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The provision of general medical services by non-medical health professionals and allied health professionals: systematic reviews, survey and mixed-methods study.

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The provision of general medical services by non-medical health professionals and allied health professionals: systematic reviews, survey and mixed-methods study

by

Bethany Fern Anthony

A thesis submitted to Bangor University for the degree of Doctor of Philosophy



APRIL 24, 2023
PRIFYSGOL BANGOR UNIVERSITY
School of Medical and Health Sciences

Declaration

'I hereby declare that this thesis is the results of my own investigations, except where otherwise stated. All other sources are acknowledged by bibliographic references. This work has not previously been accepted in substance for any degree and is not being concurrently submitted in candidature for any degree unless, as agreed by the University, for approved dual awards.'

'Yr wyf drwy hyn yn datgan mai canlyniad fy ymchwil fy hun yw'r thesis hwn, ac eithrio lle nodir yn wahanol. Caiff ffynonellau eraill eu cydnabod gan droednodiadau yn rhoi cyfeiriadau eglur. Nid yw sylwedd y gwaith hwn wedi cael ei dderbyn o'r blaen ar gyfer unrhyw radd, ac nid yw'n cael ei gyflwyno ar yr un pryd mewn ymgeisiaeth am unrhyw radd oni bai ei fod, fel y cytunwyd gan y Brifysgol, am gymwysterau deuol cymeradwy.'

Thesis Abstract

Background

The National Health Service (NHS) in Wales and the rest of the UK faces unprecedented challenges due to staff shortages and limited resources, coupled with an ageing population and the increasing prevalence of chronic conditions. The increased use of non-medical health professionals and allied health professionals (AHPs) to perform some roles instead of general practitioners (GPs) is a rapidly expanding approach that has been proposed as a potential solution to compensate for the increased pressures placed on the NHS. The broad aim of this thesis was to explore the advantages, disadvantages and consequences of role substitution.

Methods

Multiple methods were utilised in this thesis to explore role substitution within primary care. Two systematic reviews were conducted to uncover evidence of cost-effectiveness (Chapter 2) and barriers and facilitators (Chapter 3) of role substitution in primary care. An online survey was conducted to explore the extent to which role substitution was being implemented locally in general practices across Wales at cluster level (Chapter 4). A mixed-methods sequential explanatory design was implemented and involved a two-stage process: the collection and analysis of quantitative data using budget impact analysis (BIA), and then the collection (semi-structured interviews) and analysis (using Framework Approach) of qualitative data. A range of perspectives were considered, from the patient perspective through to the provider and funder perspectives, with each perspective offering an opportunity to provide a distinct piece of evidence towards a larger overarching topic of role substitution in general practice. This PhD used conceptual framework to consider the overall thesis findings in relation to the six dimensions proposed by Robert Maxwell for evaluating quality in healthcare. This thesis was also framed by an awareness of theories concerning role substitution and the system of professions.

Summary of findings

The systematic review identified six economic evaluations exploring the cost-effectiveness of nurses and pharmacists providing vertical substitution to GPs. There was some evidence that substituting GPs with nurses to treat common minor health problems is cost-effective. A separate qualitative systematic review uncovered a number of barriers and facilitators to pharmacists and physician associates providing general medical services instead of GPs.

Cluster lead survey respondents provided information on a variety of strategies to increase the uptake of role substitution including the ongoing support to employ and train AHPs and increase the uptake of independent prescribing by nurses and pharmacists. The BIA indicated an increase in vertical substitution with a reduction in GP appointments, and a rise in non-medical health professional and AHP consultations reported at the two practices between 2016 and 2018. Interview participants described conscious changes that had been introduced to reduce barriers and hierarchical structures within their practice teams. A clear lack of understanding of roles among patients and staff was an important finding. Care navigators were found to have an important role to play in the process of role substitution, but their levels of training were a concern. Physiotherapists and occupational therapists (OTs) offer a potentially acceptable role in the areas of musculoskeletal health and mental health, respectively.

Conclusion

This thesis offers unique insights into the implementation of role substitution in general practice in Wales. Novel findings across a wide range of roles are presented, including the consideration of whole-practice team dynamics to explore the costs and acceptability of role substitution in real-world settings. Clearly defined roles, good communication and teamwork are important when expanding roles in general practice. If role substitution is not clearly defined and boundaries not fully understood, this will have critical implications on how roles that are substituted, shifted and supplemented can be measured in practice and how this subsequently impacts on quality of services. Role substitution is complex and ever-changing. The approaches used for its successful implementation will vary considerably across practices and decisions must be based on the patient populations in which they serve.

Covid-19 impact statement

All data were gathered before the Covid-19 pandemic. Data analysis for chapters 2, 3, 4 and 5 were completed before the Covid-19 lockdown period. The majority of the write-up for chapters 2, 3, 4 and 5 were completed before the pandemic. Data analysis and interpretation for chapter 6 (qualitative interviews) were completed over the lockdown period when homeworking working was required. During this period, supervisory support on the analysis and interpretation of the qualitative findings was provided during online Microsoft Teams meetings. Writing of the introduction and discussion chapters (chapters 1 and 7) and finalised versions of the other chapters (2, 3, 4 and 5) were completed following the Covid-19 lockdown period when access to university facilities was fully resumed and face-to-face supervision meetings became available.

