acute conditions (such as infections) in the UK at the time of conducting the PhD was likely to be conducted by INPs whereas IPPs were prescribing mostly for chronic diseases (e.g., cardiovascular conditions and pain management) (Latter et al. 2011; Courtenay et al. 2012; GPhC 2013; Drennan et al. 2014; Carey et al. 2017; Courtenay et al. 2017; Stewart et al. 2019; Savickas et al. 2021; Deslandes et al. 2022; MacVicar and Paterson 2022; Alshehri et al. 2023). Indeed, IPP participants in the second study (Chapter 5) confirmed they were mostly prescribing for chronic conditions in GP practices. Similarly, as highlighted in the literature review (Chapter 2), the scope of practice of IPPs worldwide in GP practices and hospitals was also related to the management of chronic conditions (Feehan et al. 2017; Faruquee et al. 2018; Banh and Cave 2021; Raghunandan et al. 2021a; Ghabour et al. 2023b; Grant et al. 2023; Norman et al. 2023; Percival et al. 2023b).

Interestingly, the independent prescribing role of pharmacists in community pharmacies in Wales, as reported by the participants in the third empirical study (Chapter 6), was mostly related to acute conditions, such as UTIs and respiratory infections. This is consistent with the new PIPS specification in Wales that identified their scope of prescribing, which involved a wide range of acute conditions, such as upper respiratory infections, and ear infections (Community Pharmacy Wales 2023b). In addition, recent literature that explored this role in community pharmacies in Wales reported the same scope of practice (Mantzourani et al. 2023; Parsloe et al. 2023). Community IPPs in Scotland were also prescribing for similar acute conditions (NHS National Services Scotland 2023), while in England their practice slightly differs as this role is still being explored in both chronic and acute areas of prescribing. through their pathfinder sites (NHS England 2023). Worldwide, particularly in Canada and the pilot services of IPPs in Australia, the focus of IPPs in community pharmacies is also associated with acute conditions, but within very limited diseases (Alberta College of Pharmacists 2021; The Pharmacy Guild of Australia 2022a; The Pharmacy Guild of Australia 2022b; Alberta College of Pharmacists 2023b; Alberta College of Pharmacy 2023c; Morton 2024). The acute scope of IPPs' practice in community pharmacies in Wales and Scotland aimed to improve patient access to treatment in areas of high demand since this sector represents the first point of healthcare contact (Community Pharmacy Wales 2023b; NHS National Services Scotland 2023). In Wales, there is still a need for prior agreement between HBs and IPPs regarding their scope of practice as indicated in the new PIPS (Community Pharmacy Wales 2023b). The prescribing of IPPs for either acute (in community pharmacies) or chronic (in GP practices) diseases is increasing over time in primary care in Wales, suggesting their capabilities to manage a wide range of patients' conditions.

The PhD identified that the management approach of IPPs to their patients' conditions within community and GP practices also differed. Within GP practice it was commonly seen that GPs diagnosed and pharmacists provided ongoing management of conditions, which may reflect the scope of IPPs' practice within chronic conditions in this sector (Chapter 5). The presence of other HCPs, particularly GPs, who were already diagnosing patients in GP practices may have been one of the reasons that prevented IPPs from making patient diagnosis. In some other cases, this was related to participants believing they had inadequate training in clinical assessment and diagnosis skills. For others, there were concerns about patient safety and a lack of indemnity insurance, although now the indemnity insurance issue for IPPs in GP practices has been resolved with the GMPI scheme (NHS Wales 2019). Community IPPs, however, were seen to be diagnosing within their scope of practice (Chapter 6). HBs provided IPPs with further training and CPD that was focused on clinical assessment skills after completing their prescribing course, which supported them to diagnose their patients within their scope of practice. For IPPs in GP practices, the training related to clinical assessment and diagnostic skills requires further research to investigate this matter on a bigger sample. This would help to explore if many IPPs feel the same and allow relevant bodies to understand such an issue. The lack of IPPs' clinical assessment and diagnosis skills was also reported in other nations in the UK (Blenkinsopp et al. 2008; Stewart et al. 2009; Stewart et al. 2010; Cooper et al. 2012; McCann et al. 2012a; Ibrahim et al. 2022; Hurley et al. 2023a; Hurley et al. 2023b; Roberts et al. 2023) and worldwide (Hoti et al. 2013; Pojskic et al. 2014; Bajorek et al. 2015; Feehan et al. 2017; Cheetham et al. 2022). As a result, further research is required to understand the reasons behind it across the UK and potential solutions. In addition, to investigate if this situation is still identified in GP practices or if the role has progressed in this sector to more of a diagnostician since the time of this PhD study in 2018/2019. There was also a variation in the clinical assessment and diagnostic skills within different independent prescribing courses across the UK. The GPhC does not list patient assessment skills needed for IPPs (GPhC 2021). IPPs may therefore require further CPD support or tailoring of the prescribing course for new candidates toward their clinical needs in each sector. Regarding the new graduate pharmacists in 2026 who will be prescriber ready, as outlined in Chapter One (GPhC 2021), NHS England Workforce Training and Education, in collaboration with the Pharmacy Schools Council, developed a new indicative curriculum to guide them in the Foundation Training Year (year 5) and MPharm programme (years 1 to 4) in England (NHS England 2024). This curriculum included an updated list of clinical and physical examination skills, based on a consensus study carried out by a UK university across various healthcare sectors to determine essential skills. Such a curriculum may help in making

a standardised training programme that includes defined clinical and physical examination skills across the UK, which may resolve the current inconsistency. However, there is a need to evaluate the appropriateness of the curriculum across different healthcare settings in all UK nations.

The findings of both qualitative studies (Chapters 5 and 6) highlighted another difference between the role of IPPs in GP practices and community pharmacies. Many IPPs in community pharmacies had not started their prescribing role at the time of the third empirical study (Chapter 6) compared to IPPs in GP practices who were all practising as IPs (Chapter 5). IPPs in community pharmacies faced two challenges during the implementation of their role, including a lack of appropriate funding and access to patient medical records. The inadequate funding was related to providing equipment (e.g., IT devices and software, and some diagnostic tools, such as stethoscopes) and remuneration for their prescribing services. However, as indicated in the Introduction Chapter (Section 1.3), the WG has been supporting the role through increased funding over recent years, which has helped provide the required equipment and remuneration. Similarly, the WG was keen on addressing the issue of patient medical records and has since provided pharmacists with access to all Wales patient records through the digital WGPR within Choose Pharmacy (NHS Wales 2023). This allows IPPs to access patient information, including medical and medication history, allergy status, and laboratory findings. Accessing patients' information allows IPPs to utilise their prescribing role as it helps ensure the safety of their practice by avoiding medication errors and discrepancies. The access issue to patient records by IPPs was also identified in other UK nations (Fisher et al. 2018; Graham-Clarke et al. 2021; Graham-Clarke et al. 2022; Kauser et al. 2022). It is also an issue in other countries in the world, as IPPs cannot access patients' records either in hospitals in Australia (Hoti et al. 2013; Bajorek et al. 2015; Cheetham et al. 2022) or in community pharmacies and hospitals in Canada (Famiyeh et al. 2019; MacDonald et al. 2023). This shows the recognition of the WG of the importance of accessing patients' records by IPPs to practise safely (Welsh Pharmaceutical Committee 2019). Other countries still need to review and reflect on the utilisation of this role to ensure that its appropriately supported and pharmacists have access to the required information to practise safely and optimise patient care. However, many community IPP participants emphasised the need for granting 'write' access to patient records to be able to add to the patient's medical notes and ensure patient safety when seen by other HCPs (Chapter 6).

7.4. Views of IPPs on their role in primary care in Wales

The views of IPPs in both GP practices (Chapter 5) and community pharmacies (Chapter 6) were highly positive. It was felt that the role allowed them to provide more clinical services and feel much more valued. They reported the benefits of prescribing on their

pharmacy profession, patients, and other HCPs, and were consistent with the literature (Chapter Two), where pharmacists worldwide appreciated such a role despite differences in its implementation and scope of practice (Borrego et al. 2006; Stewart et al. 2007; Cooper et al. 2008a; George et al. 2008; Tann et al. 2010; McCann et al. 2012a; Hill et al. 2013; Weiss et al. 2015; Fisher et al. 2018; Lio et al. 2018; Stewart et al. 2019; Seamon et al. 2020; Alshehri et al. 2021; Rafie et al. 2021; Raghunandan et al. 2021a; Rodriguez et al. 2021; Mantzourani et al. 2023). However, IPPs identified high workload as a challenge to their role, particularly in community pharmacies (Chapter 6). This may be related to the fact that there are not enough adequately trained pharmacy staff who could support other clinical and non-clinical services provided by IPPs. Although some non-prescribing pharmacists in community pharmacies deliver some new clinical services as a part of the PGDs services (Community Pharmacy Wales 2023a), the high workload issue of IPPs in this sector may have still not been resolved. Therefore, there may be a need for additional support by professional bodies to hire and upskill other staff such as second pharmacists, ACTs, and pharmacy technicians to undertake the other non-prescribing duties of IPPs. As part of using the skill mix of different HCPs in primary care, a new proposal has been revealed by the UK Government (Department of Health and Social Care 2024) to amend the regulations allowing pharmacy technicians in community pharmacies in Wales, England, and Scotland to supply and administer medications to patients under PGDs. This proposed policy could help improve their skills and competence, engage them within the wider teams, provide direct healthcare services that could increase patient access to treatment, and alleviate pressure and workload on other HCPs, including IPPs, in primary care. However, many community pharmacies do not always have pharmacy technicians working within their settings (Welsh Government 2024b). In addition, this proposed new service could increase the workload on pharmacy technicians, which may negatively impact their dispensing or accredited checking role. Alternatively, using technology may help free IPPs' time in community pharmacies to conduct more clinical services. New policies in Wales emphasise the need for utilising technology to develop healthcare services (Welsh Government 2015; Welsh Pharmaceutical Committee 2019; RPS 2023; Welsh Pharmaceutical Committee 2023). The WG would financially support the adoption of innovative automated systems, such as a dispensing robot, Automated Teller Machine (ATM) style prescription, or hub and spoke dispensing systems in community pharmacies (Welsh Government 2022; UK Government Department of Health and Social Care 2024b). The implementation of such systems may help improve community pharmacies' efficiency, increase clinical services provided by staff, and allow dispensed medications to be collected by patients 24 hours a day to improve convenience (Welsh Government 2022). Although automated systems may help with the workload of community pharmacy staff, the use of such systems might be still controversial (Wilkinson and Burns 2022). This is due to potential issues

that these systems may raise, such as not being able to complete full prescriptions or a lack of clarity regarding directions of medication use, which may negatively impact patient safety (Wilkinson and Burns 2022). This may require further research to understand the impact of using technology on the workforce in this sector and the challenges associated with it since it may increase their workload instead of freeing their time.

The IPPs who participated in the PhD research also indicated a high acceptance of their role by other HCPs, particularly GPs, as they recognised the benefits of their services. This was also reported in the UK and literature related to other countries (Chapter 2). However, some other countries worldwide are still in their infancy of implementing the IPPs' role, such as Canada, or still piloting their services as in Australia. These countries are facing some resistance from medical professionals to their pharmacists' independent prescribing services, as highlighted in the Literature Review Chapter (Chapter 2). For example, GPs in Australia recently argued that the pilot services of IPPs in community pharmacies compromise patient safety (Dawson-Smith and Price 2023). They believed that the IPPs' role involved governance failures, inadequate training, conflict of interest related to profit from both prescribing and dispensing of medications and would worsen GP accessibility (Dawson-Smith and Price 2023). GPs emphasised the high potential for medication errors and inappropriate diagnosis by IPPs as they lacked the comprehensive clinical training that medical professionals undertake. Therefore, they highlighted the need for not allowing pharmacists to prescribe independently without their supervision. In the UK there was initial resistance by some GPs to the independent prescribing role of pharmacists (George et al. 2006; Hobson and Sewell 2006; Vracar and Bajorek 2008). However, this resistance has since been proven unfounded. The implementation of IPPs within an increasing number of practice settings and the success they have achieved has since demonstrated their worth. The UK nations' Governments also played an important role in increasing the acceptance of the role through formal policies related to its implementation. In Wales, the support and confidence of the WG in the pharmacy profession has helped in promoting the role both with patients and, importantly, with other HCPs, especially in primary care. Other countries may wish to reflect upon how Wales has driven this initiative and perhaps see it as a role model to learn from. However, as highlighted in the literature review (Chapter 2), there was a lack of literature investigating GPs' perceptions of the IPPs' role and its development in GP practices and community pharmacy settings, particularly in Wales. This represents a good opportunity for future research to focus on this matter to develop this role further.

7.5. Methodological considerations

The PhD provided important insights concerning the role of IPPs in GP practices and community pharmacies. An initial narrative literature review successfully summarised the

available literature and provided an understanding of pharmacists' prescribing worldwide. The literature review clearly identified a research gap about the role of IPPs in primary care settings in Wales. It involved searching through relevant databases using a pre-defined literature review question via the utilisation of PCC, keywords, a specific timeline of search, truncations, advanced Boolean (AND/OR), a specialist librarian in the pharmacy subject, and inclusion and exclusion criteria. This was to ensure the transparency of the review and make it as structured as possible in order to produce more rigorous findings.

Each study conducted in this PhD had its strengths and limitations, which have been discussed in detail in each study chapter. However, this PhD as a whole showed the value of using a mixed-methods study design that has a major strength in deeply understanding a phenomenon that has not been previously investigated (Mayoh and Onwuegbuzie 2013). This phenomenon was related to exploring the role of IPPs and its development in primary care settings in Wales. The benefits of using a mixed-methods approach have already been discussed in Chapter Three (Section 3.5.1). However, the use of multiple studies that utilise different study designs, data collection methods, and data analysis approaches has led to a better understanding of the investigated topic. In addition, the flexibility of the mixed-methods approach, in terms of involving both quantitative and qualitative approaches, resulted in producing data that has provided a broad understanding of the implementation of the role of IPPs in primary care settings, their prescribing role, their numbers and prescribing trends, and their views on their independent prescribing role.

The use of secondary data analysis in the first study (Chapter 4) successfully provided insights into the areas of practice of NMIPs', including IPPs, during the study time. It helped in describing their numbers and prescribing volume in primary care and the impact of primary care clusters. It was considered appropriate for this analysis to be conducted retrospectively, as it would not be possible to do so prospectively since the aim was to identify the number of NMIPs and their prescribing trend in primary care settings in Wales over time. Data were available to extract from the CASPA database from 2011 onward. The time period analysed (between 2011 and 2018) is believed to be long enough to explore the development of this role over time and included when GP clusters were implemented (2015). However, the CASPA system had some limitations as discussed in Chapter Four (Section 4.7.5), such as the inability to identify the profession of the NMIP and the system only capturing dispensed medications in community pharmacies. These limitations did not prevent the researcher achieving the objectives of this study. The acknowledgment of such limitations helps ensure the validity and integrity of the research.

The qualitative approaches in the second and third studies (Chapters 5 and 6, respectively) successfully collected rich data on the IPP participants' roles, experiences, and challenges in GP practices and community pharmacies. Chapter Six also explored the views

of CPLs on this role in community pharmacies. This highlights the strength of the interview schedule, which involved input from relevant key stakeholders in the field. Reaching saturation in these studies was another strength since no new information was obtained from participants during the later interviews. An exception was the CPLs' interviews as only two participants out of seven (one CPL for each HB; n= 7) responded to the study invitation which may have been impacted by the COVID-19 pandemic issue. However, rich data were obtained from these two interviews regarding the role of IPPs in community pharmacies. Another strength of these studies was the successful recruitment strategy used to recruit IPPs in both qualitative studies (Chapters 5 and 6). This was despite the small size of the study population (IPPs) in GP practices and community pharmacies at that time. This included the use of gatekeepers, the recruitment letter for IPPs in GP practices being co-signed by the Welsh Chief Pharmaceutical Officer, and all participants from GP practices being offered an incentive (Amazon voucher).

7.6. Future work

The PhD provided empirical findings on the role of IPPs in primary care settings in Wales. Future work should focus on numerous aspects of this role as their number and prescribing volume have been increasing over time (Chapter 4). The new changes in the CASPA database, which were highlighted in Chapter Four (Section 4.7.5), allow for the identification of the NMIP's profession and their practising area in primary care settings (Parsloe et al. 2023; Alshakmobarak et al. 2024). As a result, an updated secondary IPPs' prescribing data analysis over a longer time would be a good opportunity to specifically understand their prescribing patterns over recent years in both community and GP practices. This includes the number of prescribed items and BNF chapters and categories. Other data that can be used to understand the specifics around IPPs' prescribing in community pharmacies in Wales is through the Choose Pharmacy platform, where each consultation is logged (Al Hussain 2022). Such data could be used to understand IPPs' prescribing over a longer period than the study conducted by Al Hussain (2022), as the role is more established in community pharmacy settings and the number of prescribers has increased. The data from Choose Pharmacy provides more patient details, such as age, gender, time, and date of consultations, diagnosis, and medication prescribed, which may help investigate the role of IPPs at a patient level within community pharmacies and compare the conditions being treated against the IPS.

This PhD recognises the development of the IPPs' role, number, and prescribing volume. The next logical area for investigation is potentially patient outcomes associated with the role of IPPs in GP practices and community pharmacies. This is believed to be important, as it may provide more information on the difference that IPPs could make to patients. Such a difference might be through understanding whether patients required further treatment by

their GPs after having a consultation with IPPs in both settings. It might be conducted by calling patients after IPPs' consultations to investigate if the treatment provided is working or not. Another potential option might be through linking the data of patients' consultations in community pharmacies with their GP practice data to see if they had unsuccessful consultations or untreated medical conditions by IPPs. This would require the IPS data in the Choose Pharmacy platform to be linked with GP practice databases through a databank, such as the Secure Anonymised Information Linkage (SAIL). If this was possible, patients' outcomes and their GP visits post-IPPs' consultations in community pharmacies could be evaluated. The SAIL databank is a rich and reliable data source funded by Health and Care Research Wales (SAIL Databank 2021). It could support research since it is based on linking the data from patient and public records through active partnerships with the WG and NHS information agencies to allow the secure and remote accessing, linking, and analysing of routinely collected health and population data (SAIL Databank 2021).

Most IPPs in the qualitative studies in this PhD (Chapters 5 and 6) had a perception that their patients were satisfied with their role and the services they provided. Therefore, investigating patients' satisfaction and views on this role might also be an interesting area to explore, particularly with the significant development of this role over recent years. The narrative literature review in this PhD (Chapter 2) identified some studies that explored patients' perceptions of the IPPs' role in the UK. Most of these studies were conducted between 2009 and 2012 (Stewart et al. 2009b; Hobson et al. 2010; Gerard et al. 2012; and McCann et al. 2012a) and only one was a recent study (Alshehri et al. 2023). These studies were conducted in different nations in the UK, but not in Wales. As a result, it would be interesting to explore patients' perceptions of this role, their access to medical services and treatment provided by IPPs compared to GPs, and patients' satisfaction with IPPs' consultations. Such a study can be conducted by interviewing patients initially, which may help to inform the development of a questionnaire that can be accessible to patients via an online form (e.g., Microsoft Forms), QR code, paper form, or any other option to allow inclusivity. IPPs in primary care settings could be recruited to act as gatekeepers to distribute the questionnaire. Another option might be via the use of a general database, such as HealthWise Wales that allows any member of the public in Wales to sign up to this website and be informed of research (HealthWise Wales 2023). This may help to eliminate any potential bias from IPPs when they distribute questionnaires to patients. At Cardiff University, a PhD student is currently exploring patient views, feedback, and satisfaction with the IPS service provided by community IPPs in Wales. This study is still in progress and stemmed from the findings of the literature review of the PhD that identified a gap in research regarding this topic in Wales, as well as the empirical qualitative studies that provided rich information about the perceived feedback of patients on IPPs' role in the primary care sector.