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Table of Contents

Declaration	2
Thesis Abstract	3
Covid-19 impact statement	5
Table of Contents	7
List of figures	10
List of tables	10
List of appendices (see supplementary document 1)	12
List of abbreviations	13
List of definitions	15
CHAPTER 1: INTRODUCTION	17
The NHS in the UK: primary care within a complex health system for health care	17
Definitions of primary care and general practice	18
A brief history of general practice, the GP contract and subsequent changes to the gen	neral
practice workforce	20
Spotlight on General Practice Workforce in Wales	24
Funding, organisation and delivery of general practice-based primary care	25
The role of the general practitioner – increasing pressures and workloads	28
Statement of the problem and rationale for this thesis	29
Role substitution	30
What we already knew about role substitution in 2016	35
Theories relating to role substitution	40
Definition of role substitution, non-medical health professionals and AHPs in this the	sis.45
A conceptual framework to judge quality in health care	46
Thesis methodology	50
Mixed-method designs	52
Health economics – the quantitative phase of the sequential explanatory design	54
Patient and provider perspectives – the qualitative phase of the sequential explanatory	7
design	55
Aims of the thesis	57
Thesis research questions	58
Thesis structure	58
Original contribution of the thesis	60

CHAPTER 2: A QUANTITATIVE SYSTEMATIC REVIEW OF ECONOMIC	
EVALUATIONS OF ROLE SUBSTITUTION IN PRIMARY CARE	62
Introduction	62
Methods	64
Results	66
Discussion	79
Conclusion	84
CHAPTER 3: A SYSTEMATIC REVIEW OF QUALITATIVE STUDIES EXP	PLORING
ROLE SUBSITUTION IN PRIMARY CARE	86
Introduction	86
Methods	88
Results	94
Discussion	115
Conclusion	119
CHAPTER 4: THE CURRENT USE OF ROLE SUBSTITUTION IN GENERAL	ΛL
PRACTICES ACROSS WALES: AN ONLINE SURVEY	121
Introduction	121
Methods	125
Results	129
Discussion	132
Conclusion	138
CHAPTER 5: THE INCREASED USE OF ROLE SUBSTITUTION IN TWO	GENERAL
PRACTICES IN NORTH WALES: A BUDGET IMPACT ANALYSIS	139
Introduction	139
Methods	143
Results	149
Discussion	160
Conclusion	167
CHAPTER 6: A QUALITATIVE EXPLORATION OF PATIENT AND PRAC	TICE TEAM
MEMBERS VIEWS REGARDING ROLE SUBSTITUTION IN GENERAL PI	RACTICE 168
Introduction	168
Methods	170
Results	179
Discussion	214

Conclusion.	.223
CHAPTER 7: DISCUSSION	.224
Scope and approach of the thesis restated	.224
Summary of findings in relation to the research questions	.225
Sequential explanatory mixed methods - integration across the health economics and	
qualitative workstreams	.230
Critical reflection of the mixed methods process	.235
Strengths and limitations of this thesis	.238
Implications for practice and policy	.242
Comparisons with existing literature and recommendations for future research - Update	d
literature searches since systematic review searches in 2017	.245
Findings in relation to the conceptual framework of the thesis	.252
Consideration of the thesis findings in relation to theories of role substitution and the	
dynamic system of professions	.260
Critical reflection of the overarching framework of the thesis and theories of role	
substitution	.267
Original contribution of the thesis restated	.270
Conclusion.	.271
References	.273
Appendices (see supplementary document 1)	.318

List of figures

Figure 1: Structure and layout of the thesis	61
Figure 2: Systematic review flow diagram	69
Figure 3: Identification and screening of relevant studies.	98
Figure 4: Flow chart of the phases of the development and administration of the su	urvey125
Figure 5: Illustration of the patient pathway when entering general practice before	the use of
role substitution	142
Figure 6: Illustration of the patient pathway when entering a general practice using	g role
substitution	142
Figure 7: Changes in the number of consultations at Practice A between 2016 and	2018152
Figure 8: Changes in the number of consultations at Practice B between 2016 and	2018153
Figure 9: Integration through methods	232
Figure 10: Integration at the interpretation and reporting level	234
Box 1: Maxwell's six dimensions of quality (Maxwell, 1992, p.171)	for role
List of tables Table 1: General practice workforce statistics in Wales between 2013 and 2021 (h	eadcount)
Table 2: Role descriptions of common non-medical health professional and AHP	roles31
Table 3: Quality appraisal of economic evaluations of role substitution in primary	care67
Table 4: Characteristics of included studies (n = 6)	70
Table 5: Results of included studies (n=6)	76
Table 6: Quality appraisal of qualitative studies of role substitution in primary car	e96
Table 7: Characteristics of included studies (n=11)	99
Table 8: Number of general practices across clusters in Wales in 2019	123
Table 9: Use of role substitution across general practices in Wales (%)	131
Table 10: Unit costs of health service activity at Practice A	151
Table 11: Unit costs of health service activity at Practice B	153
Table 12: Differences in consultations and costs at Practice A between 2016 and 2	2018157
Table 13: Differences in consultations and costs at Practice B between 2016 and 2	2018 158

Table 14: Sensitivity analysis to vary to unit cost of GP locum consultations at Practice A between 2016 and 2018
Table 15: Planned patient sample matrix (sampling target number of cases and monitoring criteria)
Table 16: Categorisation of simple, moderate and complex cases based on number of chronic conditions
Table 17: Categorisation of occasional, normal and frequent attenders based on the number of attendances at general practice per year
Table 18: Total final sample of patients achieved
Table 19: Total sample of primary care team members achieved across both practices181

List of appendices (see supplementary document 1)

Appendix 1: Search strategy in OVID Medline

Appendix 2: PRISMA checklist

Appendix 3: Economic evaluation appraisal tool responses (Drummond et al., 2005).

Appendix 4: Search strategy in Medline database

Appendix 5: PRISMA checklist

Appendix 6: Critical Appraisal Skills Programme (CASP) qualitative checklist responses

(Public Health Resource Unit, 2006)

Appendix 7: Survey instrument (English version)

Appendix 8: HRA and Health and Care Research Wales (HCRW) approval letter

Appendix 9: Survey invitation email (Bilingual - English and Welsh)

Appendix 10: Survey reminder email (Bilingual - English and Welsh)

Appendix 11: Data sharing agreement

Appendix 12: Participant invitation letter (patients)

Appendix 13: Participant information sheet (patients)

Appendix 14: Participant reply slip (for patients and team members)

Appendix 15: Participant invitation letter (primary care team members)

Appendix 16: Participant information sheet (primary care team members)

Appendix 17: Participant consent form (patients)

Appendix 18: Participant consent form (primary care team members)

Appendix 19: Letter informing GP of study participation

Appendix 20: HRA and Health and Care Research Wales (HCRW) Approval Letter

Appendix 21: Lone worker tracking form

Appendix 22: Transcriber confidentiality agreement

Appendix 23: Interview topic guide (patients)

Appendix 24: Interview topic guide (team members)

Appendix 25: Example of Framework Index

Appendix 26: Examples of Framework matrix/chart

Appendix 27: Example of Framework interpretation exercise

List of abbreviations

ACE - angiotensin-converting enzyme

AHP – allied health professional

ANP – advanced nurse practitioner

APP – advanced paramedic practitioner

BIA – budget impact analysis

BMA – British Medical Association

CAMHS - Child & Adolescence Mental Health Services

CASP -Quality Appraisal Skills Program

CBA -cost-benefit analysis

CBT – cognitive behavioural therapy

CCA – cost-consequence analysis

CCG – clinical commissioning group

CEA – cost-effectiveness analysis

CHEERS - Consolidated Health Economic Evaluation Reporting Standards

CHP – community health practitioner

CI – confidence interval

CINAHL - Cumulative Index of Nursing and Allied Health Literature

CPP – community paramedic practitioner

CPD – continuing professional development

CUA – cost-utility analysis

DARE - Database of Abstracts of Reviews of Effects

EQ-5D – EuroQol 5 dimensions

FTE – full time equivalent

GBP – Great Britain pounds

GMS – general medical services

GP – general practitioner

HCA – health care assistant

HRQoL – health-related quality of life

ICER - incremental cost-effectiveness ratio

IT – information technology

LES – local enhanced services

LHB - local health board

MDT – multidisciplinary team

MEDLINE - Medical Literature Analysis and Retrieval System Online

MSK – musculoskeletal

NES – national enhanced services

NHS - National Health Service

NHS EED – The National Health Service Economic Evaluation Database

NICE – National Institute of Health and Clinical Excellence

NIHR - National Institute for Health and Care Research

NP – nurse practitioner

OT – occupational therapist

PA – physician associate

PBMA – programme budgeting and marginal analysis

PCN – Primary Care Network

PHC – primary health care

PICOC - Population, Intervention, Comparison, Outcome, and Context

PhD – Doctor of Philosophy

PMAS - pharmacy-based minor ailment schemes

PR – pragmatic rehabilitation

PRISMA – preferred reporting items for systematic reviews and meta-analyses

PROSPERO - The International Prospective Register of Systematic Reviews

QALY – quality-adjusted life year

QARI - Qualitative Assessment and Review Instrument

QES – qualitative evidence synthesis

QOF – Quality and Outcomes Framework

QQE - Quality in Qualitative Evaluation

RCGP – Royal College of General Practitioners

RCN – Royal College of Nurses

RCT – randomised controlled trial

SF-36 – Short Form 36

SGRQ - St George's Respiratory Questionnaire

SL – supportive listening

TAU – treatment as usual

UK - United Kingdom

UNICEF - United Nations International Children's Emergency Fund

WNWRS - Wales National Workforce and Reporting System

WHO – World Health Organization

WONCA - World Organization of Family Doctors

WTE – whole time equivalent

List of definitions

Budget impact analysis (BIA): an economic assessment that predicts the potential financial impact of the adoption of a new health technology or intervention into a health care system with finite resources.

Cost-benefit analysis (CBA): method of economic evaluation that compares costs and consequences of different interventions in monetary values. Only measures factors that can easily be assigned a monetary value.

Cost-consequence analysis (CCA): method of economic evaluation that provides information to decision maker in a simple disaggregated format and the decision maker must make their own choice.

Cost-effectiveness acceptability curve (CEAC): used by policy makers as a method for summarising the uncertainty in estimates of cost-effectiveness of an intervention.

Cost-effectiveness analysis (CEA): method of economic evaluation where costs are compared with the apeutic goal. Health benefits are measured in natural units.

Cost-minimisation analysis (CMA): method of economic evaluation where health outcomes are proven equal. Search for least cost alternative.

Cost-utility analysis (CUA): method of economic evaluation that measures the effects on morbidity and mortality Expressed in terms of cost per unit of utility e.g. QALYs.

Discounting: method to account for differential timing of costs and outcomes in economic analysis. Allows analyst to express future costs and benefits in terms of their value today.

EQ-5D: EuroQol five dimensions questionnaire (EQ-5D) is a standardized instrument for measuring generic health status.

Incremental cost: difference between the costs of an intervention and the comparator.

Incremental cost-effectiveness ratio (ICER): calculated by dividing the difference between the costs of the intervention and comparator by the difference in the outcomes i.e., cost per unit of benefit gained.

Modelling: A statistical method of extrapolating from short to long-term outcomes.

Programme Budgeting and Marginal Analysis (PBMA): An exercise that assesses previous resource allocation in specified programmes and enables decision makers to decide upon future resource allocation decisions in those same programmes.

Prudent healthcare: Prudent healthcare encourages patients to think about the care they require, (i.e., whether they can look after themselves), and to use the most appropriate healthcare services for their clinical need, not the nearest or most familiar.

Opportunity cost: refers to the value of benefits foregone by not utilising resources in their next best alternative use.

Quality-adjusted life year (QALY): Generic measure of disease burden that incorporates both the quantity and quality of life lived. One QALY equates to one year in perfect health.

Qualitative: Observational data i.e., research that deals with words and meanings.

Quantitative: Numerical data i.e., research that deals with numbers and statistics.

Randomised controlled trial (RCT): clinical trial where participants are randomly assigned to either an intervention or control group at the beginning of a trial.

Role substitution: some roles that were previously performed by a general practitioner (GP) but are now completed by a non-medical health professional or allied health professional (AHP)

Sensitivity analysis: process of recalculating outcomes under alternative assumptions in order to explore the impact of uncertainty on research findings.

Utility: Used in health economics analysis to represent the strength of research participants preferences for different health states. Also known as health state preference values.