The views and perceptions of different stakeholders and other HCPs on the IPPs' role and assessing their dynamics within the interprofessional teams could also be an important research topic. This is because the findings of the qualitative studies (Chapters 5 and 6) showed that most IPPs felt they were supported by other HCPs, particularly GPs, and other stakeholders. However, the narrative literature review (Chapter 2) identified only a few studies that explored the views of other HCPs and stakeholders on the role of IPPs that were not conducted in Wales (Blenkinsopp et al. 2008; McCann et al. 2012b; Hill et al. 2013; Maskrey et al. 2018; Ibrahim et al. 2022; Johnson et al. 2022; Hurley et al. 2023a; Hurley et al. 2023b). Negative views by doctors on the role of IPPs were reported in two studies (Blenkinsopp et al. 2008; McCann et al. 2012b), while doctors' views in Hill and colleagues' (2013) study, as well as more recent studies (Maskrey et al. 2018; Ibrahim et al. 2022; Johnson et al. 2022; Hurley et al. 2023a; Hurley et al. 2023b) were mostly positive. As this role becomes more established and recognised in GP practices and community pharmacies in Wales, it would be useful to explore doctors, other HCPs, and relevant stakeholders' views since the literature lacks a study in this nation. Such a study could be conducted via surveys and/or interviews. Stakeholders and other HCPs might be recruited via the use of IPPs, and GP cluster leads as gatekeepers to increase the response rate. A partnership with the GP cluster or using the GP practice network may also help improve the recruitment rate, after obtaining relevant ethical approval and offering feedback on the findings. Moreover, the use of different websites and social media (e.g., the Royal College of General Practitioners (RCGPs) and RPS to advertise the study may also help. These identified areas of future work might help provide guidance and evidence as to how the role can develop further.

7.7. Conclusion

In recent years, many countries around the world, particularly the UK, Canada, the USA, and Australia have extended prescribing rights to pharmacists in different ways. However, evidence suggests that the role of pharmacists as prescribers, particularly as IPs, was effectively adopted to a greater extent in the UK compared to other countries. This PhD aimed to explore the development of the NMIPs' role and their number in primary care settings in Wales, with a focus on the role of IPPs in GP practices and community pharmacies. The findings showed that the number of NMIPs, including IPPs, and their prescribing trends in GP practices in Wales has increased over time. The role of IPPs in GP practices has evolved since the WG plan in 2015 that aimed to develop the primary care sector and implement GP clusters. More recently, the role of IPPs evolved in community pharmacies in Wales and Scotland. The development of this role in community pharmacies in Wales resulted from the WG's strategy for primary care, in response to the 2030 vision published by the Welsh Pharmaceutical Committee in 2019. This showed an early recognition of the Welsh and

Scottish Governments of the IPPs' capabilities and skills in the community pharmacy sector. IPP participants in this PhD believed that the implementation of their independent prescribing role in primary care settings may have resulted in an improvement in the healthcare system and patient care. They also expressed that their role enhanced levels of prescribing, medication reviews, managing chronic and acute patient conditions, their professional development and job satisfaction, and other HCPs' practice. Most participants indicated that their role also helped reduce the pressure on GPs and other healthcare settings. The role of IPPs in community pharmacies was related more to acute conditions, while the practice of such professionals in GP practices was more associated with chronic conditions. Many of the identified challenges to the role have already been resolved. However, there is still a need to focus on supporting IPPs further, particularly in community pharmacies, to enhance their workflow by upskilling pharmacy technicians and other staff to ensure the appropriate skillmix for a community pharmacy providing an independent prescribing service. The new WG's plans for the primary care sector, the Welsh Pharmaceutical Committee's vision, and the new HEIW Pharmacy Workforce Plan could help to develop the role and maintain its sustainability. Future research should focus on further investigating IPPs' prescribing patterns in both GP practices and community pharmacies in Wales over a long time, patient satisfaction with the role of IPPs in these areas, clinical outcomes of patients associated with the IPPs' role, and the views of different stakeholders and other HCPs on the role.

8. References

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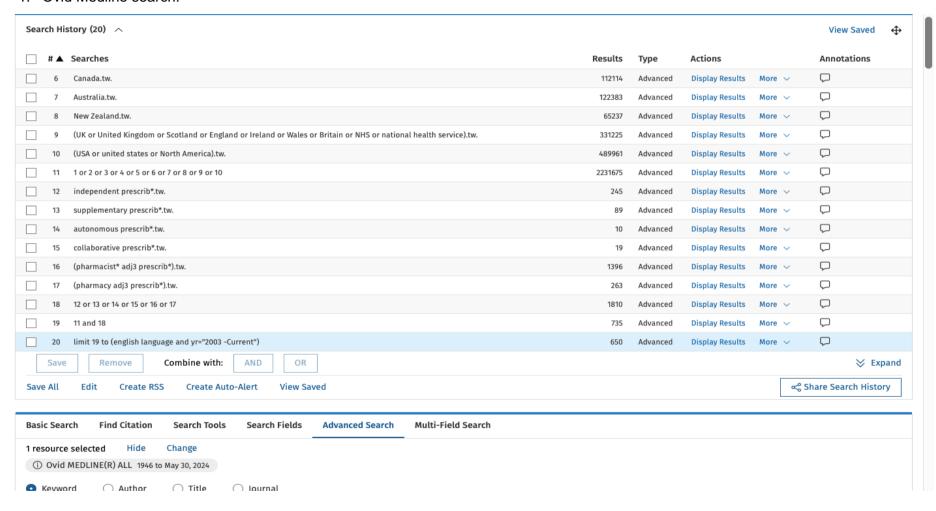
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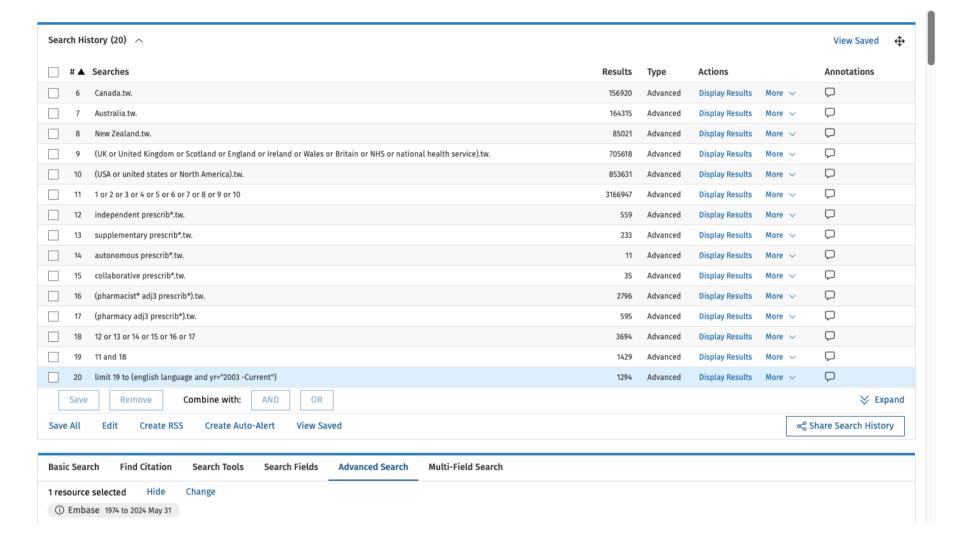
9. Appendices

Appendix 1: Screenshots of the databases' search:

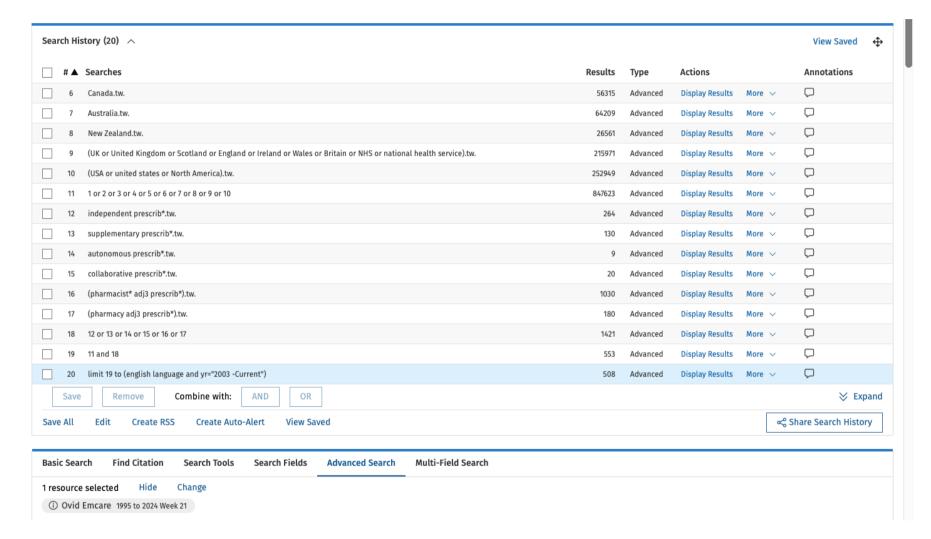
1. Ovid Medline search:



2. Ovid Embase search

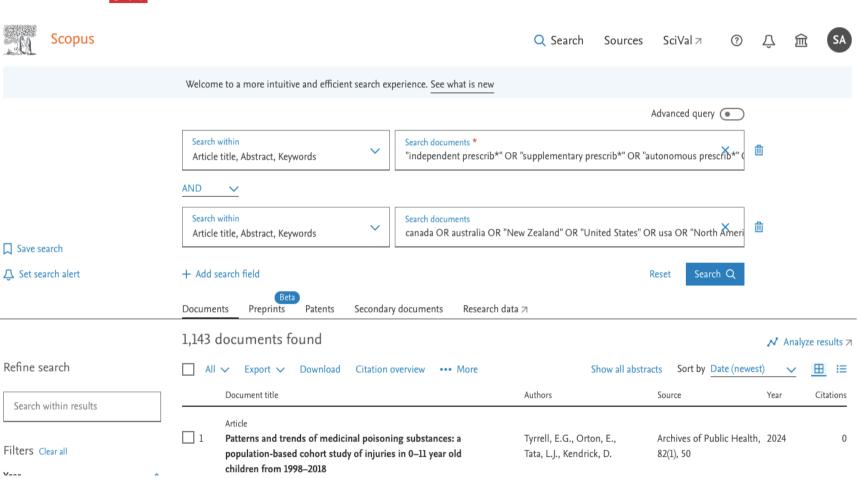


3 Ovid Emcare search

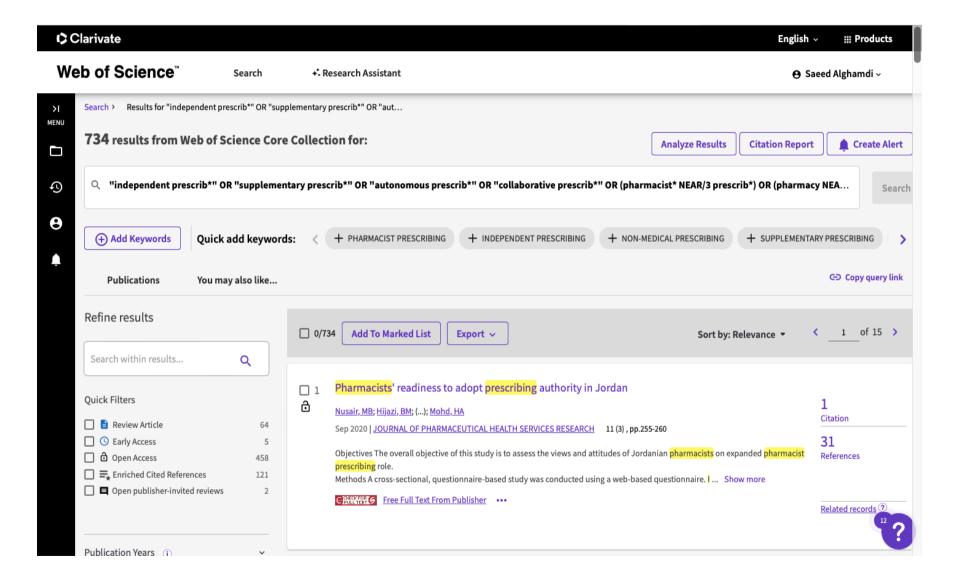


4. Scopus search





5. Web of Science search



Appendix 2: Keywords used to conduct the literature search

Keywords
S1) Canada/
S2) Australia/
S3) New Zealand/
S4) exp United Kingdom/
S5) United States/
S6) Canada.tw.
S7) Australia.tw.
S8) New Zealand.tw.
S9) (UK or United Kingdom or Scotland or England or Ireland or Wales or Britain or NHS
or national health service).tw.
S10) (USA or united states or North America).tw.
S11) 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10
S12) independent prescrib*.tw.
S13) supplementary prescrib*.tw.
S14) autonomous prescrib*.tw.
S15) collaborative prescrib*.tw.
S16) (pharmacist* adj3 prescrib*).tw.
S17) (pharmacy adj3 prescrib*).tw.
S18) 12 or 13 or 14 or 15 or 16 or 17
S19) 11 and 18
S20) limit 19 to (english language and yr="2003 -Current")

Appendix 3: The inclusion and exclusion criteria of literature search

Inclusion criteria	Exclusion criteria	Justification	
All types of primary research	Non-empirical, secondary, and grey literature.	To include only evidence-based and peer-reviewed empirical studies	
Full peer review articles	Abstract or conference papers	Full details and results required	
Studies related to pharmacist prescribing role	Studies related to other pharmacists' professions or evaluating specific services that are not related to the IPPs' role.	To address the project focus and literature review question, which is to identify empirical studies on the pharmacist prescribers' role in the USA, Australia, New Zealand, Canada, and UK.	
Studies conducted in the USA, Australia, New Zealand, Canada, and UK	Studies conducted outside these countries.	Since the pharmacist prescribing role mainly implemented in these countries.	
Studies reported in the English language	Studies reported in other languages.	The main and official language in the USA, Australia, New Zealand, Canada, and UK is English	
Studies published from 2003 to May 2024	Studies published before 2003	Because the initiation of the pharmacist prescribing role was in 2003 in the UK (DoH 2006)	

Appendix 4: The Honorary Contract (Study 1, Chapter 4)



CARDIFF AND VALE UNIVERSITY HEALTH BOARD (UHB)

HONORARY CONTRACT

Name: Saeed Alghamdi

Position: PhD Student

Dept/Directorate: AWTTC, CD&T

Clinical Board: AWTTC

Date of Commencement: 1ST March 2018

Date of expiry of Contract: 31st December 2018

Responsible to: Kath Haines, Head of WAPSU, AWTTC/CD&T

1. Standards of Conduct

You are required to ensure that your conduct and practice whilst at work are of the highest standard at all times, ensuring that any work you undertake is carried out in line with the agreed protocols, ensuring the integrity and confidentiality of patient, clinical and other records, and for reporting any events, incidents or misconduct through the appropriate systems, in line with UHB policy.

This includes complying with the appropriate code of conduct pertaining to your chosen profession.

Certain offences constitute unacceptable behaviour and must not be committed. You are required to observe the rules of behaviour that apply to all UHB staff, and any breach of these rules may lead to disciplinary action up to and including withdrawal of your honorary contract in accordance with section 2 below.

Discipline

All cases of alleged misconduct will be referred back to your **Employer / Academic Body** (where such a body exists) for the appropriate action. However, in cases of serious misconduct, the UHB reserves the right to suspend your Honorary Contract pending the outcome of any investigation. Any individual found guilty of a serious breach of conduct or rules will have their honorary contract withdrawn.

You should ensure you are aware of your Employer / Academic Body's policy for dealing with misconduct.

3. Confidentiality

At Cardiff and Vale University Health Board, we strive to provide the best quality care for patients and the highest standard of service to staff and managers. Respect for the confidential nature of personal information is fundamental to both these aims. You must, at all times, be aware of the importance of maintaining confidentiality and security of information gained by you during the course of your Honorary Contract. This will, in many cases, include access to personal information relating to service users. You must treat all information, whether corporate, staff or patient information, in a discreet and confidential manner in accordance with the provisions of the Data Protection Act 1998. Therefore, all information and matters of a confidential nature must not be divulged or passed on to an unauthorised person(s) or a third party under any circumstances, either during or after your Honorary

Contract with the UHB. Confidential information may therefore only be divulged in the proper course of your work undertaken during your Honorary Contract or as required by law, by the UHB or both. Such matters will include without limitation:

- clinical and patient identifiable information, including all and any details relating to the treatment and care of patients;
- · all and any personal information, including for example employees' confidential records;
- all and any business and commercial information, including for example, details of contract prices and terms.

Under no circumstances may any information be given to representatives of the media on any subject concerning the UHB's services, facilities, its patients or staff, without authority vested in the post or permission specifically given by an officer of appropriate seniority.

If you are unsure about the use or sharing of patient information, seek advice from the Cardiff and Vale UHB Caldicott Guardian.

Breach of confidentiality is viewed most seriously by the UHB and your Honorary Contract could be terminated immediately should this occur. Breach of confidentiality could also result in possible legal action by other organisations or individuals.

4. Access to UHB information systems

Security of information systems is important and access can only be granted to fully identified, system trained individuals that have the correct permissions.

Before you can access an information system e.g. PMS, the UHB authorising manager must complete the processes to:

- Issue you with a NADEX number
- Enable you to undertake the required level of training for the IT system(s)

You must

- · Sign an IT security declaration form
- · Have a system password.

You can **NOT** access any system until this is all in place. You cannot use another member of staff's password – of any seniority.

Passwords

The use of passwords is set out in the IT Security Policy and procedures.

As an Honorary contract holder you must:

- · Have your own password
- Not share it with anyone else

Breach of information/|IT security is viewed most seriously by the UHB and your Honorary Contract could be terminated immediately should this occur. Breach of information/|IT security could also result in possible legal action by other organisations or individuals.

5. Performance and Development

Your Honorary Contract is issued in the belief that you have been trained or will have received training or are qualified and/or skilled for the work in which you are engaged and it is expected that these skills will be consistently demonstrated during the course of your honorary contract.

At no time should you work outside of your defined level of competence. If you have concerns regarding this, you should immediately discuss them with your supervisor. You have a responsibility to inform your supervisor if you are not competent to perform a duty.