CHAPTER 1: INTRODUCTION

The National Health System (NHS) in the United Kingdom (UK) has seen the provision of general medical services change over time, with more roles now competed by non-medical health professionals and allied health professionals (AHPs), which has been proposed as a potential solution to workforce shortages and to compensate for the increasing pressures placed on primary care services (Francetic et al., 2022). This introductory chapter firstly sets the scene by providing a background to primary care and general practice and then provides contextual detail about general medical services in England and Wales, including changes to the general practitioner (GP) contract and the general practice workforce over time, information relating to the funding, organisation and models of primary care based general practice and the types of services provided by general practice.

This chapter then presents the concept of role substitution and considers why it is being increasingly implemented across general practices. This introductory chapter follows on by considering the theories relating to role substitution, which will be applied within each of the subsequent thesis chapters and then re-examined in the final discussion chapter when elucidating the overall findings in relation to the thesis research questions. An overarching conceptual framework is then presented and used to describe some of the potential benefits, risks and harms of role substitution in relation to quality of healthcare. This framework is applied to the findings of each chapter and then returned to in the discussion chapter to critically discuss and synthesise the overall findings from this thesis.

To explore existing knowledge on the topic of role substitution in general practice and gaps in existing knowledge, a presentation of published literature on the topic of role substitution in primary care is described and considered in terms of its impact on clinical and patient outcomes, quality of care, costs, and perspectives of role substitution. Finally, this introductory chapter outlines the research methodology used in this thesis and presents the research questions and an overview of the structure and content of this thesis.

The NHS in the UK: primary care within a complex health system for health care

In the UK, healthcare has been centrally funded through the NHS since its creation in 1948 (Kmietowicz, 2006; Nuffield Trust, 2022). The NHS is a complex health system made up of several component parts (Burton et al., 2018), providing care through primary frontline health services before referral to secondary and tertiary specialist services where required to treat health conditions within the population (Roland, Guthrie and Thome, 2012). Primary

care has been recognised as the section within the health care system that provides the first point of contact for personal medical care to the whole UK population and serves as a gateway for patients to access specialist secondary care (Goodwin et al., 2011). General practice-based primary care is frequently described as the cornerstone of the NHS serving as the frontline provider of healthcare in the UK (Lewith, Peters and Manning, 2016). Approximately 90% of all patient contacts within the NHS take place in general practice (NHS, 2015; The King's Fund, 2011) and in England, approximately 1 million consultations take place in general practice each day (NHS Digital, 2016). The funding, organisation, and delivery of general medical services in the UK and Wales are discussed in more detail later in this chapter.

Definitions of primary care and general practice

The World Health Organization (WHO) and the United Nations International Children's Emergency Fund (UNICEF) define primary health care (PHC) as: "a whole-of-society approach to health that aims to ensure the highest possible level of health and wellbeing and their equitable distribution by focusing on people's needs and preferences (as individuals, families, and communities) as early as possible along the continuum from health promotion and disease prevention to treatment, rehabilitation and palliative care, and as close as feasible to people's everyday environment" (WHO and UNICEF, 2018, p.2).

The critical role of PHC has been discussed internationally with key declarations highlighting the critical role of primary care in public health (WHO, 2022). In 1978 the Alma-Ata Declaration "emerged as a major milestone of the twentieth century in the field of public health, and it identified primary health care as the key to the attainment of the goal of Health for All" (WHO, 2022). The benefits of PHC have been extensively reported on and it is recognised by the WHO that: "Health systems that rely relatively more on primary health care and general practice in comparison with systems more based on specialist care in terms of better population health outcomes, improved equity, access and continuity and lower cost (Atun, 2004). In 2018 the Declaration of Astana reaffirmed and built on these commitments to developing equitable and sustainable universal healthcare, with the strengthening of PHC at the core of the declaration (WHO, 2019). The core principles of PHC are based on equity whereby all patients deserve the right to healthcare within their community. Moreover, the PHC approach should meet patients' health needs throughout their lives, while tackling the wider determinants of health through multisectoral policy and should encourage patients to take responsibility of their own health (WHO and UNICEF, 2018).

According to the WHO, the terms PHC, primary care and general practice are often used interchangeably in the literature (Atun, 2004), and a number of different definitions exist which often makes the distinctions between these concepts unclear (Jamoulle et al., 2017). Professor Barbara Starfield, an eminent primary care researcher (Roland, 2011), defined primary care as "first-contact, continuous, comprehensive, and coordinated care provided to populations undifferentiated by gender, disease, or organ system" (Starfield, 1994, p.1129). In the UK NHS, primary care is considered to be general medical practices, general dental practices, community pharmacies and opticians (NHS Digital, 2021). There are differences in the organisation of healthcare within the UK with health considered independently by each of the four countries with the UK since devolution in 1998 (Greer, 2016; Roland et al., 2004). In Wales, primary care is described as all healthcare personnel and services that deliver care locally to meet the physical, mental, and social health and wellbeing needs of a local community (Welsh Government, 2018a).

Statistics for Wales define general practices as organisations that provide primary care medical services by a qualified GP to patients who can be registered at the practice and kept on the practice patient list (Statistics for Wales, 2020). The King's Fund define general practices as "small to medium-sized businesses whose services are contracted by NHS commissioners to provide generalist medical services in a geographical or population area" (Beech and Baird, 2020). The European definition of a GP or family physician states that they are personal doctors who are principally responsible for providing comprehensive and continuous care to every patient regardless of age, sex and illness and care for patients in the context of their family community and culture whilst always upholding their patients' autonomy (WONCA Europe, 2005). General medical practice (also known as general practice-based primary care) is a subset of primary care and for the purpose of this thesis, I will refer to it as general practice for brevity.