6. Health and Safety

In accordance with the provisions of the Health & Safety at Work Act 1974, the UHB undertakes to ensure, so far as is reasonably practicable, the health, safety and welfare at work of all its staff, including honorary contract holders. Such provisions are included in the Health and Safety policy.

It is your duty as an Honorary Contract holder to take reasonable care for the health and safety of yourself and of others who may be affected by your acts or omissions at work. You are therefore required to co-operate with the UHB, to ensure that all and any health and safety requirements or duties imposed on the UHB are complied with.

Therefore, you are required not to intentionally or recklessly interfere with anything provided, including personal protective equipment, for the health, safety and welfare of staff at work or of patients or visitors. You are encouraged to bring to the attention of the appropriate manager any example you perceive of unsafe practice, arrangement, equipment, facilities or overall environment.

Any injury sustained by you as a result of an incident or untoward occurrence on UHB premises or in the course of performing your duties should be reported to your Manager and recorded on an Incident Form.

If you are found to have intentionally or recklessly interfered with or misused anything which may endanger the health, safety or welfare of any member of staff, patient or visitor it will be regarded as gross misconduct and may lead to the suspension of your honorary contract, and ultimately withdrawal of your honorary contract in accordance with section 2 above.

7. Occupational Health and Disclosure and Barring Service Checks

Your appointment may be subject to satisfactory pre-employment health assessment which may include where appropriate the need to comply with Hepatitis B Immunisation requirements.

Depending on the nature of your work, you may also be subject to a Disclosure and Barring Service Check, and will not be allowed to commence work until a satisfactory check has been completed.

Failure to comply with any pre-employment checks required to undertake your role will result in a delay in your commencement date.

8. Disclosure of Convictions, Cautions and Reprimands

If you are convicted or found guilty of a criminal offence you are required to inform your supervisor as soon as possible. Failure to disclose such convictions or findings of guilt will be investigated and may result in the termination of your Honorary Contract. This includes any charges or cautions.

At any time during the period of your Honorary Contract, you are required to inform your supervisor of any child protection or vulnerable adult investigations which you may be subject to, both inside and outside of the workplace.

Smoke Free Policy

Smoking is prohibited and you must adhere to the UHB Smoke Free Policy at all times. A copy of this policy is available from the UHB Internet site, your manager or the Human Resources Department.

10. Loss or Damage of Personal Belongings

No liability can be accepted for loss or damage to personal belongings.

11. Discovery and Inventions / Ownership of Information

The UHB wishes to stress that all information generated during the course of your Honorary Contract is the property of the UHB and remains so, irrespective of origin or authorship.

Subject to the provisions of the Patents Act 1977, any invention made by you in the course of your employment will belong to the UHB and you are required to co-operate fully with the UHB to enable it to protect the invention by letters, patent or otherwise howsoever.

12. Support and Supervision

The UHB will ensure that you are made aware of the relevant UHB policies, procedures and working protocols, and that you receive an outline of your role and responsibilities with clear objectives, during your placement.

The UHB will also ensure that you receive adequate advice, supervision and support to achieve these objectives, and to ensure that you are not put in a situation where you exceed your level of competence in performing your duties.

It is your responsibility to inform a supervising member of UHB staff if you are not competent to perform a duty

13. Promoting Diversity

The UHB is committed to promoting diversity. It recognises that discrimination is unacceptable and that it is in the best interests of the organisation and the population it services to utilise the skills of the total workforce. Failure to comply with or adhere to the Equal, Diversity and Human Rights Policy will be treated as misconduct and may result in the termination of your Honorary Contract.

14. Harassment / Dignity at Work

Harassment at work will not be acceptable in any form. Failure to comply with or adhere to the All Wales Dignity at Work Policy will be treated as misconduct and may result in the termination of your Honorary Contract.

Raising Concerns

If you ever have a concern that something untoward is happening at work and wish to report this to the UHB in a confidential manner, please refer to the Procedure for NHS Staff to Raise Concerns, a copy of which is available from the UHB Internet Site, your manager or the Human Resources Department.

16. Research Governance

Cardiff and Vale University Local Health Board manages all research in accordance with the requirements of the Research Governance Framework (Welsh Assembly Government, 2009). As an honorary contract holder with the UHB, you must comply with all reporting requirements, systems and duties of action put in place by the UHB to deliver Research Governance.

17. Professional Registration

The UHB currently operates a Professional Registration Policy which requires that, where appropriate, any professional staff holding a honorary contract with the UHB must be registered with the appropriate professional body.

The Employer / Academic Body will be required to verify and provide evidence of the individual's professional registration and qualifications prior to commencing their duties with the UHB.

The UHB regards it as the responsibility of the individual to ensure that they maintain their registration such as is necessary to enable them to practise their profession within the UHB.

18. Notification of Changes

You are required to notify your supervisor immediately of any changes that will affect your ability to undertake the duties associated with your Honorary Contract. You are also required to notify the Human Resources Department if your Honorary Contract ceases prior to its expiry date.

I hereby confirm that I understand and accept this Honorary Contract with Cardiff and Vale University Health Board on the terms and conditions set out above. I have retained a copy of this statement for my own information.

Signed....

Designation...

Honorary Contract Holder

Signed on Behalf of the UHB

Signed

Human Resources Officer Workforce and OD Directorate

Appendix 5: Reviewers' comments (Study 1, Chapter 4)

- Reviewer 2's comments: I am not familiar with using ARIMA and this paper would benefit
 from being reviewed by someone with knowledge of the technique to ensure that the
 results are presented in the most appropriate manner.
- Reviewer 4's comments: I am not sure the statistical analysis is correct. The description for ITSA does not appear to be correct. The ARIMA component is used to describe the residuals of a regression model, plots of the ACF and partial ACF are probably best as part of supplementary material but would demonstrate the rigor of statistical analysis and ideally included. The regression model should be fully specified, outlining the phase period, intercept, trend, interaction etc.
- Reviewer 5's comments after submitting the new analysis (ordinary-least squares regression) to the journal instead of the ARIMA analysis: I prefer the OLS [ordinary-least squares] approach for ITS analysis reported in this version to the ARIMA approach previously used. The analytical framework and model is clearer and, as a result, the results more interpretable relative to using ARIMA and the use of robust standard errors/auto-correlation lag structure is sufficient to address any concerns about the errors being properly estimated.

Appendix 6: The ARIMA analysis of the NMIPs data (Study 1, Chapter 4)

9.1. The methodology of the ARIMA analyses

The ARIMA analyses were conducted by following the Cochrane Effective Practice and Organisation of Care (EPOC) guidance (2017). The IBM SPSS software (Version 25) was used to conduct the ARIMA statistical analysis. The change in the trend and level of prescribing by NMIPs and medical prescribers were examined. The difference in slope between the pre- and post-intervention regression lines is the change in the trend. Whereas the change in the level, which is also known as a step change, is the difference between the outcome at the first post-intervention time point and that anticipated by the pre-intervention trend. In order to understand whether the changes in prescribing over time occurred at a gradual or abrupt onset, the step changes were observed at five time points after the intervention (3, 6, 9, 12 and 24-month time points). One of the major advantages of the time series analysis is that it allows for the changes to be presented graphically in order to enable visual inspection of these changes over time (Wagner et al. 2002).

The difference between pre- and post-intervention prescribing trends (interact), as well as the numerical values for the pre-intervention prescribing trend (time point) are given in the parameters of the SPSS ARIMA model. The post intervention prescribing trend resulted from the sum of these values. Time point was calculated to identify the underlying pre-intervention prescribing trend. In addition, time point was used in all of the following analyses when calculating the intervention effect in order to ensure that the existing trend was considered. Whereas the SPSS 'Phase' numerical value illustrates the level effect of the intervention. This effect was observed at the five post-intervention time points (3, 6, 9, 12 and 24-months).

In a similar manner to the step changes observed at different post-intervention time points, a Bonferroni adjustment can also be used for multiple comparisons. This is to reduce type 1 error, which is that the high probability of a statistically significant value that may occur by chance following multiple analyses that were applied on the same variable (Sedgwick 2012). Nevertheless, applying the Bonferroni adjustment increases the likelihood of missing significant findings allowing for this adjustment to be conservative (Casella and Berger 2002). Consequently, the findings were presented in two tables, one with a p value assumed significant at p<0.05 (Table A2), while the other one presented with the use of a Bonferroni adjusted p value (Table A3). Confidence intervals (CIs) were calculated by using the following formula:

Difference in pre/post-intervention trend +/- tinv(0.05*79)* Standard error

The difference in pre and post-intervention prescribing trend and standard error are given in the SPSS ARIMA model parameters, tinv is a mathematical function, 0.05 is the probability (p) value for significance, and 79 is the degrees of freedom (the number of data points minus five) (Cochrane EPOC 2017).

Confidence intervals were calculated in order to be 95% certain that the range of values contains the true mean of the data (Field 2018). This formula involves the use of the standard error values for differences in the pre- and post-intervention prescribing trends. However, CIs were not calculated for the post-intervention prescribing trends due to the absence of the standard error values for the slopes of these trends in SPSS. In order to increase the power in identifying the underlining trends, the number of data points was maximised by choosing monthly data over quarterly data (Penfold and Zhang 2013). In addition, the pre- and post-intervention periods were clearly defined before conducting the ITS analysis (Bernal et al. 2016). For this reason, data were organised in three periods as follows: pre-intervention phase (April 2011 to September 2015), intervention phase (October 2015) and post-intervention phase (November 2015 to March 2018).

9.2. The findings of the ARIMA analyses

9.2.1. Pre- and post-intervention differences in prescribing trends by NMIPs

The pre- and post-intervention differences of the prescribing trends carried out by NMIPs have been investigated by conducting eight ARIMA analyses on these trends. Seven of these ARIMA analyses were carried out, one for each HB and one for all Wales. Table A1 summarises the findings of these analyses in order to compare between HBs, as well as all Wales. The positive values represent an increase in the average of the number of items prescribed by NMIPs per month, while a decrease is represented by negative values. The significant change in the difference between the pre- and post-intervention of the prescribing trends are represented by the p value (p value < 0.05 is significant). The differences in pre- and post-intervention of the prescribing trends of all Wales, as well as five HBs out of seven are statistically significant (Table A1).

Table A1 Pre- and post-intervention differences of the prescribing trends carried out by NMIPs in primary care in Wales. Statistically significant results are in green colour, whereas non-significant results are in red colour

Number	All Wales and HBs	Pre-intervention slope	Post- intervention slope	Difference in p value
1	All Wales	497	1732	0.000
2	BCUHB	243	430	0.014
3	ABHB	110	245	0.001
4	CVUHB	6	68	0.043
5	HDHB	45	431	0.000
6	PTHB	-20	518	0.004
7	ABMUHB	75	140	0.188
8	СТНВ	-525	-501	0.473

9.2.2. Differences in the pre- and post-intervention of the prescribing trends by NMIPs in all Wales and each HB

Figures A1 to A8 illustrate the results of the ARIMA analyses of the pre- and post-intervention slopes of prescribing trends conducted by NMIPs in primary care from April 2011 to March 2018 for all Wales and each HB.

9.2.2.1. All Wales

The number of items prescribed by NMIPs in primary care across Wales and dispensed in community pharmacies increased by an average of 497 items per month pre-intervention. Whereas it increased by an average of 1,732 items per month post-intervention (Figure A1). The difference in the pre- and post-intervention of the prescribing trend was statistically significant (P=0.000, 95% CI [1,016 to 1,454]).

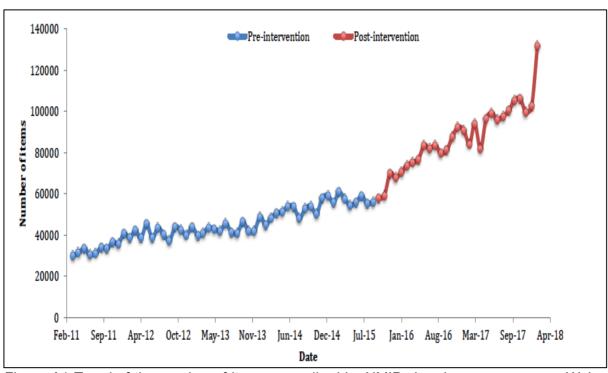


Figure A1 Trend of the number of items prescribed by NMIPs in primary care across Wales from April 2011 to March 2018

9.2.2.2. BCUHB

The number of items prescribed by NMIPs in primary care in BCUHB and dispensed in community pharmacies in Wales increased by an average of 243 items per month pre-intervention. Whereas it increased by an average of 430 items per month post-intervention (Figure A2). The difference in the pre- and post-intervention of the prescribing trend was statistically significant (P=0.014, 95% CI [38 to 337]).

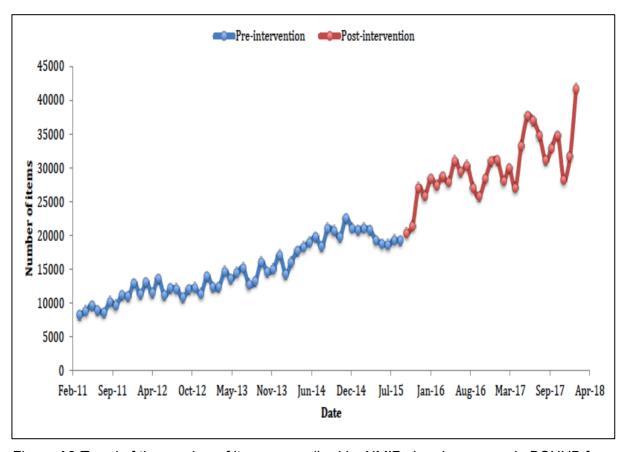


Figure A2 Trend of the number of items prescribed by NMIPs in primary care in BCUHB from April 2011 to March 2018

9.2.2.3. ABHB

The number of items prescribed by NMIPs in primary care in ABHB and dispensed in community pharmacies in Wales increased by an average of 110 items per month pre-intervention. Whereas it increased by an average of 245 items per month post-intervention (Figure A3). The difference in the pre- and post-intervention of the prescribing trend was statistically significant (P=0.001, 95% CI [54 to 217]).

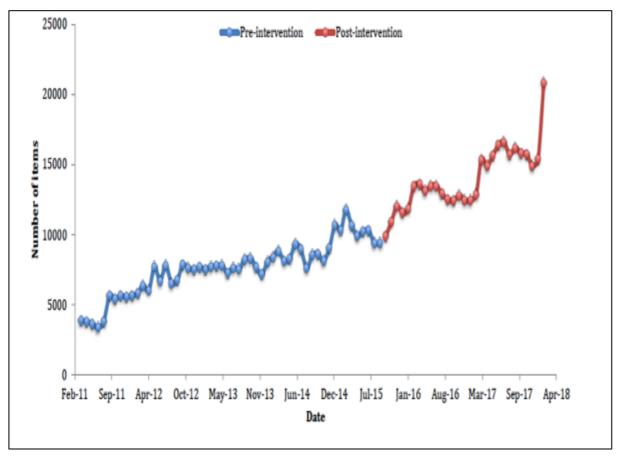


Figure A3 Trend of the number of items prescribed by NMIPs in primary care in ABHB from April 2011 to March 2018

9.2.2.4. CVUHB

The number of items prescribed by NMIPs in primary care in CVUHB and dispensed in community pharmacies in Wales increased by an average of 6 items per month pre-intervention. Whereas it increased by an average of 68 items per month post-intervention (Figure A4). The difference in the pre- and post-intervention of the prescribing trend was statistically significant (P=0.043, 95% CI [13 to 122]).

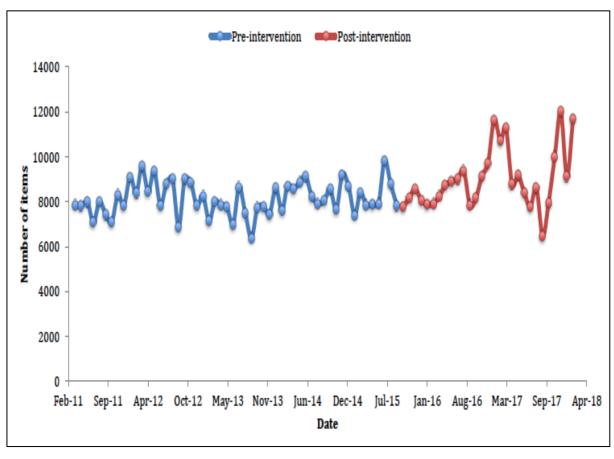


Figure A4 Trend of the number of items prescribed by NMIPs in primary care in CVUHB from April 2011 to March 2018

9.2.2.5. HDHB

The number of items prescribed by NMIPs in primary care in HDHB and dispensed in community pharmacies in Wales increased by an average of 45 items per month pre-intervention. Whereas it increased by an average of 431 items per month post-intervention (Figure A5). The difference in the pre- and post-intervention of the prescribing trend was statistically significant (P=0.000, 95% CI [262 to 510]).

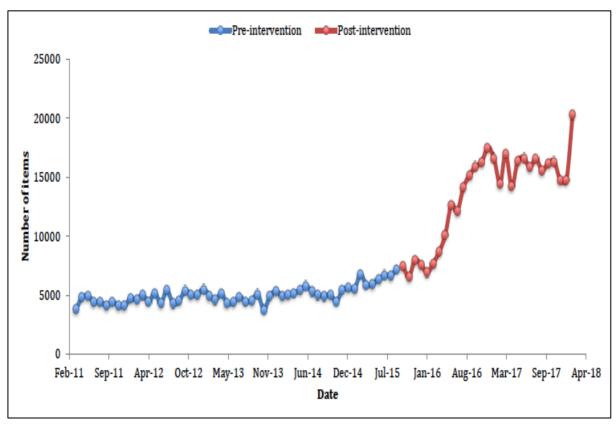


Figure A5 Trend of the number of items prescribed by NMIPs in primary care in HDHB from April 2011 to March 2018

9.2.2.6. PTHB

The number of items prescribed by NMIPs in primary care in PTHB and dispensed in community pharmacies in Wales decreased by an average of 20 items per month pre-intervention. Whereas it increased by an average of 518 items per month post-intervention (Figure A6). The difference in the pre- and post-intervention of the prescribing trend was statistically significant (P=0.004, 95% CI [180 to 897]). The large increase in the number of items prescribed by NMIPs from June 2017 to March 2018 could be responsible for the difference in the post-intervention prescribing trend.

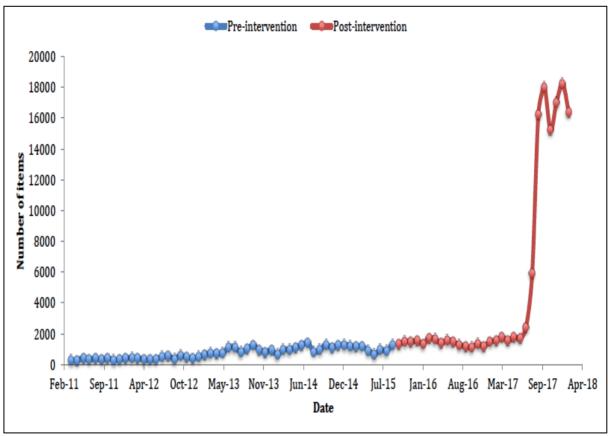


Figure A6 Trend of the number of items prescribed by NMIPs in primary care in PTHB from April 2011 to March 2018

9.2.2.7. ABMUHB

The number of items prescribed by NMIPs in primary care in ABMUHB and dispensed in community pharmacies in Wales increased by an average of 75 items per month pre-intervention. Whereas it increased by an average of 140 items per month post-intervention (Figure A7). The difference in the pre- and post-intervention of the prescribing trend was not statistically significant (P=0.188, 95% CI [-32 to 162]).