A wider team of health care professionals within primary care works closely with general practice and is often housed on the same premises. This team includes community services such as midwives, health visitors, district nurses, community occupational therapists (OTs) and community physiotherapists, and could also include social work teams and community mental health care teams. More recently, additional roles have been developed that are managed by primary care networks (PCNs), which are a group of general practices in England, where the equivalent groupings of general practices in Wales are called primary care clusters, which are described further down in this chapter. These additional roles may

include health and wellbeing coaches and social prescribing coordinators (NHS England and NHS Improvement, 2020; Drinkwater, Wildman and Moffat, 2019).

A brief history of general practice, the GP contract and subsequent changes to the general practice workforce

The nineteenth century gave rise to the GP, where they first began as private traders who only provided care to patients who could afford their services (Kmietowicz, 2006; Bloor, 1978). In 1911, Lloyd George introduced the National Insurance Act which meant that low paid workers had free access to a GP, although this did not include cover for their spouses, children or the unemployed (Livingstone and Widgery, 1990). Nevertheless, circumstances dramatically changed in 1948 when the NHS was established, and every person was eligible to see a GP for free at the point of access (Kmietowicz, 2006). According to a report commissioned by the King's Fund, approximately 90% of the UK population had registered with a GP within one month of the foundation of the NHS (Goodwin et al., 2011).

Changing patient needs, such as increasing life expectancy and dealing with a wider scope of problems, including social and psychological issues (Litchfield et al., 2017), alongside key changes to public policy, such as the drive to deliver more services outside of hospitals (National Assembly for Wales, 2017), have required significant changes within the organisation of general practice. In the beginning, GPs used to work independently, typically assisted by a receptionist, often from the doctor's home residence (Hasler, 1992). The number of roles and the complexity of the general practice team has increased over time, beginning with the introduction of practice nurses and practice managers (Loudon, Horder and Webster, 1998), and more recently with the widening of teams to include other health professionals and administrative staff (Statistics for Wales, 2020). The Family Doctor Charter 1966 provided a "contractual framework" (Hasler, 1992, p.233) which impacted the ways GPs were paid, allowing for full reimbursement of premises costs and for employment of staff, with 70% of costs eligible for reimbursement. With this change, the number of receptionists and secretaries increased, and the employment of practice nurses became a viable option (Hasler, 1992). The vast changes in the number and types of personnel in general practice over time can be contextualised by changes to GP contracts over the years.

In 1987 the UK Government set out plans in the white paper for promoting better health through the increased role of primary care to address health promotion and the prevention of ill-health (Wilson, 1987). Following these proposals, a new GP contract was

introduced in 1990 to strengthen health services and to link GP pay more firmly to performance. In order to increase GP involvement in preventative healthcare, GPs received performance related payments for the provision of different services, for example, for running health promotion clinics, collecting patient health check information (such as height, weight and blood pressure), and for meeting immunisation and screening targets (Bunton, Burrows and Nettleton, 2003). GPs were also granted budgets to commission services to meet the demands of the patient populations in which they served (Leese, Drummond and Hawkes, 1994). During this period, GPs had greater responsibility for local resource allocation and experienced increasing workloads (Sibbald et al., 2000). To meet the requirements of the 1990 GP contract, there was a significant investment in practice nurses who became a core element of general practice, which resulted in a marked rise in their employment in the 1990s and early 2000s. For example, between 1995 and 2005, the number of GP practice nurses in England increased by a quarter, from 18,243 to 22,904 (NHS Digital, 2006). Moreover, the number of consultations undertaken by nurses in general practice increased from 21% to 34% between 1995 and 2006 (The Information Centre, 2008). In Wales, data is available from 2000 through the StatsWales repository, which demonstrated an increase in the number of whole time equivalent (WTE) practice nurses from 713 to 748 between 2000 and 2005 (Statistics for Wales, 2006).

The increase in the number of GP nurses during this time period can be further explained by a survey conducted in 1990 of GPs in England and Wales which revealed that 50.7% of survey respondents had established new nursing posts in order to meet the conditions of the new 1990 GP contract, and 83.1% had expanded the roles of nurses already employed at their practices (Robinson, Beaton and White, 1993). There was also an increase in the administrative workload of GPs that stemmed from the reforms of the 1990 contract (Leese and Bosanque, 1996; Hannay, Usherwood and Platts, 1992), which consequently led to an increase in the numbers of administrative staff in general practice. For example, between 1995 and 2005, the number of administrative and non-clinical staff in general practices in England increased from 79,551 to 89,190 (NHS Digital, 2006). Data for Wales is available from 2000, which demonstrated an increase in the number of WTE administrative and clerical roles from 3151 in 2000, to 3216 in 2005 (Statistics for Wales, 2006). During this time the number of GPs also rose with targets outlined in the 2000 NHS Plan to provide government funding for an extra 2,000 GPs and 450 GPs in training by 2004 exceeded, as the

number of qualified GPs in England had increased by 3,330 by 2004 (Department of Health, 2005).

In 2004, a new general medical services (GMS) contract was introduced in the UK which presented major changes to general practice (Peckham, 2007). The new contract was practice-based, with patients required to register with practices rather than with a single GP (Peckham, 2007). The new contracts were based on workload management with core and enhanced service levels. Contractual changes provided greater opportunity for GPs to manage their workloads as they could opt out of providing some services such as out of hours (Wales Audit Office, 2007). Practices were also able to obtain separate funds to improve their administration and information technology (IT) systems, with modernisation of practice infrastructure a core principle of the new contract (Peckham, 2007). The new GMS contract brought forward three main funding systems: the global sum (based on a practice's patient workload to deliver essential and additional services), enhanced services and the Quality and Outcomes Framework (QOF). A major introduction was the QOF, a points-based system, which provided financial incentives for GPs to work towards government set guidelines primarily for the management of chronic conditions (Peckham, 2007).

In response to the minimum standard of care set for patients with long term conditions, nurses have played a vital role in the delivery of QOF, with opportunities for nurses to gain more specialist skills in managing long term conditions resulting in increased role responsibility and workload (McGregor et al., 2008). The provision of enhanced services under the new contract also meant that more specialised services were undertaken in general practice by nurses with special interests and AHPs. GPs also started to employ healthcare assistants (HCAs) in order to provide capacity for nurses to concentrate on their specialised work and there was an increased incentive to educate and increase the development of nursing roles in general practice (Bosley and Dale, 2008).

For the next decade, between 2004 and 2014, the total number WTE general practice staff in England increased by 23%, from 72,006 to 88,396 WTEs (Health and Social Care Information Centre, 2015). Over the same period, the number of WTE GPs (excluding registrars and retainers) increased by 15%, WTE nurses increased by 11%, and WTE administrative and clerical staff increased by 17% (Health and Social Care Information Centre, 2015). It is challenging to compare the number of GPs and wider practice staff over time across the UK devolved nations as different sources of information exist which cover different time periods. In Wales, between 2004 and 2014, the number of GPs (by headcount,

excluding registrars, retainers and locums) also increased by 10.5% (Statistics for Wales, 2015). Official government statistics in Wales (Stats Wales, 2022; Welsh Government, 2022) provides data for nurses and the wider practice team which is available from 2013 onwards and is presented in Table 1 and referred to throughout this chapter.

Table 1: General practice workforce statistics in Wales between 2013 and 2021 (headcount)

Year	GPs	Advanced nurses	Extended nurses	Practice nurses	Total nurses	Direct patient care	Admin and clerical
2013	2,026	126	163	1,007	1,296	885	4,740
2014	2,006	141	161	986	1,288	900	4,694
2015	1,997	170	223	894	1,287	909	4,834
2016	2,009	200	273	804	1,327	955	4,722
2017	1,926	239	258	810	1,312	990	4,666
2018	1,964	279	263	789	1,338	1,038	4,793
2019	**	**	**	**	**	**	**
2020	1,962	258	160	950	1,409	1,114	5,142
2021	2,002	271	150	948	1,408	1,237	5,345

Source: Data for September 2013 -2018 obtained from GMS Census (Welsh Government, 2022); **Data for 2019 not available; Data for March 2020 – June 2021 (Statistics for Wales, 2022) obtained from Wales National Workforce Reporting System (WNWRS).

The findings of a retrospective analysis of GP and nurse consultations in England between 2007 and 2014 reported a substantial increase in practice consultation rates and lengths, and total patient-facing clinical workload (Hobbs et al., 2016). Despite the changes to the GP contract and an increase in the number of general practice staff between 2004 and 2014, these factors were argued to be inadequate to compensate for rising demands on general practice and workload continued to rise (Hobbs et al., 2016).

Notable changes to general practice in England also included further changes to the GMS contract in 2015 which comprised of the compulsory publication of GP net earnings, a named accountable GP for all patients, a compulsory patient participation group within practices, and an increased commitment to improve and enhance online services (Kmietowicz, 2014). Moreover in 2015, the RCGP produced an updated General Practice Nurse Competency Framework to be utilised by the four devolved nations of the UK which acknowledged the expanding roles of nurses in general practices including the progression towards expertise in more specialised areas within their practice (RCGP, 2015). This is demonstrated in the general practice workforce statistics which shows that the number of

extended role practice nurses (defined as nurses who have received additional training in a specialist area such as diabetes, asthma, learning disability, mental health and sexual health) increased by 100 between 2013 and 2018 in Wales (Table 1). There has been a substantial rise in the number of advanced nurses (defined as nurses who have high levels of clinical skill, competence and autonomous decision-making) which demonstrates their increasing contribution to general practice teams in Wales (Table 1).

In 2015, the Secretary of the State in the UK Government at the time, Jeremy Hunt, pledged an extra 5,000 GPs for the NHS by 2020 to help deliver the 'NHS Five Year Forward Pan', which also outlined an agenda to increase the number of GPs in training as quickly as possible while also training more nurses and other wider general practice staff (Fitzmaurice, Moger and Storey, 2015; The King's Fund, 2015). Nevertheless, this promise was not realised and instead it was forecast that there would be a shortage of 7,000 GPs by 2024 (Nussbaum et al., 2021). Similarly, by 2017 the GP workforce in Wales was at its lowest level for a decade with a GP count of 1,926 (Table 1).

In 2019, changes to the GP contract as part of the 'NHS long Term Plan' introduced primary care networks (PCNs) in England which provided opportunities for neighbouring practices to join networks and work together to enhance integrated community-based healthcare services with an emphasis on expanding multi-disciplinary teams in general practice (British Medical Association and NHS England, 2019). To support PCNs, the Additional Roles and Reimbursement Scheme was introduced to allow PCNs access to funding to employ 26,000 additional roles including clinical pharmacists, social prescribing link workers, physician associates, physiotherapists and paramedics (NHS England and NHS Improvement, 2019).

Spotlight on General Practice Workforce in Wales

In Wales there has been a strong policy drive to invest in the development of the wider primary care workforce. Primary care clusters were first introduced in Wales in 2010 and are described later in this introductory chapter (under the 'Funding, organisation and delivery of general practice-based primary care' subheading). In 2015 the 'Planned Primary Care workforce' strategy document outlined plans to introduce a more robust approach to workforce planning and to supporting the continuing development of primary care clusters (Welsh Government, 2014). In 2015/16, Welsh Government allocated £6 million directly to

clusters to support the development of the wider primary care workforce to deliver more accessible and prudent healthcare which financially incentivised the employment of more roles in general practice such as advanced practice pharmacists, physiotherapists, OTs, advanced practice paramedics and physician associates (Welsh Government, 2015). Investments made to expand the general practice workforce in Wales have resulted in the rapid increase in the number of direct patient care staff in general practice which has increased by almost 40% between 2013 and 2021 (Table 1). Direct patient care staff is defined as "anyone who is directly involved in delivering patient care but who is not a nurse or GP. This includes health care assistants (HCAs), physiotherapists, pharmacist, phlebotomist, chiropodists, dispensers, counsellors, and complementary therapists" (Statistics for Wales, 2019, p.20).