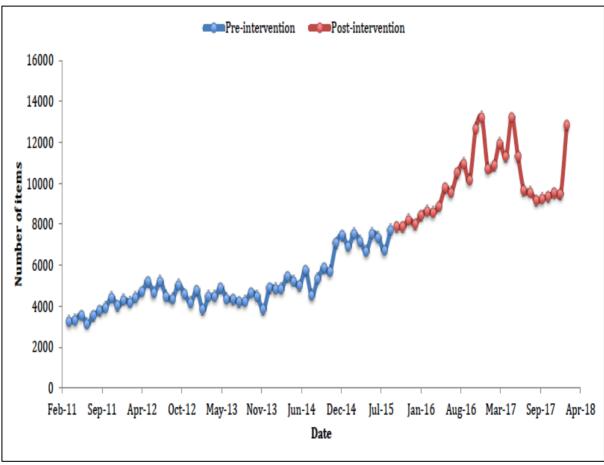


Figure A7 Trend of the number of items prescribed by NMIPs in primary care in ABMUHB from April 2011 to March 2018

9.2.2.8. CTHB

The number of items prescribed by NMIPs in primary care in CTHB and dispensed in community pharmacies in Wales decreased by an average of 525 items per month pre-intervention. Whereas it decreased by an average of 501 items per month post-intervention (Figure A8). The difference in the pre- and post-intervention of the prescribing trend was not statistically significant (P=0.473, 95% CI [-43 to 91]).

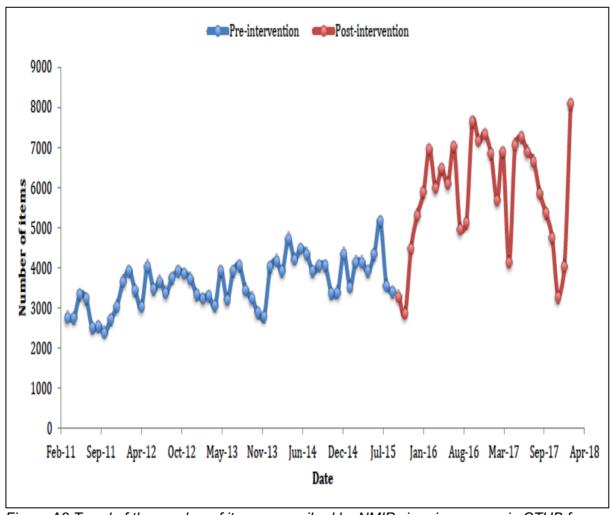


Figure A8 Trend of the number of items prescribed by NMIPs in primary care in CTHB from April 2011 to March 2018

9.2.3. Step changes analyses

Table A2 demonstrates the step changes in the prescribed number of items by NMIPs in primary care and dispensed in community pharmacies in all Wales, as well as in each HB at five post-intervention time points. At all post-intervention time points, step changes were significant in all Wales, BCUHB and HDHB. Step changes in PTHB were significant at 9, 12 and 24 post-intervention months' points, whereas step changes in ABMUHB and ABHB were significant at 12 and 24 post-intervention months' points. However, step changes in CVUHB and CTHB were not statistically significant.

Table A2 step changes in the prescribed number of items by NMIPs in primary care and dispensed in community pharmacies in all Wales and in each HB. Statistically significant results are in green colour, while non-significant results are in red colour

	post-intervention time points: n & (p value)				
All Wales and HBs	3 months	6 months	9 months	12 months	24 months
All Wales	6801 (0.001)	10506 (0.000)	14211 (0.000)	17917 (0.000)	32738 (0.000)
всинв	2821	3384	3947	4509	6759
	(0.032)	(0.008)	(0.002)	(0.001)	(0.000)
HDHB	1796	2955	4113	5272	9907
	(0.049)	(0.001)	(0.000)	(0.000)	(0.000)
PTHB	730 (0.586)	2346 (0.133)	3961 (0.040)	5577 (0.018)	12039 (0.006)
ABMUHB	950 (0.177)	1145 (0.100)	1340 (0.063)	1535 (0.047)	2314 (0.046)
АВНВ	364	770	1176	1582	3206
	(0.575)	(0.225)	(0.068)	(0.020)	(0.001)
СУИНВ	-96	89	274	458	1197
	(0.857)	(0.861)	(0.587)	(0.373)	(0.082)
СТНВ	852	925	997	1070	1360
	(0.138)	(0.095)	(0.071)	(0.061)	(0.080)

9.2.4. Step changes analysis with Bonferroni adjusted P Value

Table A3 shows the results of the step changes with Bonferroni adjusted p value of number of items prescribed by NMIPs in primary care in all Wales and in each HB and dispensed in community pharmacies. The Bonferroni adjusted p value was calculated by multiplying the number of HBs plus all Wales (8) by the number of post-intervention time points (5), resulting in 40 comparisons. Thereafter, the p value (0.05) divided by the resulting number

of comparisons (40) and the result is 0.00125. Therefore, the Bonferroni adjusted p value is considered significant if it is less than 0.00125. At all post-intervention time points, step changes with Bonferroni adjusted p value were significant in all Wales. In HDUH, it was significant at 6, 9, 12 and 24 post-intervention months' points. It was significant in BCUHB at 12 and 24, as well as in ABHB at 24 post-intervention months' points.

Table A3 step changes with Bonferroni adjusted p value in the prescribed number of items by NMIPs in primary care and dispensed in community pharmacies in all Wales and in each HB. Statistically significant (p value < 0.00125) results are in green colour, while non-significant results (p value > 0.00125) are in red colour

	Post-intervention time points: n & (p value)				
All Wales and HBs	3 months	6 months	9 months	12 months	24 months
All Wales	6801	10506	14211	17917	32738
	(0.001)	(0.000)	(0.000)	(0.000)	(0.000)
HDHB	1796	2955	4113	5272	9907
	(0.049)	(0.001)	(0.000)	(0.000)	(0.000)
всинв	2821 (0.032)	3384 (0.008)	3947 (0.002)	4509 (0.001)	6759 (0.000)
АВНВ	364	770	1176	1582	3206
	(0.575)	(0.225)	(0.068)	(0.020)	(0.001)
PTHB	730	2346	3961	5577	12039
	(0.586)	(0.133)	(0.040)	(0.018)	(0.006)
АВМИНВ	950	1145	1340	1535	2314
	(0.177)	(0.100)	(0.063)	(0.047)	(0.046)
СУИНВ	-96	89	274	458	1197
	(0.857)	(0.861)	(0.587)	(0.373)	(0.082)
СТНВ	852	925	997	1070	1360
	(0.138)	(0.095)	(0.071)	(0.061)	(0.080)

9.2.5. Pre- and post-intervention differences in prescribing trends by medical prescribers

An ARIMA analysis was also conducted on the number of items prescribed by medical prescribers in primary care across Wales and dispensed in community pharmacies (Figure A9). It increased by an average of 11,450 items per month pre-intervention and decreased by an average of 12,518 items per month post-intervention. The difference in the pre- and post-intervention of the prescribing trend was statistically significant (P=0.010, 95% CI [-3073 to -21963]).

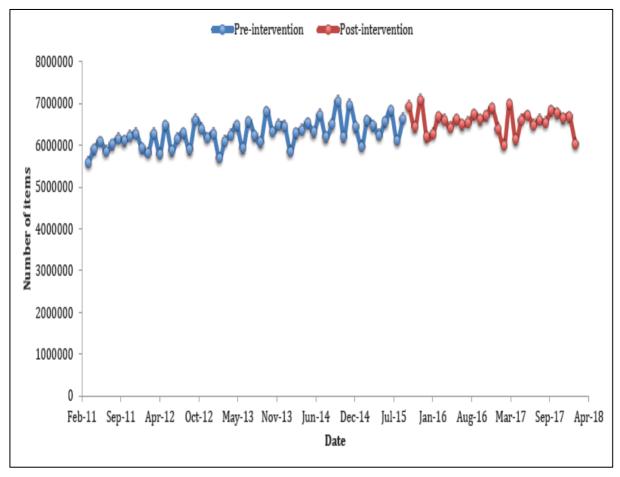


Figure A9 Trend of the number of items prescribed by medical prescribers in primary care across Wales from April 2011 to March 2018

9.2.6. Step changes analysis

Table A4 shows the step changes in the prescribed number of items by medical prescribers in primary care and dispensed in community pharmacies across Wales at five post-intervention time points. It was only significant at 24 post-intervention months' points.

Table A4 step changes in the prescribed number of items by medical prescribers in primary care and dispensed in community pharmacies across Wales. Significant results are in green colour, while non-significant results are in red colour

Prescribing by medical prescribers across Wales		
Post-intervention time point	Step changes	P value
3 months	-16743	0.848
6 months	-54303	0.515
9 months	-91863	0.262
12 months	-129422	0.119
24 months	-279658	0.010

Appendix 7: PTHB Lead response (Study 1, Chapter 4)

Hi Saeed,

90% of the increase comes from one practice, Newtown, where they have employed a pharmacist as an independent prescriber, and who has been taking on repeat prescribing for patients with ongoing long-term conditions.

We also have a community pharmacy in Llanidloes who is using independent prescribing to extend the scope and reach of the Common Ailments Scheme, in collaboration with the local GP practice.

I hope this information is helpful

Kevin Smith

Appendix 8: CTMUHB Lead response (Study 1, Chapter 4)

HI, I am not aware of any policies which would correlate with the timings you show, however, there were significant service changes which could align with the changes:

The WG made available cluster funding for primary care which resulted in increased MDT and other professions working in primary care including prescribing i.e., the recruitment of cluster-based pharmacists across three of the four localities who have independent prescribing qualifications and prescribe in practices.

The implementation of an enhanced service for GPs to prescribe DOACs in primary care – a number of anticoagulant clinics are run by pharmacists in primary care

I cannot comment on the nurses or physio services

I am afraid if you want more detailed explanations then you will need to undertake more granular research or maybe those copied in can help

Hope this helps Regards Suzanne Scott-Thomas

Appendix 9: CVUHB Lead response (Study 1, Chapter 4)

Hi Saeed

My first thoughts/queries,

Has this been mapped against the scope of practice of new independent prescribers coming out of universities, as numbers increase i.e. are there more new independent prescribers with a scope including anticoagulants management/hypertension/heart failure resulting in the trends of increased cardiovascular prescribing – rather than existing independent prescribers prescribing more cardio drugs – and this has shifted the mean significant proportion new independent prescribers that I know of in recent years had their scope sitting in the cardiovascular BNF chapter

BNF chapter is very high level – category a little more meaningful Guidance would only influence prescribing within scope of practice

Not all independent prescribers are equal - Some independent prescribers would only ever have a very restricted scope e.g., physios & pain/muscle spasm – which is unlikely to expand with experience; others e.g., pharm/nurse could extend scope into many chronic diseases or minor illness - where, depending upon casemix of population and pressures on GPs

(this may reflect in higher antibacterial items – useful for us to know to specifically target independent prescribers in the work we do, I know some practices triage minor presentations to nurse or doctor – so nurse may be seeing more acute infections etc) BNF categories –

Respiratory - our COPD guidance approach has been encouraging practices to review steroids and ensure on appropriately, minimum effective dose.

Also looking to identify and review asthma patients collecting lots of bronchodilators and step up treatment so better control and less bronchodilators needed.

We have a community model in diabetes where practices have links into a named consultant – part of that model was to upskill the practice team in the management of patients to reduce need for referrals – as more independent prescribers get involved in this it could reflect in more items by them instead of the GPs – plus triple therapy more common now – we also have some diabetes specialist nurses in community (not sure if they are independent prescribers)

Karen May

Head of Medicines Management, Primary Care and Community Clinical Board

Appendix 10: First study poster 1 (Study 1, Chapter 4)



Prescribing trends over time by non-medical independent prescribers (NMIPs) in primary care settings across Wales: a secondary database analysis



Saeed S Alghamdi, Rhian Deslandes, Karen Hodson, Molly Courtenay, Paul Deslandes
Cardiff University, Cardiff, United Kingdom



Introduction

- In 2015, the Welsh Government developed a plan to improve primary care services in Wales. [1] This included training non-medical healthcare
 professionals as independent prescribers (IPs).
- In addition, primary care clusters, which are groups of adjacent general practices (GPs) linked together aiming to provide some of the advanced
 medical services locally in order to relieve pressure on hospitals, were implemented in late 2015 in Wales. [2] Many of these clusters chose to
 employ independent prescribing pharmacists to help improve patient care and overcome some of the issues caused by the shortages of GPs.
- . The aim of this research was to identify the number of NMIPs and the associated trend of items prescribed and dispensed in primary care in Wales.

Methodology

- A two retrospective secondary data analysis were carried out on the number of items per 100,000 population prescribed by NMIPs in primary care
 and dispensed in community pharmacies in Wales; and the number of NMIPs in primary care in Wales from April 2011 to March 2018.
- Dispensing data were obtained from the Comparative Analysis System for Prescribing Audit (CASPA) (Version 4), accessed via the All Wales Therapeutic and Toxicology Centre (AWTTC) at Cardiff and Vale University Health Board.
- The number of NMIPs who prescribed items in primary care and dispensed in community pharmacies in Wales over the study period was obtained from NHS Wales Shared Services Partnership.
- · Ethical approval is not needed for this study.
- . The data were analysed descriptively using IBM SPSS (version 25) and Microsoft Excel (version 16.15).

Results

Over the study period:

- . 600 NMIPs had prescribed at least one item that had been dispensed (figure 1).
- Nurse IPs increased by 108%. Pharmacist IPs increased by 325% (from July 2015 to March 2018 increased by 240%).
- The number of items prescribed by NMIPs as a proportion of the total number of items prescribed in primary care in Wales increased from 0.57% in 2011 to 1.7% in 2018.
- The total number of items per 100,000 population per year prescribed by NMIPs increased by 200%; the largest increase was between the last quarter of 2015 and March 2018 by 90% (Figure 2).
- The total number of items per 100,000 population per year prescribed by NMIPs for the top BNF chapters and group of medicines increased over time, with the largest increase between the last quarter of 2015 and March 2018 (Figure 3 and 4).

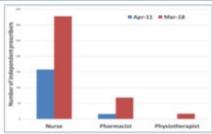


Figure 1 Numbers of NMIPs in primary oper in Misles since April 2011 until March 2018

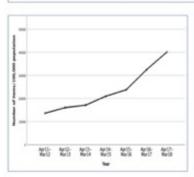


Figure 2 Trend of the total number of items per 100,000 population prescrib by NMIPs

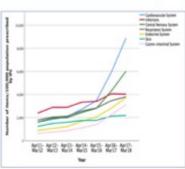
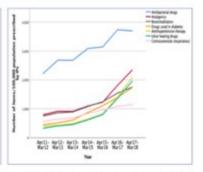


Figure 3: Trend of the number of items per 100,000 population prescribed by NMINs based on the top BNF chapters



igure 4 Trend of the number of items per 100,000 population prescribed by NMIRs ased on the top BTM group of medicines

Conclusion

- The number of NMIPs and their volume of prescribing in primary care in Wales is increasing, with the largest increase for pharmacist prescribers occurring post 2015.
- This may suggest that the Government's recommendations of utilising NMIPs in primary care have been implemented. [1,2]
- A limitation of the CASPA system is that it only records prescriptions dispensed in community pharmacies in Wales. Therefore, prescriptions issued by NMIPs that haven't been dispensed were not captured by the system.

References

- Welsh Government. 2015. Our plan for a primary care service for Wales up to March 2018. NHS Wales: February: 2015.
- [2] The National Assembly for Wales. 2017. Inquiry into Primary Care: Clusters. Cardiff: Health, Social Care and Sport Committee: October: 2017.

Poster Number: 69

Appendix 11: First study poster 2 (Study 1, Chapter 4)



A comparison of non-medical independent prescribers (NMIPs) and their prescribing in primary care across different health boards (HBs) in Wales: a secondary database analysis



Saeed S Alghamdi, Rhian Deslandes, Karen Hodson, Molly Courtenay, Paul Deslandes Cardiff University, Cardiff, United Kingdom



Introduction

- Since 2015, HBs in Wales have prioritised funding for non-medical healthcare professionals in primary care to train as independent prescribers.
- This was in response to the Welsh Government Primary Care Plan [1] and implementation of primary care clusters (groups of adjacent general practices (GPs) linked together aiming to provide some of the advanced medical services locally instead of being delivered at hospitals) [2], which aimed to increase patient access to treatment and relieve pressure on GPs.

Aim

To compare the number of NMIPs, and the number of NMIP prescription items prescribed and dispensed in each HB in Wales.

Methodology

- A two retrospective secondary data analysis were carried out on the number of items per 100,000 population prescribed by NMIPs in primary care in each HB and dispensed in community pharmacies in Wales; and the number of NMIPs in primary care in Wales from April 2011 to March 2018.
- Dispensing data were obtained from the Comparative Analysis System for Prescribing Audit (CASPA) (Version 4), accessed via the All Wales Therapeutic and Toxicology Centre (AWTTC).
- The number of NMIPs who prescribed items in primary care in each HB and dispensed in community pharmacies in Wales over the study period was obtained from NHS Wales Shared Services Partnership.
- Ethical approval is not needed for this study.
- The data were analysed descriptively using IBM SPSS (version 25) and Microsoft Excel (version 16.15).

Results

- 600 NMIPs had prescribed at least one item that had been dispensed.
- Nearly 40% of NMIPs were based in Betsi Cadwaladr University HB (BCUHB) and only 6% in Powys Teaching HB (PTHB) (Figure 1).
- Overall, NMIPs/1000 population in Wales was 0.19, with the highest number in BCUHB (0.36) and the lowest in Abertawe Bro Morgannwg University HB (ABMUH) (0.12).
- The data suggest that BCUHB was an early adopter of NMIPs, whereas PTHB appears to be a late adopter with the number increasing largely from 2016 to 2018 (Figure 2).
- Other HBs had a larger increase post 2015 when primary care clusters were implemented.
- The highest percentage of prescribed items by NMIPs was within BCUHB (30%; 2.47 item/population), while the lowest percentage was in PTHB (4%; 1.5 item/population).
- Over the study time, BCUHB had showed a continuous increase in the trend of total prescribed items/100,000 population per year (235%).
- The prescribing trend in PTHB showed a large increase from 2016 to 2018 (670%).
- The prescribing trends of all other HBs, except Cardiff & Vale HB, had showed a large increase between the last quarter of 2015 and 2018 (Figure 2).
- The top BNF chapter prescribed by NMIPs in each HB was cardiovascular, except in BCUHB where it was infection.

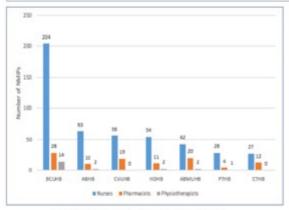


Figure 1 Numbers of NMIPs in each health board in primary care in Wales since April 2011 until March 2018

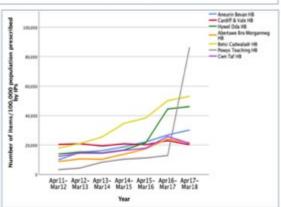


Figure 2 Trend of the total number of items per 100,000 population prescribed by NMIPs in each health board

Conclusion

- The number of NMIPs and the number of items prescribed by them have increased in the majority of HBs, particularly since the implementation of primary care clusters.
- The findings of this study will be shared with the stakeholders in HBs and Chief Pharmaceutical Officer for Wales in order to inform future policies in this area at the local and national level.
- A limitation of the CASPA system is that it only records prescriptions dispensed in community pharmacies in Wales, not those issued by NMIPs that haven't been dispensed.

References

[1] Welsh Government. 2015. Our plan for a primary care service for Wales up to March 2018. NHS Wales: February: 2015.

[2] The National Assembly for Wales. 2017. Inquiry into Primary Care: Clusters. Cardiff: Health, Social Care and Sport Committee: October: 2017.

Poster Number: 34

Appendix 12: The study published in the BMJ Open (Study 1, Chapter 4)



Appendix 13: Ethics approval of the second study (Study 2, Chapter 5)

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: Independent pharmacist prescribers' views of their role as prescribers in primary care settings in Wales

This is a/an:	Undergraduate project	
	ERASMUS project	
	Postgraduate project	Х
	Staff project	\top

Name of researcher: (PG/Staff projects only)	Saeed S. Alghamdi
Name of supervisor(s):	Dr Rhian Deslandes & Dr Karen Hodson

STATEMENT OF ETHICS APPROVAL

This project has been considered and has been approved by the Cardiff School of Pharmacy and Pharmaceutical Sciences Research Ethics Committee

Signed Name Date 07/05/2019
(Deputy Chair, School Research Ethics Committee)

Appendix 14: Invitation Email (Study 2, Chapter 5)

The Invitation Email Subject: Invitation-Participation in a research study on independent pharmacist prescribers' views of their role as prescribers in primary care settings in Wales

The Email Body

Dear independent pharmacist prescriber,

We would like to invite you to participate in a research study regarding your role as an independent pharmacist prescriber in a GP practices in Wales. This role has been implemented in Wales, as well as in the whole UK, in order to increase patients' access to health care and treatment. In recent years, the Welsh Government has supported the high influx of independent pharmacist prescribers in primary care in Wales in order to overcome the GPs shortage and improve patient access to medicines. However, specific details on how independent prescribing is used by pharmacists in primary care in Wales is lacking and there is currently a gap in research regarding this matter.

My name is Saeed Alghamdi, and I am a PhD student currently studying at Cardiff School of Pharmacy and Pharmaceutical Sciences at Cardiff University, under the supervision of Dr Rhian Deslandes and Dr Karen Hodson. My PhD is about exploring the role of independent pharmacist prescribers in GP practices in Wales. My initial study was to look at the prescribing data carried out by non-medical independent prescribers in primary care. A future study will be conducted to explore the views of other HCPs and patients in GP practices regarding the role of independent pharmacist prescribers. Whereas this study aims to explore the views of the independent pharmacist prescribers of their role as independent prescribers in GP practices in Wales. Therefore, this study hopes to provide an understanding of prescribers' scope of practice, satisfaction regarding their role, the perceived benefits, and barriers and facilitators to their role. The finding of this study will be reported to the Welsh Government and professional bodies, which may help in informing future policies regarding this role.

This study will involve your participation in a focus group discussion. However, if you are unable to attend a focus group, we would like to interview you. The focus group or interview will take place at a time and a location convenient to you and will take approximately 60 to 90 minutes for the focus group or 30 to 60 minutes for the interview. I have attached a Participant Information Sheet, which provides further information on this research. If you agree to take part, please complete and sign the attached Participant Consent Form, then send it back or bring with you on the day of the focus group or interview. In addition, we would like you to complete a Demographic Information Sheet if you would like to participate through this link: https://docs.google.com/forms/d/viewform; which will provide us with your contact

details, some background information about you and whether you would like to participate in either a focus group or an interview. Also, as this study is a part of a bigger project, we would like to ask you if you are happy to act as a gatekeeper in order to recruit other HCPs for future studies.

If you are happy to participate in this study, we would like to offer you a £25 Amazon voucher as a recognition of your time and contribution to this study. Please respond directly to me (at this email: -----) within 2 weeks so that we can arrange for dates, times and locations that would be suitable for you.

Your participation is much appreciated and hopefully will help in informing the future development of this role in Wales, as well as in the rest of the UK. However, if you have any enquiries or concerns, please do not hesitate to contact us.

Yours sincerely,

PhD Student

Saeed Saad A Alghamdi Contact Email:

Phone number:

PhD supervisors:

Dr Rhian Deslandes Contact Email:
Dr Karen Hodson Contact Email:

Chief Pharmaceutical Officer for Wales

Dr Andrew Evans Contact Email:

PP.

Appendix 15: Participant Information Sheet (Study 2, Chapter 5)



Participant Information Sheet

Project Title

Independent pharmacist prescribers' views of their role as prescribers in primary care settings in Wales.

Introduction

Over the last 15 years, the practice of independent prescribing of medicines in the United Kingdom has evolved to involve pharmacists and other healthcare professionals in order to increase patients' access to health care and treatment. In recent years, the Welsh Government has supported and funded the high use of independent pharmacist prescribers in primary care in Wales in order to overcome the GPs shortage. Although the benefits of this role are acknowledged, specific details on how independent prescribing is utilised by pharmacists in primary care in Wales is lacking and there is currently a gap in research regarding this matter.

My name is Saeed Alghamdi, and I am a PhD student currently studying at the School of Pharmacy and Pharmaceutical Sciences at Cardiff University. For my PhD project, I am investigating the views of independent pharmacist prescribers on their role as prescribers in primary care settings in Wales. My supervisors: Dr Rhian Deslandes and Dr Karen Hodson are members of staff at the school. Before making a decision whether to be involved in the study or not it is vital that you understand what the study is concerning and also the responsibilities associated with taking part. Therefore, it is important that you read the information provided carefully, and then make your voluntary decision. If you do require further information on anything regarding the research or, have any unanswered questions then please do not hesitate to contact me. Ethical approval for this project has been obtained from the Research Ethics Committee at Cardiff School of Pharmacy and Pharmaceutical Sciences.

What is the purpose of this study?

The aim of this research is to explore the views of independent pharmacist prescribers of their role within primary care in Wales. This will involve an investigation to their satisfaction about their role, their responsibilities and area of practice, and their views of the barriers and facilitators related to their role as prescribers. The finding of this study will be fed back into information for professional bodies and the Welsh Government, which may help in informing the future development of this role in Wales, as well as in the rest of the UK.

Why have I been selected to participate in this study?

You have been selected to participate in this project because you are an independent pharmacist prescriber and work in GP practices in Wales. Your participation is highly appreciated and may provide information to help future development of this role in Wales. Your consent is required in order to participate in this project. If you do not want to participate in this research, you do not need to do anything further in relation to this request.

What will I have to do if I take part?

Ideally, your participation in this project will involve an audio-recorded focus group discussion with other participants or individual interview with consent, which will be moderated by myself with an assistant moderator also present. This will take the form of a series of questions in which you are invited to give your views and opinions on the topics and discuss any relevant information with other participants. If you are unable to attend a focus group, an interview can be arranged. The focus group discussion or interview will take place at a time and a location of your convenience, and we anticipate will take approximately 60 to 90 minutes for the focus group or 30 to 45 minutes for the interview. In addition, you will be given a £25 Amazon voucher at the end of the focus group or interview as a gesture of showing respect for the time that you are giving me and your contribution to the study.

What will occur with the information I provide in this study?

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 ----. 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

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.

All the provided information by you, will be audio-recorded and then will be transcribed. All information will be treated as confidential and when transcribed, the names and points of view will be made anonymous so not to identify any individual from any result. Once the audio-recordings have been transcribed and quality assured, they will be deleted immediately, and the anonymised transcript will be kept secure on a password protected computer. The only people to gain access to the information will be myself and my project supervisors. All the information you provide in the focus group discussion or interview will be kept secure until the end of this project plus five years. It is anticipated that the results of the study will be published in academic journals and reported to professional bodies and the Welsh Government. You will also be offered a summary of the project if you wish to have one.

What do I need to do to participate in this study?

If you decided to take part in this study, then we only need you to sign two copies of the participant consent form and initial each section in it before the focus group discussion or interview. One copy should be returned to the project team either in person at the time of the focus group discussion/interview or by email, and the second copy is to be kept by you. In addition, we would like you to complete a Demographic Information Sheet through this link: https://docs.google.com/forms/d/viewform; this will provide us with your contact details, some background information about you and whether you would like to participate in a focus group or interview, and whether or not you could potentially help in recruiting other HCPs for future studies as stated in the invitation letter.

What if I no longer would like to participate in this study?

The participation in this project is entirely voluntary. You are able to withdraw from this project at any time and you do not need to provide any justification. Moreover, you can request to withdraw and leave at any time during the focus group discussion or interview. If you withdraw from the study, we will keep the information about you that we have already obtained. However, to safeguard your rights, we will anonymise all the obtained information, delete the recording and keep anonymised data secure on a computer protected by a password until the end of this project plus five years.

What if I want to raise any concerns or complaints?

In case you have any concerns or complaints throughout the time of this project, please contact my supervisors, Dr Rhian Deslandes and Dr Karen Hodson (emails stated below), 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.

Thank you for taking the time to read this information sheet.

If you have any enquiries related to this project and the information provided or require further details regarding this focus group or interview, please do not hesitate to contact me.

PhD Student

Saeed Saad A Alghamdi Contact Email:

Phone number:

PhD supervisors:

Dr Rhian Deslandes Contact Email:
Dr Karen Hodson Contact Email:

Chief Pharmaceutical Officer for Wales

Dr Andrew Evans Contact Email:

Appendix 16: Participant consent from for interviews and focus groups (Study 2, Chapter 5)



Participant Consent Form for Interview (6th March 2019 version 2)

Focus Group Number:

Project Title: Independent pharmacist prescribers' views of their role as prescribers in primary care settings in Wales

Name of Interviewer: Saeed Saa	ad A Alghamdi	Please in	nitial box		
1. I confirm that I have read the p March 2019 (version 2) for the abothe information, ask questions, ar appropriate.	ove project. I have had	d the opportunity to consider			
2. I understand that my participati at any time without giving any rea	-				
3. I agree to the focus group being audio recorded.					
4. I agree that any information pro and direct quotes, may be include including articles or presentations used will be anonymised with no	ed in the PhD researcl by the project team.	n or in other publications, All transcripts and quotes			
5. I agree that I will keep the cont	ent of the focus group	discussions confidential.			
6. I agree to take part in a focus g	group discussion for th	ne above project.			
Name of Participant	Date	Signature	_		
Name of Researcher	 Date	Signature	_		



Participant Consent Form for Focus Group (6th March 2019 version 2)

Interview Number:			
Project Title: Independent pharma in primary care settings in Wales	acist prescribers' views	of their role as prescriber	S
Name of Interviewer: Saeed Saad	A Alghamdi	Please in	nitial box
1. I confirm that I have read the par March 2019 (version 2) for the abov the information, ask questions, and appropriate.	e project. I have had th	e opportunity to consider	
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected.			
3. I agree to the interview being audio recorded.			
4. I agree that any information prov direct quotes, may be included in the including articles or presentations bused will be anonymised with no ide	ne PhD research or in o by the project team. All t	ther publications, ranscripts and quotes	
5. I agree that I will keep the conter			
6. I agree to take part in an intervie	w for the above project.		
Name of Participant	Date	Signature	_
Name of Researcher	 Date	Signature	_

Demographic Information Sheet

Background Information

Re	equired	
1.	1- Name: *	
2.	2- Age: *	
3.	3- Gender: • Mark only one oval. Female Male	•
4.	4- Job title: *	
5.	5- E-mail: *	
6.	6- In which health board is your workplace in Mark only one oval.	ocated: *
	Abertawe Bro Morgannwg University He Aneurin Bevan Local Health Board Betsi Cadwaladr University Health Board Cardiff & Vale University Health Board Cwm Taf University Health Board Hywel Dda Local Health Board Powys Teaching Health Board	
7.	7- You are employed by: * Mark only one oval.	
	Health Board General Practice	

8.	8- Years of experience (as a pharmacist): *	
9.	9- Years of experience (as an independent pharmacist prescriber): *	
10.	10- Years of experience as an independent pharmacist prescriber in primary care: *	
11.	11- What postgraduate qualification(s) do you have in addition to independent prescribing? •	
12.	12- What is/are the role(s) that you are doing prescribing? *	exactly in regard to independer
13.	13- How many general practices do you work within as a prescriber? *	
14.	14- How many independent pharmacists' prescribers work with you in the same general practice? *	
15.	15- What was your clinical area of speciality for independent prescribing? *	
16.	16- What do you usually prescribe more? * Mark only one oval.	
	Prescriptions for acute conditions	
	Repeat prescriptions (for chronic condition	ons)

17.	medicines that you tend to prescribe for your patients?
18.	18- You are happy to participate in this study in: * Mark only one oval.
	a focus group
	a face to face Interview
19.	19- Are you willing to help with recruiting stakeholders and patients for future studies?
	Mark only one oval.
	Yes
	◯ No

Appendix 18: Reminder Email (Study 2, Chapter 5)

The Invitation Email Reminder Subject: Reminder - Participation in a research study on independent pharmacist prescribers' views of their role as prescribers in primary care settings in Wales

The Email Body

Dear independent pharmacist prescriber,

In follow-up to our email sent on we would like to remind you that the deadline for accepting the invitation to participate in this research, which aims to explore the views of the independent pharmacist prescribers of their role as independent prescribers in GP practices in Wales, is shortly approaching.

My name is Saeed Alghamdi, and I am a PhD student currently studying at Cardiff School of Pharmacy and Pharmaceutical Sciences at Cardiff University, under the supervision of Dr Rhian Deslandes and Dr Karen Hodson. My PhD is about exploring the role of independent pharmacist prescribers in GP practices in Wales. My initial study was to look at the prescribing data carried out by non-medical independent prescribers in primary care. A future study will be conducted to explore the views of other HCPs in GP practices regarding the role of independent pharmacist prescribers. Whereas this study aims to explore the views of the independent pharmacist prescribers of their role as independent prescribers in GP practices in Wales. Specific details on how independent prescribing is used by pharmacists in primary care in Wales is lacking and there is currently a gap in research regarding this matter. Therefore, this study hopes to provide an understanding of prescribers' scope of practice, satisfaction regarding their role, the perceived benefits, and barriers and facilitators to their role. The finding of this study will be reported to the Welsh Government and professional bodies, which may help in informing future policies regarding this role.

This study will involve your participation in a focus group discussion. However, if you are unable to attend a focus group, we would like to interview you. The focus group or interview will take place at a time and a location convenient to you and will take approximately 60 to 90 minutes for the focus group or 30 to 60 minutes for the interview. I have attached a Participant Information Sheet which provides further information on this research as well as a Participant Consent Form in order for you to complete and sign, then to send it back or bring with you on the day of the focus group or interview. In addition, we would like you to complete a Demographic Information Sheet through this link: https://docs.google.com/forms/d/viewform; this will provide us with your contact details, some background information about you and whether you would like to participate in either a focus group or an interview. Also, as this study is a part of a bigger project, we would like to ask you if you are happy to act as a gatekeeper in order to recruit other HCPs for future studies.

If you are happy to participate in this study, we would like to offer you a £25 Amazon voucher as a recognition of your time and contribution to this study. Please respond directly to me (at this email: ----) as soon as possible so that we can arrange for dates, times and locations that would be suitable for you.

Your participation is much appreciated and hopefully will help in informing the future development of this role in Wales, as well as in the rest of the UK. However, if you have any enquiries or concerns, please do not hesitate to contact us.

Yours sincerely,

PhD Student

Saeed Saad A Alghamdi Contact Email:

Phone number:

PhD supervisors:

Dr Rhian Deslandes Contact Email:
Dr Karen Hodson Contact Email:

Chief Pharmaceutical Officer for Wales

Dr Andrew Evans Contact Email:

PP.

Appendix 19: Focus Group / Interview Schedule (Study 2, Chapter 5)

Focus Group / interview Schedule

Project Title

Independent pharmacist prescribers' views of their role as prescribers in primary care settings in Wales

Topic Guide

The role of pharmacists as prescribers has evolved over the last 15 years. The aim of this project is to explore the views of pharmacist prescribers on their role as independent prescribers in GP practices in Wales. This will involve questions about your responsibilities and area of practice, your opinions and satisfaction about your role, how your role has changed over time, your perceived benefits to the role, and your views of the barriers and facilitators related to your role as prescribers.

Introduction and Explanations

- At the beginning I would like to thank you for agreeing to be a part of this project.
- I also would like to confirm that you have signed the two copies of the participant consent form and you have a copy while the other copy is kept by me.
- This <u>focus group discussion</u> / interview will be audio-recorded as stated in the participant information sheet and that all your responses and quotes will be transcribed, and then will be analysed after the completion of this discussion / interview.
- I also would like to assure you that the entire <u>focus group discussion</u> / interview
 will be confidential, and all of the responses, direct quotes and personal
 information provided by you will be anonymised for this project or other related
 publications.
- I also would like to clarify that your contribution in this project is entirely voluntary and at any time during this <u>focus group discussion</u> / interview, you are able to withdraw from the project and you don't have to provide any justifications.
- The aim of this <u>focus group discussion</u> / interview is to explore your views as a pharmacist prescriber of your role as an independent prescriber in primary care

- settings in Wales. You will be asked for your views and thoughts on your role, your responsibilities and area of practice, and your views of the barriers and facilitators related to your role as a prescriber.
- I also would like to clarify that there will be no judgment to your responses as
 well as there will be no right, or wrong answers and you are free to not answer
 any questions if you don't want to. Also, to confirm that (if it is a focus group
 discussion) responses should be directed to the group, not to the researcher.
 Moreover, it is better for the language that you will use to be as simple as
 possible.
- You are able to request any clarification needed for any unknown terminologies
 used at any time during the <u>focus group discussion</u> / interview in order to keep
 it as simple as possible. Also, I may ask for the clarification of any unfamiliar
 terms used by you.
- If you have any questions or concerns, that you would like to clarify prior the beginning of the <u>focus group discussion</u> / interview you can ask me now.
- Before we start and for the purposes of the audio-recording:

Part 1: Professional responsibilities and areas of prescribing:

- For each participant:
 - Could you please tell me your name? your clinical area for independent prescribing?
 and your current role in regard to your independent prescribing?
- Prompts to be used if needed:
 - Would you explain further?
 - Can you give me an example?
 - Would you say more?
 - Is there anything else?
 - Please describe what you mean?