In Wales, the number of administrative and clerical roles have also increased from 4,740 to 5,345 between 2013 and 2021, respectively (Table 1). Shifts in administrative work between clinicians and non-clinicians has meant that the roles of receptionists and administration staff have expanded (Litchfield et al., 2017). An example of shifts in administrative work in general practice has been the introduction of protocols for clerical staff to deal with incoming clinical correspondence in order to reduce the administrative burden on GPs (NHS England, 2016). Moreover, the role of many general practice receptionists has now expanded to perform a care navigation role (described further below in this chapter under the 'role substitution' sub-heading).

Funding, organisation and delivery of general practice-based primary care

Primary and specialist care available from the NHS is mostly free at the point of access to patients and is funded nationally by general taxation (Roland, Guthrie and Thome, 2012). In Wales, funding is allocated to Local Health Boards (LHBs) from Welsh Government, and the funding received to deliver primary care is ring fenced (apart from general dental services), which means that health boards are required to spend their whole allocation on these services (Wales Audit Office, 2018). In 2016-2017 in Wales there was £1.39 billion spent on primary care, equating to 22% of the £6.32 billion total health board spending (Wales Audit Office, 2018). When considering trends in spending over time, spending on primary care increased between 2010 and 2016 in absolute terms, however, when considering rates of inflation, a real terms reduction in spending on primary care has been reported (Wales Audit Office, 2018). In 2019-2020 primary healthcare services in

Wales were reported as £1.56 billion, equating to 16% of £9.60 billion in total expenses (Wales Audit Office, 2022). While this trend for a reduction in real terms spending has appeared to continue over time, despite an increasing emphasis on primary care in NHS policy, precise figures of expenditure are difficult to assess with acknowledgement that "expenditure by health boards on primary care is not consistently categorised and as such it is likely that the figure recorded in the accounts does not represent the totality of primary care expenditure" (Wales Audit Office, 2018, p.8).

The fundamental premise of general practice is that GPs must provide essential services to manage their list of registered patients when they are unwell (or believe themselves to be ill). Essential services as outlined in the GMS contract may be delivered through direct consultation, examination, prescribing and issuing further investigations such as referrals to specialists (Welsh Government, 2006). General practices may also provide additional services including prevention, screening, vaccinations and immunisations and diagnostic services. General practices may also provide optional enhanced services which can be divided into three categories: direct enhanced services (DES), national enhanced services (NES), and local enhanced services (LES). DES are negotiated nationally with a nationally agreed rate but are optional, such as extended opening hours. NES meet local needs that are also paid through nationally agreed rates and are commissioned nationally. Examples include minor injury and anticoagulation services. LES are locally developed services which are developed to meet the local population health needs, for example, specific disability services. These types of enhanced services are commissioned by clinical commissioning groups (CCGs) in England and LHBs in Wales, and are paid through locally agreed rates. Locally commissioned services may also be commissioned by non-NHS organisations such as local authorities and general practices.

Since devolution in 1999, the four nations of the UK have different policy approaches to organising general practice within their healthcare systems. Healthcare policy in England is created by the UK Government and from 2014-2022 CCGs had the responsibility for commissioning general medical services within their regions. There were 106 CCGs across England (NHS Confederation, 2021) which were replaced by Integrated Care Systems in July 2022 (NHS England, 2022).

In Wales, LHBs are responsible for planning and delivering services within their areas based on the local needs of the population, in both primary and secondary care. Since the last re-organisation in 2009, there are seven LHBs in Wales and three national NHS trusts (NHS

Wales, 2019). In 2010, primary care clusters were introduced by LHBs in Wales which brought together neighbouring GP practices to plan and provide coordinated primary care services based on a geographical locality basis (NHS Wales, 2019). There are 64 clusters across the seven LHBs, each serving patient populations of between 30,000 and 50,000 (NHS Wales, 2019) and each health board is responsible for the delegation of funding to their clusters (Auditor General for Wales, 2018). There are a number of different ways in which general practice staff are employed which often allows some staffing and functions to be shared across practice clusters; however, the extent to which this occurs varies between clusters and health boards (NHS Wales, 2019). Different employment options include: "Health board directly employed staff, staff employed by one practice on behalf of all the practices and alternative models, such as federations of practices within, or between cluster networks" (NHS Wales, 2019, p.13).

GPs have traditionally worked as independent contractors in general practices which are typically GP-owned businesses which they own and run in partnership with a handful of other GPs whereby the majority of their income comes from contracts with the NHS to provide patient care – this is known as the traditional partnership model of general practice (Watson, 2019). Although partners are usually GPs, in some instances partners can also be nurses and practice managers. General practice partners have a contract to provide general medical services and directly make decisions about staffing and the division of labour (Drennan et al., 2017).

There have been substantial changes to general practices in the UK, with average GP practice lists increasing to more than 9,000 patients, equating to a 30% rise between 2013 and 2020 (Bostock, 2020). In Wales, the number of general practices overall reduced from 501 in 2004 to 404 in March 2020 (Statistics for Wales, 2020). In some parts of Wales where it has not been possible to locate independent GP contractors, some general practices are being directly managed by their LHBs who employ all practice staff and has significent rise in GPs who are employed on a salaried basis and provided an alternative model of general practice-based primary practice delivery. In 2018, there were 24 practices that were managed directly by five LHBs in Wales (Wales Audit Office, 2018).

The role of the general practitioner – increasing pressures and workloads

Traditionally, the role of the GP 'family doctor' enabled patients to develop good therapeutic relationships through repeat consultations with the same GP who knew their family and medical history well (Murphy and Salisbury, 2020). Moreover, the longstanding relationships with the family physician has been linked to increased satisfaction, improved health promotion, improved medication adherence, lower hospital use and lower mortality rates (Pereira Gray et al., 2018). Nevertheless, the traditional role of the family physician has slowly diminished over the years due to changes in the organisation of services, such as the increased specialisation and fragmentation of general medical services, workforce redesign and the importance of quick access to services in response to the intensifying pressures placed on general medical services (Levene et al., 2018). There have been concerns regarding a decrease in the number of GPs and the challenges that this would raise in order to cope with demographic changes and the increasing burden of chronic conditions (WHO, 2020; RCGP, 2015).