Part 2: Describing the role and how it has changed over time

- For the group (if interview: for each participant):
 - Has the role of independent pharmacist prescribers changed over time since it has been started?
 - o If yes:
 - How it has been changed?
 - What change is actually happened?
 - What was the driver for this change?
 - How have you manged this change?
 - Has your scope of independent prescribing practice extended over time? How?
 - How have you showed the competence to continue in doing your role with this change within primary care?
 - o If no:
 - Do you think there is a need for a change in this role? Why? Please explain more.
 - Please describe your role and position within the team (working with other healthcare professionals)? What do you think about this?
 - Could you please describe your relationship with other members in the team? Has it been changed over time? How and why, it has been changed/developed? what do you think about this?
 - What do you think about the way of patients are being referred to be seen by you?
 - What do you think about the way of patients are booked in for appointments with you?
- Prompts to be used if needed:
 - Would you explain further?
 - Can you give me an example?
 - Would you say more?
 - Is there anything else?
 - Please describe what you mean?

Part 3: Role and satisfaction

- For the group (if interview: for each participant):
 - How would you describe your satisfaction about your role as independent prescribers in general?
 - In your opinion, what could be the factors that make you satisfied about your role as independent prescribers?
 - In your opinion, what could be the factors that make you unsatisfied about your role as independent prescribers?
 - What do you think about the number of appointments that you have with your patients per day?
 - What do you think about the average time of appointment that you usually have with your patients?
 - What do you think about prescribing for acute conditions and/or repeat prescriptions?
 - What do you think about working within more than one GP practice? How do you think this may affect the prescribing of medicines?
- Prompts to be used if needed:
 - Would you explain further?
 - Can you give me an example?
 - Would you say more?
 - Is there anything else?
 - Please describe what you mean?

Part 4: Role and their perceived benefits

- For the group (if interview: for each participant):
 - What feedback have you had from other health care professionals regarding your role?
 - What feedback have you had from patients regarding your role?
 - How do you get this feedback? What do you think about this?
 - What are the perceived benefits regarding your role? Could you please explain it more in terms of the benefits to practice, patients, and other health care professionals?
 - What are the benefits for you that you think you have gained from your role?
- Prompts to be used if needed:
 - Would you explain further?
 - Can you give me an example?
 - Would you say more?
 - Is there anything else?
 - Please describe what you mean?

Part 5: Facilitators and Barriers

- For the group (if interview: for each participant):
 - What do you think are the initial facilitators and barriers of the implementation of independent prescribing by pharmacists in GP practices?
 - What do you think are the continued facilitators and barriers of the independent prescribing by pharmacists in GP practices?
 - What do you think are the facilitators and barriers regarding your role within the GP practice team?
 - In your opinion, what could prevent independent pharmacist prescribers from prescribing medicines or managing patient's condition?
 - What are your thoughts about the current clinical supervision regarding your role as a prescriber?
 - What do you think about the current indemnity insurance and protection regarding your independent prescribing role in your practice?
 - What are your thoughts about the received support regarding your role as prescribers?
 - What do you think about the number of independent pharmacist prescriber who work in one GP practice setting?
- Prompts to be used if needed:
 - Would you explain further?
 - Can you give me an example?
 - Would you say more?
 - Is there anything else?
 - Please describe what you mean?

Summary and Closing

- At the end of this <u>focus group discussion</u> / interview, I would like to thank you for taking part in this project as well as for your time and responses to the <u>focus group</u> / interview questions.
- If <u>anyone</u> / you would like to add any comments or go back to anything because you could not have the opportunity to do that during the <u>focus group discussion</u> / interview time, please feel free to do that now, <u>and if so, to clarify it by prompting questions</u> stated in the guide.
- As I said before, the entire <u>focus group discussion</u> / interview will be confidential, and all of the responses, direct quotes and personal information provided by you will be anonymised for this PhD project or other related publications. The analysis of the data will be carried out right away by myself (the PhD student). This research is a part of a PhD project conducted by myself and will be submitted to the Cardiff School of Pharmacy and Pharmaceutical Sciences; I could also provide a summary of the project to you if you wish to have one once the research accomplished.
- Do you have any questions to ask at the end of this <u>focus group discussion</u> or interview?
- Thank you so much for your participation and this is a £25 Amazon voucher to show you our appreciation for your time and contribution to this study.

Appendix 20: A portion of transcript (extracted from IPP1 interview) of the thematic analysis process that was conducted iteratively for each IPP in GP practice interview (Chapter 5, Section 5.5.2)

Step 1: Involved reading and re-reading of the transcript to be familiarised with the data

I have a system where I take direct referrals from the doctor or nurses for a particular patient, I think it's a system that works very well. Initially, I just ran lists of patients, and then we'd try and invite them in, by post or by telephone call. And there were a lot that did not attend or missed appointments through that system, so I found that having a direct referral from a patient seen by the other healthcare specialist has resulted in more patient contact and patients knowing what to expect to some extent when they do see me. So, myself personally, I'm happy and satisfied with that. So, I do three or three and a half hours' worth of IP sessions on four days a week. However, this will be reduced in the very near future to two sessions per week. So, I'm not, there are reasons for that. But, of course, as I said before, that for me is not a great move. Although it will be reviewed in six months' time. I do also- if, of course, there are slots available, I do searches on the GP's clinical system to identify patients that I feel might be appropriate for me to be reviewed. And then usually with that list, what would be that I would run the list by the lead GP first to make sure that they're happy that I see that patient. I am very fortunate, and I do have 15 to 30-minute appointment times with patients. So usually, the first time I see a patient, that does necessitate the 30-minute appointment, purely because I'm trying to understand the patient's problems, help them, provide an education and try and reach an agreed goal or strategy. I would say that it does sometimes put me under a lot of pressure, and sometimes with complex patients, consultations can overrun, which then puts pressure on you because you've got other patients waiting. So really, that's just part and parcel of being a prescriber really with a pre-booked appointment. And that does take time, and that really is where I feel that it is where the value of my role is. And the follow-up appointment can be a quarter of an hour and not as long as the first appointment. I think probably one of the main issues is because, as an IP working one session a week in different practices, is that should there be any problems, I'm harder for the patient to get hold of because I'm there only one a once a week basis, so it's always important to make sure that they understand that should there be any problems, they can speak to a GP in the practice. And, of course, all of this is recorded in the patient consultation record. I personally quite like it. I like the variety. However, the downside of that is I am literally in, you know, I work in about six or seven different surgeries altogether, and you only have that contact once a week on that session. But I don't see that there's any other way around that myself. Otherwise, the patients in the many different practices wouldn't benefit from my interventions. Everyone that I can think of in my team, including myself, all work in multiple practices. We tend to only be one. And, of course, they only have their particular clinical area that they're working with, and we all have different clinical areas that we work in.'

Step 3: Reviewing the codes and searching for sub-themes and themes, which involved linking, merging, defining, and naming of concepts

Sub-themes

- Working across multiple GP practices (□)
- Number of IPPs (□)

Step 2: Generating initial codes

Appointment approaches (referral)

Number of IP sessions

Appointment approaches (self-findings

Appointment duration (long)

Appointment duration (short)

Working in multiple GP practices (drawbacks)

Working in multiple GP practices (benefits)

Number of IPPs in a GP practice

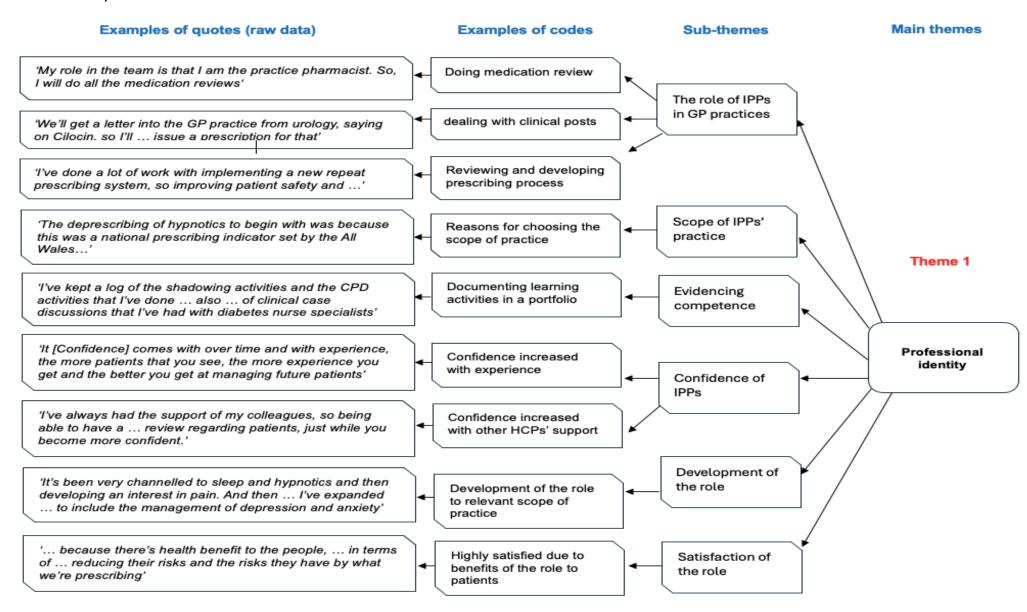
Step 4: defining, reviewing, comparing and identifying relationship

Main theme: Practicalities and logistics with the role

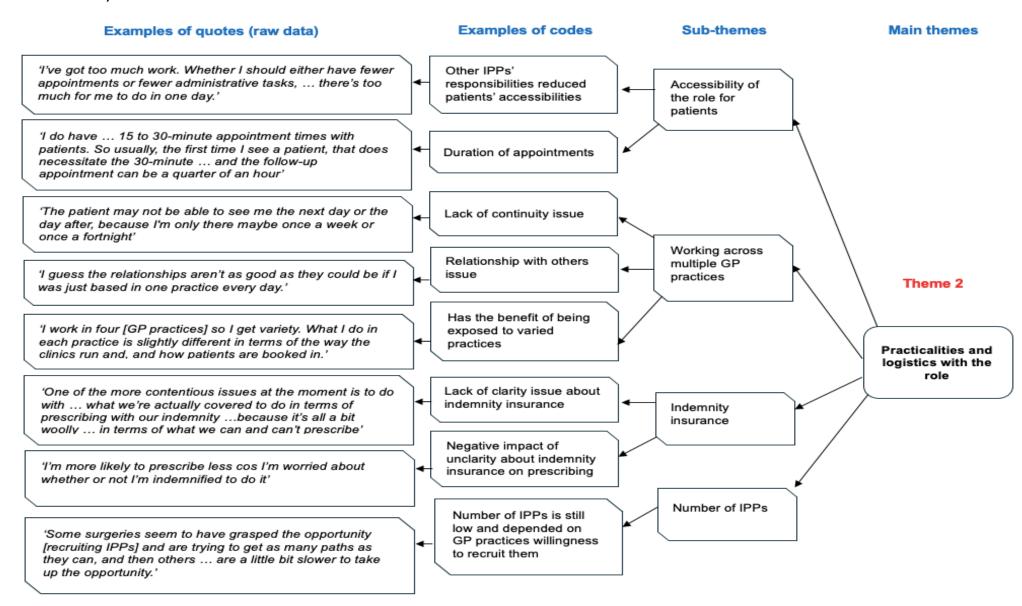
Step 5: Reviewing and confirming themes and sub-themes by the researcher and supervisors

Final Main theme: Practicalities and logistics with the role

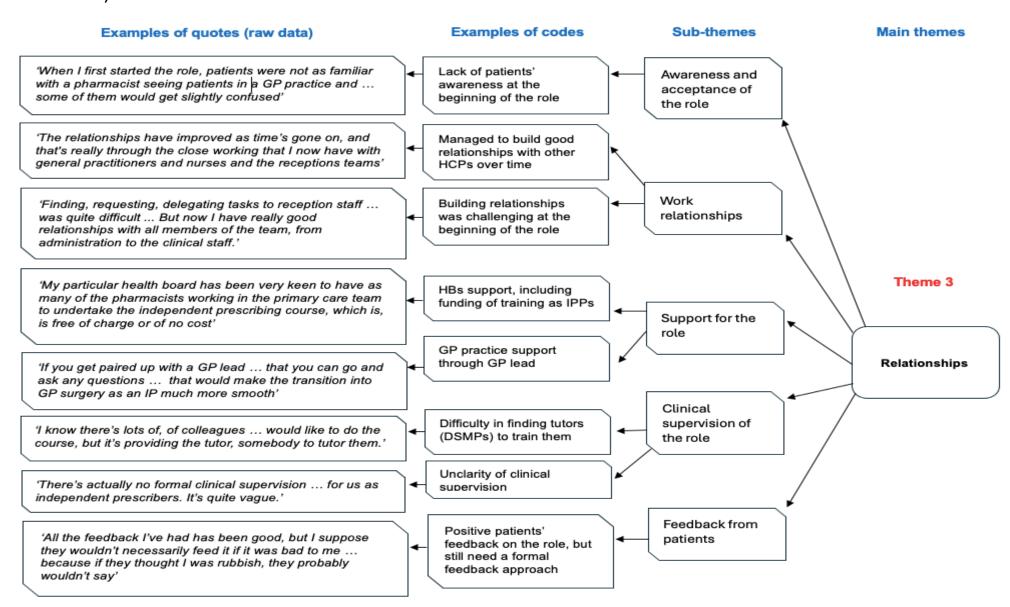
Appendix 21: Examples of quotes, used codes, and final sub-themes and themes of IPPs in GP practices thematic analysis (Chapter 5, Section 5.5.2)



Appendix 21: Examples of quotes, used codes, and final sub-themes and themes of IPPs in GP practices thematic analysis (Chapter 5, Section 5.5.2) *Cont.*



Appendix 21: Examples of quotes, used codes, and final sub-themes and themes of IPPs in GP practices thematic analysis (Chapter 5, Section 5.5.2) *Cont.*



Appendix 22: Invitation letter to community IPPs and community pharmacy leads (Study

3, Chapter 6)

INVITATION LETTER TO COMMUNITY IPPS

Dear Community Pharmacist / Community Pharmacy lead.

As you know, an increasing number of community pharmacists are being trained as, and utilising

their skills as, independent prescribers within the community pharmacy setting. We, at the Cardiff

School of Pharmacy and Pharmaceutical Sciences, in collaboration with Keele University, are

conducting a project to gain an understanding of the experiences of community pharmacists trained

as independent prescribers, both on the training and implementation of the role, and of the

community pharmacy leads within each Health Board. The project is being carried out by our

undergraduate students, Katie Isaac and Naz Maolod from Cardiff University and Elizabeth Hyde

from Keele University, as well as our PhD student Saeed Alghamdi from Cardiff University.

We would like to invite you to take part in a one-to-one interview, either face to face or over the

telephone, at a date and time to suit you. We anticipate that the interview will last approximately 30-

45 minutes. We have attached the participant information leaflet and the consent form for you to

provide more detailed information on the project. If you are interested in taking part please contact

the project supervisor, Rhian Deslandes, on the details below. She will then arrange for one of the

project students to contact you to arrange an appropriate time.

Your views are important for us to understand how the role is being used in practice, anonymised

results will be shared with policy makers, such as Welsh Government, to inform future developments.

Many thanks in advance of your support,

Rhian Deslandes

Tel: 02920 876432

346

INVITATION LETTER TO COMMUNITY PHARMACY LEADS

Dear Community Pharmacy lead,

As you know, an increasing number of community pharmacists are being trained as, and utilising their skills as, independent prescribers within the community pharmacy setting. We, at the Cardiff School of Pharmacy and Pharmaceutical Sciences are conducting a project to gain an understanding of the experiences of community pharmacists trained as independent prescribers, both on the training and implementation of the role, and of the community pharmacy leads within each Health Board. The project is being carried out by a PhD student, Saeed Alghamdi, who is doing this project as part of his PhD study, under the supervision of Dr Rhian Deslandes and Dr Karen Hodson.

We would like to invite you to take part in a one-to-one interview, either face to face or over the telephone, at a date and time to suit you. We anticipate that the interview will last approximately 30-45 minutes. We have attached the participant information leaflet and the consent form for you to provide more detailed information on the project. If you are interested in taking part please contact the PhD student, Saeed Alghamdi, on the details below. He will then contact you to arrange an appropriate time.

Your views are important for us to understand how the role is being used in practice, anonymised results will be shared with policy makers, such as Welsh Government, to inform future developments.

Many thanks in advance of your support,

Yours sincerely,

PhD Student

Saeed Saad A Alghamdi Contact Email:

Phone number:

PhD supervisors:

Dr Rhian Deslandes Contact Email:
Dr Karen Hodson Contact Email:

Appendix 23: Participant information sheet for community IPPs and community pharmacy leads (Study 3, Chapter 6)



PARTICIPANT INFORMATION SHEET (COMMUNITY IPPS)

Exploring Independent Prescribing by Community Pharmacists

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. Thank you for reading this.

1. What is the purpose of this research project?

Community pharmacists are increasingly being trained as independent prescribers. This is a relatively new development in the pharmacy profession and is encouraged by the 'Pharmacy: Delivering a healthier Wales' document. This project aims to gain an understanding of the experiences of community pharmacists trained as independent prescribers, both on the training and implementation of the role, and of the community pharmacy leads within each Health Board. The study is being conducted by undergraduate final year pharmacy students Katie Isaac and Naz Maolod from Cardiff University and Elizabeth Hyde from Keele University. They are supervised by Rhian Deslandes and Karen Hodson at Cardiff and Simon White at Keele. A PhD student in Cardiff University, Saeed Alghamdi, is also part of the research team.

2. Why have I been invited to take part?

You have been invited because you are a community pharmacist who has trained as an independent prescriber, or you are a community pharmacy lead within your Health Board. As a prescribing pharmacist, you may or may not have implemented the role into your practice. We would like to hear your views on the training and the barriers and facilitators to its implementation.

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 to take part, we will discuss the research project with you and ask you to sign a consent form. If you decide not to take part, you do not have to explain your reasons and it will not affect your legal rights. You are free to withdraw your consent to participate in the research project at any time, without giving a reason, even after signing the consent form.

4. What will taking part involve?

You will be asked to participate in a one-to-one interview with one of the project students. This is anticipated to last between 30 and 45 minutes, at a time and date appropriate to you. It may be conducted either face to face or over the telephone, dependent on location and what is most convenient for yourself. Face to face interviews will be conducted at a mutually agreed location, such as at the community pharmacy or your place of work. The interview will be audio recorded. Please ensure that you either conduct the interview in your own time, or if during work time, you have explicit permission from your line manager.

If you are a prescribing pharmacist, we would also like to ask if you would be willing to share the coursework you completed as part of the independent prescribing training course. This will be used as a means of informing the interview and the discussion around your prescribing role. If possible, we would like to read this before the interview. We would ask if you could either forward this to the project supervisor or give permission for your course director to forward this onto the research team.

If you would like to take part, please contact Rhian Deslandes on the details below who will pass your contact details onto one of the students to arrange a time for the interview.

5. Will I be paid for taking part?

You will not be paid for taking part in the project.

6. What are the possible benefits of taking part?

There are no direct benefits to you from taking part in the project. However, by expressing your views and sharing experiences on the training and implementation of your prescribing role or the community pharmacist prescribing role within your Health Board we aim to inform future developments and improve practice.

7. What are the possible risks of taking part?

There are no risks to taking part in this project. We will only ask you to provide 30 to 45 minutes of your time.

8. Will my taking part in this research project be kept confidential?

All information collected from and about you during the research project will be kept confidential and any personal information you provide will be managed in accordance with data protection legislation. Please see 'What will happen to my Personal Data?' (below) for further information.

9. What will happen to my Personal Data?

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. Further information about Data Protection, including:

- your rights
- the legal basis under which Cardiff University processes your personal data for research
- Cardiff University's Data Protection Policy
- how to contact the Cardiff University Data Protection Officer
- how to contact the Information Commissioner's Office

may be found at https://www.cardiff.ac.uk/public-information/policies-and-procedures/data-protection. Printed copies can be made available, on request.

We will collect your contact details (name, telephone and email) only for the purpose of organising the interview and receiving your coursework material. The audio recorded interviews will be transcribed immediately after the interview by the student who conducts the interview. Once transcribed and quality assured, the recording will be deleted. The research team will anonymise all the personal data it has collected from, or about, you in connection with this research project, with the exception of your consent form.

Your consent form will be retained for 2 years post publication and may be accessed by members of the research team and, where necessary, by members of the University's governance and audit teams or by regulatory authorities. Anonymised information will be kept for a minimum of 2 years post publication. The transcripts and all electronic materials containing personally identifiable information will be stored on a university password protected computer. The written consent forms and coursework material will be held securely at Cardiff University School of Pharmacy and Pharmaceutical Sciences, or Keele University, in a locked filing cabinet, in the supervisor's office. Should you withdraw from the project before publication, your data will be removed from any future publications.

10. What happens to the data at the end of the research project?

The transcripts will be shared with the research team, which includes all three undergraduate students, the PhD student and their supervisors so that they may analyse the data. The data will be held securely at the end of the research project. Anonymised results will be shared with policy makers, such as Welsh Government, to inform future developments.

11. What will happen to the results of the research project?

It is our intention to publish the results of this research project in academic journals and present findings at conferences. Participants will not be identified in any report, publication or presentation. Anonymised, verbatim quotes will be used from participants in order to present the findings. If you would like a copy of the results, please inform the student who conducts your interview so that they may make arrangements for this.

12. What if there is a problem?

If you wish to complain or have grounds for concerns about any aspect of the manner in which you have been approached or treated during the course of this research, please contact the project supervisor, Dr Rhian Deslandes, or Dr Simon White on the contact details below. If your complaint is not managed to your satisfaction, please contact the Director of Research, Cardiff School of Pharmacy and Pharmaceutical Sciences, Redwood Building, King Edward VII Avenue, Cardiff CF10 3NB, or Dr Judith Rees, Chair of the School of Pharmacy and Bioengineering Research Ethics Committee, at Keele University on

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, you may have grounds for legal action, but you may have to pay for it.

13. Who is organising and funding this research project?

The research is organised by Dr Rhian Deslandes and Dr Karen Hodson from the Cardiff School of Pharmacy and Pharmaceutical Sciences in Cardiff University and Dr Simon White from Keele University. The students completing the project are: Naz Maolod, Katie Issac, Elizaberth Hyde, and Saeed Alghamdi

14. 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 School Research Ethics Committee, Cardiff University.

15. Further information and contact details

Should you have any questions relating to this research project, you may contact us during normal working hours:

Dr Rhian Deslandes
Cardiff School of Pharmacy and Pharmaceutical Sciences
Cardiff University
Redwood Building
King Edward VII Avenue
Cardiff
CF10 3NB
Tel:
Email:

Thank you for considering taking part in this research project. If you decide to participate, you will be given a copy of the Participant Information Sheet and a signed consent form to keep for your records.



PARTICIPANT INFORMATION SHEET (COMMUNITY PHARMACY LEADS)

Exploring Independent Prescribing by Community Pharmacists

You are being invited to take part in a project. Before you decide whether or not to take part, it is important for you to understand why the project 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. Thank you for reading this.

1. What is the purpose of this project?

Community pharmacists are increasingly being trained as independent prescribers. This is a relatively new development in the pharmacy profession and is encouraged by the 'Pharmacy: Delivering a healthier Wales' document. This project aims to gain an understanding of the experiences of community pharmacists trained as independent prescribers, both on the training and implementation of the role, and of the community pharmacy leads within each Health Board. The study is being conducted by a PhD student in Cardiff University, Saeed Alghamdi, who is doing this project as part of his PhD study at the Cardiff School of Pharmacy and Pharmaceutical Sciences, under the supervision of Dr Rhian Deslandes and Dr Karen Hodson.

2. Why have I been invited to take part?

You have been invited because you are a community pharmacist who has trained as an independent prescriber, or you are a community pharmacy lead within your Health Board.

3. Do I have to take part?

No, your participation in this project is entirely voluntary and it is up to you to decide whether or not to take part. If you decide to take part, we will discuss the project with you and ask you to sign a consent form. If you decide not to take part, you do not have to explain your reasons and it will not affect your legal rights. You are free to withdraw your consent to participate in the project at any time, without giving a reason, even after signing the consent form.

4. What will taking part involve?

You will be asked to participate in a one-to-one interview with the PhD student (Saeed Alghamdi). This is anticipated to last between 30 and 45 minutes, at a time and date appropriate to you. It may be conducted either face to face or over the telephone, dependent on location and what is most convenient for yourself. Face to face interviews will be conducted at a mutually agreed location, such as your place of work. The interview will be audio recorded. Please ensure that you either conduct the interview in your own time, or if during work time, you have explicit permission from your line manager.

If you are a prescribing pharmacist, we would also like to ask if you would be willing to share the coursework you completed as part of the independent prescribing training course. This will be used as a means of informing the interview and the discussion around your prescribing role. If possible, we would like to read this before the interview. We would ask if you could either forward this to the project supervisor or give permission for your course director to forward this onto the project team. If you would like to take part, please contact Saeed Alghamdi on the details below who will contact you to arrange a time for the interview.

5. Will I be paid for taking part?

You will not be paid for taking part in the project.

6. What are the possible benefits of taking part?

There are no direct benefits to you from taking part in the project. However, by expressing your views and sharing experiences on the training and implementation of your prescribing role or the community pharmacist prescribing role within your Health Board we aim to inform future developments and improve practice.

7. What are the possible risks of taking part?

There are no risks to taking part in this project. We will only ask you to provide 30 to 45 minutes of your time.

8. Will my taking part in this project be kept confidential?

All information collected from and about you during the project will be kept confidential and any personal information you provide will be managed in accordance with data protection legislation. Please see 'What will happen to my Personal Data?' (below) for further information.

9. What will happen to my Personal Data?

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. Further information about Data Protection, including:

- your rights
- the legal basis under which Cardiff University processes your personal data for such projects
- Cardiff University's Data Protection Policy
- how to contact the Cardiff University Data Protection Officer
- how to contact the Information Commissioner's Office

may be found at https://www.cardiff.ac.uk/public-information/policies-and-procedures/data-protection. Printed copies can be made available, on request.

We will collect your contact details (name, telephone and email) only for the purpose of organising the interview and receiving your coursework material. The audio recorded interviews will be transcribed immediately after the interview by the PhD student who conducts the interview. Once transcribed and quality assured, the recording will be deleted. The project team will anonymise all the personal data it has collected from, or about, you in connection with this project, with the exception of your consent form.

Your consent form will be retained for 2 years post publication and may be accessed by members of the project team and, where necessary, by members of the University's governance and audit teams or by regulatory authorities. Anonymised information will be kept for a minimum of 2 years post publication. The transcripts and all electronic materials containing personally identifiable information will be stored on a university password protected computer. The written consent forms and coursework material will be held securely at Cardiff University School of Pharmacy and Pharmaceutical Sciences, in a locked filing cabinet, in the supervisor's office. Should you withdraw from the project before publication, your data will be removed from any future publications.

10. What happens to the data at the end of the project?

The transcripts will be shared with the project team, which includes the PhD student and his supervisors so that they may analyse the data. The data will be held securely at the end of the project. Anonymised results will be shared with policy makers, such as Welsh Government, to inform future developments.

11. What will happen to the results of the project?

It is our intention to publish the results of this project in academic journals and present findings at conferences. Participants will not be identified in any report, publication or presentation. Anonymised, verbatim quotes will be used from participants in order to present the findings. If you would like a copy of the results, please inform the PhD student who will conduct your interview so that he may make arrangements for this.

12. What if there is a problem?

If you wish to complain or have grounds for concerns about any aspect of the manner in which you have been approached or treated during the course of this project, please contact the project supervisors, Dr Rhian Deslandes, or Dr Karen Hodson on the contact details below. If your complaint is not managed to your satisfaction, please contact the Director of Research, Cardiff School of Pharmacy and Pharmaceutical Sciences, Redwood Building, King Edward VII Avenue, Cardiff CF10 3NB.

If you are harmed by taking part in this project, there are no special compensation arrangements. If you are harmed due to someone's negligence, you may have grounds for legal action, but you may have to pay for it.

13. Who is organising and funding this project?

The project is organised by Dr Rhian Deslandes, Dr Karen Hodson and the PhD student Saeed Alghamdi, from the Cardiff School of Pharmacy and Pharmaceutical Sciences in Cardiff University. The PhD student is going to complete the project.

14. Who has reviewed this project?

This project has been reviewed and given a favourable opinion by the Cardiff School of Pharmacy and Pharmaceutical Sciences School Research Ethics Committee, Cardiff University.

15. Further information and contact details

Should you have any questions relating to this project, you may contact us during normal working hours:

PhD Student

Contact Email:

Phone number:

Saeed Saad A Alghamdi Cardiff School of Pharmacy and Pharmaceutical Sciences Cardiff University Redwood Building King Edward VII Avenue Cardiff CF10 3NB

PhD supervisors

Dr Rhian Deslandes Contact Email:

Dr Karen Hodson Contact Email:

Thank you for considering taking part in this project. If you decide to participate, you will be given a copy of the Participant Information Sheet and a signed consent form to keep for your records.

Appendix 24: Participant consent form for community IPPs and community pharmacy leads (Study 3, Chapter 6)



PARTICIPANT CONSENT FORM (COMMUNITY IPPS)

Title of research project: Exploring Independent Prescribing by Community Pharmacists
Name of Chief/Principal Investigator: Project supervisors: Rhian Deslandes (Cardiff), Saeed
Alghamdi

Please initial box

I confirm that I have read the information sheet dated October 2019 version 1 for the	
above research project.	
I confirm that I have understood the information sheet dated October 2019 version 1 for	
the above research project and that I have had the opportunity to ask questions and that	
these have been answered satisfactorily.	
I understand that my participation is voluntary and I am free to withdraw at any time	
without giving a reason and without any adverse consequences.	
I consent to the processing of my personal information, name, telephone number and	
email address, for the purposes explained to me. I understand that such information will	
be held in accordance with all applicable data protection legislation and in strict	
confidence, unless disclosure is required by law or professional obligation.	
I agree to the interview transcripts being accessed by the research team from Cardiff	
University and Keele University	
I understand who will have access to personal information provided, how the data will	
be stored and what will happen to the data at the end of the research project.	
I agree to provide my reflective log from my independent prescribing training course,	
for the purpose of informing the interview	
I agree to taking part in a one to one interview, either over the telephone or face to face	
I consent to the interview being audio recorded and I understand how it will be used in	
the research.	
I understand that anonymised verbatim quotes from my interview may be used as part	
of the research publication.	
I understand how the findings and results of the research project will be written up and	
published.	
I agree to take part in this research project.	
Name of participant (print) Date Signature	



PARTICIPANT CONSENT FORM (COMMUNITY PHARMACY LEADS)

Title of project: Exploring Independent Prescribing by Community Pharmacists

Name of interviewer: Saeed Saad A Alghamdi

Please initial box

I confirm that I have read the information sheet dated December 2019 version 2 for the above project.	
I confirm that I have understood the information sheet dated December 2019 version 2	
for the above project and that I have had the opportunity to ask questions and that these have been answered satisfactorily.	
I understand that my participation is voluntary, and I am free to withdraw at any time	
without giving a reason and without any adverse consequences.	
I consent to the processing of my personal information, name, telephone number and	
email address, for the purposes explained to me. I understand that such information will	
be held in accordance with all applicable data protection legislation and in strict	
confidence, unless disclosure is required by law or professional obligation.	
I agree to the interview transcripts being accessed by the project team from Cardiff	
University	
I understand who will have access to personal information provided, how the data will	
be stored and what will happen to the data at the end of the project.	
I agree to taking part in a one to one interview, either over the telephone or face to face	
I consent to the interview being audio recorded and I understand how it will be used in	
the project.	
I understand that anonymised verbatim quotes from my interview may be used as part	
of the project publication.	
I understand how the findings and results of the project will be written up and published.	
g	
I agree to take part in this project.	

Name of Participant	Date	Signature
		_
Name of Researcher	Date	Signature

THANK YOU FOR PARTICIPATING IN OUR PROJECT YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP

Appendix 25: Reminder Email (Study 3, Chapter 6)

THE INVITATION EMAIL REMINDER SUBJECT TO COMMUNITY IPPS: REMINDER - PARTICIPATION IN A RESEARCH STUDY ON INDEPENDENT PHARMACIST PRESCRIBERS' VIEWS OF

THEIR ROLE AS PRESCRIBERS IN COMMUNITY PHARMACIES IN WALES

Dear Community Pharmacist / Community Pharmacy lead,

In follow-up to our email sent on we would like to remind you that the deadline for

accepting the invitation to participate in this research is shortly approaching.

As you know, an increasing number of community pharmacists are being trained as, and

utilising their skills as, independent prescribers within the community pharmacy setting. We,

at the Cardiff School of Pharmacy and Pharmaceutical Sciences, in collaboration with Keele

University, are conducting a project to gain an understanding of the experiences of community

pharmacists trained as independent prescribers, both on the training and implementation of

the role, and of the community pharmacy leads within each Health Board. The project is being

carried out by our undergraduate students, Katie Isaac and Naz Maolod from Cardiff University

and Elizabeth Hyde from Keele University, as well as our PhD student Saeed Alghamdi from

Cardiff University.

We would like to invite you to take part in a one-to-one interview, either face to face or over

the telephone, at a date and time to suit you. We anticipate that the interview will last

approximately 30-45 minutes. We have attached the participant information leaflet and the

consent form for you to provide more detailed information on the project. If you are interested

in taking part please contact the project supervisor, Rhian Deslandes, on the details below.

She will then arrange for one of the project students to contact you to arrange an appropriate

time.

Your views are important for us to understand how the role is being used in practice,

anonymised results will be shared with policy makers, such as Welsh Government, to inform

future developments.

Many thanks in advance of your support,

Rhian Deslandes

Tel:

- 357 -

THE INVITATION EMAIL REMINDER SUBJECT TO HBS COMMUNITY PHARMACY LEADS: REMINDER - PARTICIPATION IN A RESEARCH STUDY ON HBS COMMUNITY PHARMACY LEADS' VIEWS OF THE ROLE OF IPPS IN COMMUNITY PHARMACIES IN WALES

Dear Community Pharmacy lead,

In follow-up to our email sent on we would like to remind you that the deadline for accepting the invitation to participate in this research is shortly approaching.

As you know, an increasing number of community pharmacists are being trained as, and utilising their skills as, independent prescribers within the community pharmacy setting. We, at the Cardiff School of Pharmacy and Pharmaceutical Sciences are conducting a project to gain an understanding of the experiences of community pharmacists trained as independent prescribers, both on the training and implementation of the role, and of the community pharmacy leads within each Health Board. The project is being carried out by a PhD student, Saeed Alghamdi, who is doing this project as part of his PhD study, under the supervision of Dr Rhian Deslandes and Dr Karen Hodson.

We would like to invite you to take part in a one-to-one interview, either face to face or over the telephone, at a date and time to suit you. We anticipate that the interview will last approximately 30-45 minutes. We have attached the participant information leaflet and the consent form for you to provide more detailed information on the project. If you are interested in taking part please contact the PhD student, Saeed Alghamdi, on the details below. He will then contact you to arrange an appropriate time.

Your views are important for us to understand how the role is being used in practice, anonymised results will be shared with policy makers, such as Welsh Government, to inform future developments.

Many thanks in advance of your support,

Yours sincerely,

PhD Student

Saeed Saad A Alghamdi Contact Email:

Phone number:

PhD supervisors:

Dr Rhian Deslandes Contact Email:
Dr Karen Hodson Contact Email:

Appendix 26: Interview schedule for community IPPs and community pharmacy leads (Study 4, Chapter 7) (Study 3, Chapter 6)

Interview Schedule (community IPPs)

Introduction:

Hello, my name is Saeed Alghamdi and I'm a PhD student from Cardiff University. I would like to take this opportunity to thank you once again for agreeing to participate in this interview. To begin, I'd like to provide a brief overview of the study. The aim of this project is to investigate the opinions of independent pharmacist prescribers working in a community pharmacy setting on their role as an IP, the future of IP, the changing role of the profession and the facilitators and barriers they face when using their qualification. To gather detailed information, I am interviewing a number of independent prescribers working in community pharmacy, including those who use their qualification regularly and those who do not.

OR The aim is to investigate the views of Health Board community pharmacy leads on the independent prescribing role within the community pharmacy setting.

During this interview I will ask a number of questions surrounding the topic. I may also use prompt questions to investigate your opinion in greater detail. I am interested in gathering your true opinion so please speak freely and honestly, there is no right or wrong answer. Any information you do provide will be anonymous when writing my final report.

Before we start, can I check you have read the information sheet and have signed the consent form? Whenever you are ready, please can you confirm that you are happy for me to start the recording? If you have any questions before we start or throughout the interview, please feel free to ask.

(RECORDING STARTS)

For community pharmacy independent prescribers:

To begin, I would like to discuss your training as an independent prescriber working in community pharmacy.

Why did you train as an independent prescriber?

- Job requirement / personal choice
- For how long have you been a prescriber?
- To what extent has the role met your expectations?

What was your experience with training to become an IP?

- Where did you train to become an IP?
- What was your specific scope of practice when training / how did you choose it?
- What aspect did you find the most beneficial?
- What did you like / dislike about the course?
- Which parts did you find most / least valuable?

- On a scale of 1-10, how useful did you think this course was? Why have you given this score?
- Was the training well suited to your role as a community pharmacist?

How did the course prepare you for the particular challenges of being an IP in a community pharmacy setting?

- How did the course prepare you to confidently prescribe within your area of competence?
- Is there anything more that would have been useful to include on the course?
- How much of what you did on the course have you been able to directly apply to your practice as an IP AND to your practice as a pharmacist in general?
- Is there anything you would change about the course? If so what changes would you suggest? Why?

How was your experience with working with your DSMP (or equivalent) on the course?

- Could anything have been done to make finding a DSMP/convincing them to train you easier?
- Where did you complete your required number of practice hours? (could be a number of places)
- Did you work with only your DSMP or did you also work with other prescribers as well? If others what profession(s) were they? How do you feel this affected your learning (how did the different professional qualities of these people affect your learning?)
- How helpful did you find your DSMP? Is there anything you did not like about the time
 you spent with them, or any way you believe that they could have improved your
 experiences in practice?
- In the future, would you be willing to be a DSMP yourself?
- Looking back at your experiences, would you have been happy to be trained by an alternative medical professional (i.e. a pharmacist or a nurse prescriber)?

Questions if minor ailments competency fulfilled/supplemented by a course

- What did the course involve?
- Do you believe that undertaking this course has improved your ability to practice as an IP pharmacist if so how?
- Which aspects of the course did you feel benefitted you the most?
- Are there any parts of the course that you did not find helpful?
- What would you change about the course?

Next, I would like to discuss your role as an IP in practice.

Could you tell me about how you use (or plan to use) your independent prescribing qualification in community pharmacy?

- How did you initially find the role of IP pharmacist in your first few weeks (if appropriate)?
- How has the role changed over time, if at all / how have you adapted to the role?
- For those who have been practicing as an IP for a longer period (e.g. 6 months plus):
 - o How have you developed the scope of your clinical knowledge since undertaking the independent prescribing course?

- Are there any gaps in your clinical knowledge that you would like to remove by further training?
- How have you demonstrated competency with minor ailments?

Have you worked as an independent prescriber in another area of care, for example, secondary care? If so how does it compare to community?

• Difference / similarities

What do you think the main barriers are to expanding role of community pharmacists to include IP?

- Have you come across any challenges to the role?
- How will the expanding role affect workflow of a Pharmacy? Time? Capacity? How have you managed the potential for prescribing and dispensing the same Rx?
- Has your scope of practice extended as your experience as an IP has developed?
- How would you evidence your competence as your scope extends?

What do you think are the main facilitators of the expanding role of community pharmacists to include IP?

• What do you think is already in place that can aid the independent prescribing role in community pharmacy?

Do you think access to the patient's GP record is important for you seeing patients in community pharmacy?

- If Yes, why is this, if No, why not.
- If access is not available, what were the issues you encountered with gaining access to patient records? Technological, political, legal, practical

What do you think the impact of you becoming a prescriber is/will be on your colleagues, patients etc?

- How has / will this role affect working relationships in a pharmacy?
- How do patients respond to being prescribed medication by a pharmacist? (positive/negative/ any problems with wanting a doctor or other medical professional/ appreciate easier than having to go to GP or minor ailments?)
- Do you feel that this service is beneficial to the patients you see? How? Do you feel it helps with risk management/early diagnosis? How?

What effect has becoming an IP had on your job satisfaction (or do you perceive it will in the future)? Can you give reasons why?

• Difference to patient's care / more patient facing aspects / recognition from patients

To finish the interview, The 2030 vision for pharmacists includes Pharmacists focusing on prescribing and having an independent prescriber in every community pharmacy. What are your thoughts on this?

- How do you think this will impact upon patient experiences with healthcare?
- In your opinion, what other changes within the pharmacy team will have to be undertaken to achieve this goal?

Are there any other comments you would like to add?

Do you have any questions?

Thank you very much for your time and involvement in this interview. The information you have given me today will be very valuable in exploring the role of independent pharmacists in community pharmacy.

Interview Schedule (community pharmacy Leads) Introduction:

Hello, my name is Saeed Alghamdi and I'm a PhD student from Cardiff University. I would like to take this opportunity to thank you once again for agreeing to participate in this interview. To begin, I'd like to provide a brief overview of the study. The aim is to investigate the views of Health Board community pharmacy leads on the independent prescribing role within the community pharmacy setting. To gather detailed information, I am interviewing each Health Board community pharmacy lead.

During this interview I will ask a number of questions surrounding the topic. I may also use prompt questions to investigate your opinion in greater detail. I am interested in gathering your true opinion so please speak freely and honestly, there is no right or wrong answer. Any information you do provide will be anonymous when writing my final report.

Before we start, can I check you have read the information sheet and have signed the consent form? Whenever you are ready, please can you confirm that you are happy for me to start the recording? If you have any questions before we start or throughout the interview, please feel free to ask.

(RECORDING STARTS)

- At the beginning, I would like to know your view about expanding the independent prescribing authorisation to include qualified health care professionals, other than GPs, after they complete their essential training?
- What do you think about this role for pharmacists in particular?

Recently, the Welsh Government decided to introduce the independent pharmacist prescribing role in community pharmacy in Wales; so

- How did your Health Board initially think about (visualised) the use of this qualification in community pharmacy?
 - O What about the funding for this role?
 - o Were there any anticipated logistical issues?
 - Were there any concerns for any barriers regarding the implementation of this role?
 - Finding DSMPs and practitioners for training.
 - Capacity, capability and motivation of pharmacists to do it
 - Did you identify any clinical areas for this role? Such as common ailments.
 - o How did you identify pharmacists for this role?
 - Did you dictate pharmacists on their scope of practice? Or did pharmacists choose their scope of practice?
 - o Did you planned to implement this role in certain pharmacies? Based on what?
 - Was there any strategic plan in your Health Board on how to use and optimise this role with the funding given for it?

Now, after the implementation of the independent pharmacist prescribers' role within community pharmacy:

- What are your thoughts about it? Were there any changes in their role over time? Why?
- To what extent has the role met your expectations? Why?

- How do you compare the role of the other healthcare providers who have the prescribing authority to the role of independent pharmacist prescribers in community pharmacy? In terms of:
 - knowledge
 - o diagnosis and consultation skills
 - prescribing, changing the dose, or stop taking any medicine if it is needed for any condition for their patients
 - o confidence and attitude
 - managing acute and/or chronic conditions as well as simple and complex
- How did you choose the courses (universities) in order to send pharmacists to obtain this qualification? Did you dictate pharmacists which courses pharmacists should take or it has been left to pharmacists to decide that?
 - O What criteria were used to make that decision?
- Do you think the current courses and its contents for independent pharmacist prescribers are fit for practice in community pharmacy?
 - Are there any suggestions from your experience of community pharmacist prescribers on the courses so that it could be improved? Are there things that should be included in these courses?
- One aspect of these courses was the training of community pharmacist prescribers with their DSMPs:
 - Did the Health Board or pharmacists choose their DSMPs? How did DSMPs been chosen for pharmacists and did you have any funding for them?
 - What your involvement as a Health Board towards the community pharmacist prescribers until they completed the course?
 - Have the community pharmacist prescribers provided any feedback regarding these courses as well as their practice with their DSMPs? If so, what were your action to this?
- SO, you have trained community pharmacist prescribers to do their role in community pharmacies:
 - How many pharmacists have completed the courses and became qualified in your Health Board?
 - How many of them using their qualifications in community pharmacy?
 - For those who were not using their qualifications, why they have not started using it yet? (if appropriate); what were the barriers or issues for this?
 - For those who were using their qualifications, what helped you so that those community pharmacist prescribers started quickly to use their qualifications after completing the courses?
- What are (or going to be "if they did not start this role yet") the advantages and benefits
 of the community pharmacist prescribers' role in community pharmacy? Do you think
 that this service is beneficial to the patients they see? How?
- What are (or going to be "if they did not start this role yet") the disadvantages / problems of the independent pharmacist prescriber role in community pharmacy?
- Do you as a Health Board have any strategy for community pharmacist prescribers' role in community pharmacy?
 - o If so, what is this strategy?
 - What are the plans in place that would facilitate the community pharmacist prescribers' role in community pharmacy?

- What are your plans in order to expand their role in community pharmacy?
- O you have a plan that involve identifying certain pharmacies to implement this role within? Based on what criteria? In what clinical areas specifically? How are these services going to be commissioned? Who is going to provide funding for the required equipment in order to do these services?
- Have any challenges/barriers faced independent pharmacist prescribers in community pharmacy in your Health Board been reported to you? What were they?
 - o If not, are you anticipating any barriers?
- Do you provide any kind of support to independent pharmacist prescribers in community pharmacy since they qualified? If yes, what kind of support?
 - o How is this financed?
 - Or if they are not using their qualification yet, are there any supporting mechanisms in place for them to sustain their competence until they start using their qualification? How is this financed?
- What are your responsibilities if community pharmacist prescribers would like to expand or change their scope of practice? What is your role in this? Do you have any role in finding a relevant course for them?
- Do all of your community pharmacist prescribers have access to the patient's GP record when they see their patients in community pharmacy?
 - o If Yes, what do you think about this? If no, why not and is there a plan for this?
- Form interviews conducted with community pharmacist prescribers, indemnity insurance was raised as an issue for them across Wales, what is the current situation in your Health Board for indemnity/insurance protection for community pharmacist prescribers? Are they covered by the Health Board? What is the actual issue with them? Do you check if they have indemnity/insurance protection?
- For community pharmacist prescribers in your Health Board, how many IP sessions are commissioned? And what are you aiming to? Is that the model that they are working to? How about common ailment? What is the current remuneration provided by your Health Board for each session?
- How is the relationship of community pharmacist prescribers with other prescribers or with GP practices?
- Do you provide any supervision or monitoring to the community pharmacist prescribers in community pharmacy? How?
- To finish the interview, the 2030 vision for pharmacists includes Pharmacists focusing on prescribing and having an independent prescriber in every community pharmacy. What are your thoughts on this?
 - O What is your vision about this?
 - o Are you promoting this role in order to achieve this goal?
 - What other changes will have to be undertaken to achieve this goal?

Are there any other comments you would like to add?

Do you have any questions?

Thank you very much for your time and involvement in this interview. The information you have given me today will be very valuable in exploring the role of independent pharmacists in community pharmacy.

Appendix 27: A portion of transcript (extracted from IPP8 interview) of the thematic analysis process that was conducted iteratively for each IPP in community pharmacy interview (Chapter 6, Section 6.5.1.1)

Step 1: Involved reading and re-reading of the transcript to be familiarised with the data

Step 2: Generating initial codes

Every Monday now we do a drug withdrawal clinic, so the doctor identifies patients who are addicted to prescribed medication, they get referred to me and I take over their prescribing then for that drug, either we wean them down to a more suitable level or too high a dose or we get them ideally off the medication over however long it takes. So, we have fortnightly appointments with the patients assess them, come up with a reduction plan then we reduce ideally in line with the plan we've set out or sometimes you have to stall it if people are struggling things like that. Then we've started to do some private things. Private prescriptions for Viagra or finasteride or norethisterone, and then I did further training then to do Botox as well for cosmetic and sweating things like that too, so we've used it quite a bit actually and hopefully we'll start doing the minor ailments plus scheme in the pharmacy but there's some issues at the moment with them allowing us access to GP records. I think these guys because I've worked there and they know so these guys will send most of their patients here for the triage anyway you know we've had couple people over today, go over and see [pharmacists name] for your chest and that's not a normal pharmacist's role to listen to someone's chest they would need a GP appointment. So, I think it will just be a standardisation of what I'm already doing really and rather than me referring them to doctors when I know what it is I would write the prescription anyway, I can't see it having much of an impact, just utilising my skills better. You know it's added in pressure you know because people ask to see me at certain times or want consultations but the contract is a service based contract and so it's always going to be the same and we have to make adjustments in the way we work to make the time up so we try to find an ACT and doing that but it definitely does have an impact on my time which affects the flow of the shop. We just have to work harder at the moment its purely shorter lunch breaks, coming in early and finishing late, probably the same story in every pharmacy you go to. It has increased the workload, running an IP workload is time consuming but it is very rewarding.

Scope of practice

Seeing patient approach (GP referral)

IP role in CPs

Follow-up appointment

IP role in CPs

Scope of practice

Lack of GP records access

Seeing patient approach (GP referral)

High workload issue

Step 3: Reviewing the codes and searching for sub-themes and themes, which involved linking, merging, defining, and naming of concepts

Sub-themes

- Scope of practice (□)
- Access to GP records (■)
- Workload (□)

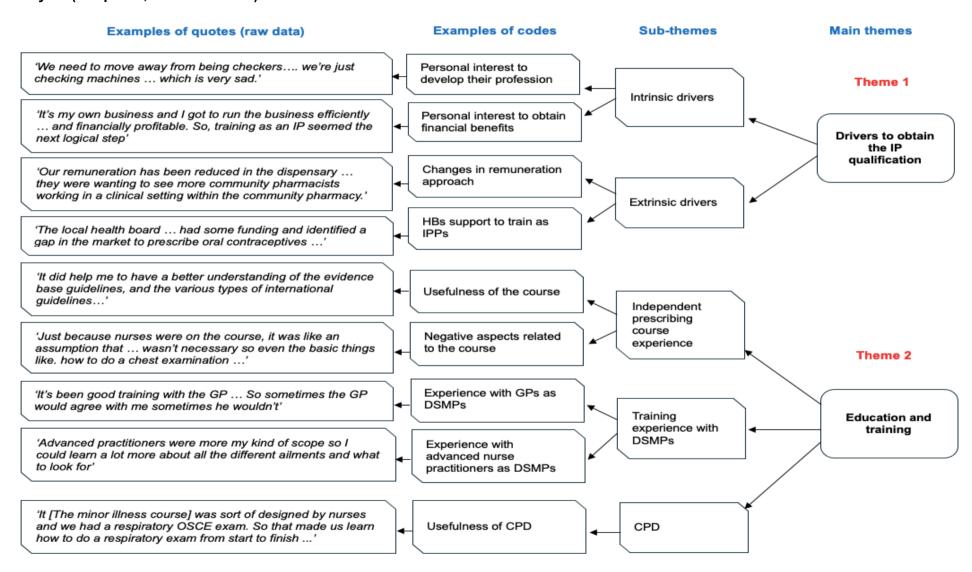
Step 4: defining, reviewing, comparing and identifying relationship

Main theme: Role of IPPs

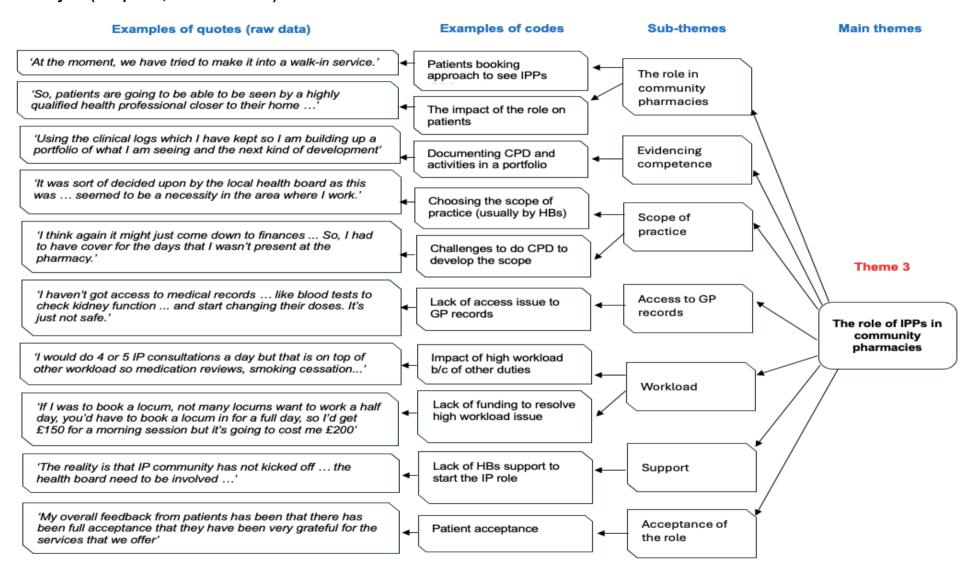
Step 5: Reviewing and confirming themes and sub-themes by the researcher and supervisors

Final Main theme: The role of IPPs in community pharmacies

Appendix 28: Examples of quotes, used codes, and final sub-themes and themes of IPPs in community pharmacies thematic analysis (Chapter 6, Section 6.5.1.1)



Appendix 28: Examples of quotes, used codes, and final sub-themes and themes of IPPs in community pharmacies thematic analysis (Chapter 6, Section 6.5.1.1) *Cont.*



Appendix 29: A portion of transcript (extracted from CPL1 interview) of the thematic analysis process that was conducted iteratively for each CPL interview (Chapter 6, Section 6.5.1.3)

Step 1: Involved reading and re-reading of the transcript to be familiarised with the data

'So, the first logistical issue was the sharing of patient information. Having read and write access to, to GP systems, and we had, we had problems with it. Getting the IT involved, so we had to buy laptops with remote access. Icons that they could remotely access the individual practices, and get the sharing agreements, the information sharing agreements signed off. The other issues were, we didn't have a clue how much to pay for the service, right. So, we had to develop our own SLAs [Service Level Agreements], working with other health boards, because, you know, we wanted to have a similar cost structure, because it doesn't help if we're different from the other health boards. There was a lot of debate about that. So that took a long time to put together, and then to ratify it through the health board mechanisms. Which can sometimes be a bit slow. They're probably doing five half days a week. A half day is one session, yeah because we don't know yet what the demand is, so it's really awkward, to be honest, to convert it into sessions, because, we tried that with the common ailments service, that's why I sort of stumble on the figures, but we've come around more to like a transaction based, we pay for so many consultations, and they could happen at any time. I was trying to work out, you know, what that translates. So, we pay for a maximum, I don't know, say of 18 consultations or what have you. I can't remember what the exact number is. And we then try and convert it to sessions. It's based on consultations, but the payment is based on sessional rate. It's really complicated. Because we don't really know what we're doing in terms of our like, financial modelling. We're trying to pay a rate for capacity for the service. So, that's sort of a dark art at the moment. We looked at areas where our practices were struggling where there were service issues, where we had patients who weren't very happy with the level of services that we were giving from our practices. So, we picked practices within those geographical areas. The practices that we tend to pick would be those ones who really engage with us on delivery of enhanced services. So, you're more likely to be successful in getting one of these if you really delivered a full range of the enhanced services that we want the pharmacies to do, so that was another selection criteria for us, and really having the right person there, who could be developed as an IP really. So, there's no point sort of asking, say, a pharmacy aide to do it, if they haven't got a pharmacist there who's desperate to do the course. Another issue was, actually we trained the IPs, they got their qualification and left. To go into primary care. Because they were looking for a career move anyway, so that was very difficult. So out of the seven we trained, three of them left to become IPs in practices."

Step 2: Generating initial codes

Access to GP records (challenges)

Remuneration for IP sessions (unclarity)

Number of IP sessions

Remuneration for IP sessions (unclarity)

Choosing of GP practices to implement IPPs' role

Choosing of pharmacists to do IP role

IPPs commitment to do the role in CPs

Step 3: Reviewing the codes and searching for sub-themes and themes, which involved linking, merging, defining, and naming of concepts

Codes linking to a theme

- National strategies (□)

Step 4: defining, reviewing, comparing and identifying relationship **Main themes:** 1- National strategies: 2- Local implementation

Step 5: Reviewing and confirming themes and sub-themes by the researcher and supervisors

Final Main theme: 1- National strategy; 2- Local implementation and startegies

Appendix 30: Examples of quotes, used codes, and final sub-themes and themes of CPLs in HBs thematic analysis (Chapter 6, Section 6.5.1.3)