Factors including practice culture, increased cognitive demands and complexity, and the emotional toll of their work mean that GPs have higher rates of workplace stress and burnout compared to the general UK population (Riley et al., 2017). Burnout is closely linked with recruitment and retention problems in the healthcare workforce (Galleta-Williams et al., 2020; Panagioti et al., 2018). There are also significant concerns regarding the association between GP burnout and detrimental impacts on patient safety (Panagioti et al., 2018; Hall et al., 2016). In 2019, a cross-sectional survey of 232 GPs in the UK demonstrated that 93.8% of respondents were categorised as 'likely suffering from a minor psychiatric disorder' and 94% were experiencing mild (22%) or severe (74%) exhaustion (Hall et al., 2019). Moreover, 86.8% reported mild or severe disengagement and additional modelling analyses found that lower GP wellbeing, due to factors such as increased hours spent on administrative tasks and a perceived lack of support, was associated with an increased probability of having reported a 'near miss' incident in the workplace (Hall et al., 2019). With increasing complexity and pressures in general practice, there are now no 'easy' consultations which is further adding to increased GP cognitive demands and stress levels (Iacobucci, 2021; Procter et al., 2014).

Despite being proposed as a potential solution to workforce crises in general practice and as a way to reduce GP workload, policy initiatives to address workforce crises have been found to have little impact on GP retention (Owen et al., 2019). In their cross-sectional survey of GPs in England, Owen and colleagues found that 48.5% of the GPs surveyed had

brought forward their plans to leave general practice and 18% planned on leaving general practice within two years (an increase of 5% in three years). Despite initiatives to expand the GP workforce, increased GP workload was a significant factor for GPs wanting to leave the profession earlier than initially planned (Owen et al., 2019). There has also been a significant rise in GPs opting for early retirement, from 198 to 721 between 2007 and 2017, respectively (Moberly, 2018). Research funded by the National Institute for Health and Care Research (NIHR) found that improving teamwork in general practice teams has the potential to increase morale and alleviate burnout (Galleta-Williams et al., 2020).

Statement of the problem and rationale for this thesis

General practice in the UK faces significant challenges due to an ageing population and the increasing prevalence of chronic conditions (ONS, 2018). Additional pressures also come from advances in treatments and technologies and increased public expectations. As demand for general practice rises, workload pressures on GPs and their teams increase. There is also a recruitment and retention crisis in the GP workforce. Large numbers of GPs are retiring early or leaving the profession, and many of those who remain in general practice do not undertake full-time clinical work (Mitchell et al., 2018). There is a significant shortage of GPs in the UK needed to compensate for the significant weights placed on the NHS (RCGP, 2015). Despite the government's target of increasing the number of GPs by 2020 there has been a decline in the number of qualified full-time GPs in the UK and an increase in nonpermanent GPs such as locums (Atkins et al., 2020; Buchan et al., 2019). A survey conducted in 2018 highlighted that 23% of GPs said they were unlikely to be working in general practice in the next 5 years (RCGP, 2018). While the number of specialists continues to increase, medical graduates seem less attracted to pursue a career in general practice (Lambert, Smith and Goldacre, 2017), with factors including schedules and income, highworkload, financial pressures and externally imposed directives also implicated in the decision-making process (Barber et al., 2018). Moreover, evidence has also indicated that undergraduate medical students' exposure to comments made by their clinical teachers regarding unfair criticism of general practice is also an issue that impacts career choices about entering general practice (Carlin, Alberti and Davies, 2021).

Workload pressures on primary care has increased considerably in recent years; demands on general practice have become more complex and there has been a lack of growth

in funding to cope with rising pressures. Between 2018 and 2019, the number of primary care consultations that were conducted in England increased by 3.77 million (BMA, 2020a). In addition to this, funding for primary care as a share of the NHS total budget dropped from 9.6% to 8.1% between 2005/06 and 2018/19, respectively, which equates to a reduction of £1.8 billion (BMA, 2020a; 2020b). Due to the rising pressures and significant underinvestment in primary care, the NHS Long term Plan included a pledge to invest an extra £4.5 billion a year in primary and community health services by 2023/24 (NHS, 2019).

Role substitution

In response to these growing demands, new models of primary care are needed (Fuller, 2022). GPs are dealing with increasing workloads that are becoming more intense and complex (Croxson, Ashdown and Hobbs, 2017). The King's Fund has acknowledged that in order to safeguard the future of general practice, a willingness to do things differently is required and the restructuring of the primary care workforce through the increased use of non-medical health professionals and AHPs has been proposed as a potential solution (Baird et al., 2018). Consequently, due to the mounting pressures placed on the NHS along with the increasing shortage of GPs, 'role substitution' is being carried out in many general practices. Role substitution in this thesis refers to the substitution of some tasks and roles that were previously completed by a GP but now completed by a non-medical health professional or AHP. A full list of the different non-medical health professionals and AHPs that may be employed in general practices to perform role substitution is provided later in this chapter under the 'definition of role substitution, non-medical health professionals and AHPs in this thesis' subheading. By 2023, the NHS Long Term Plan has vowed to bring in 20,000 more non-medical health professionals such as pharmacists, physiotherapists and physician associates into the general practice workforce (King's Fund, 2020). Descriptions of some of the most common non-medical health professional and AHP roles in general practice can be viewed in Table 2 below; however, it is important to note that there may be some variation in roles across the devolved nations.

Table 2: Role descriptions of common non-medical health professional and AHP roles

Role	Role description	Reference
Non-medical health professionals		
Practice nurse	 Work as part of a multidisciplinary team in practices Assess, screens and treat patients of all ages. Provide wound care, immunisations and administration of medicines Run clinics for patients with chronic conditions e.g., asthma, heart disease and diabetes. Provide health promotion advice in areas such as contraception, weight management, smoking cessation and travel immunisations 	Queen's Nursing Institute, 2017
Nurse practitioner (NP)	 Make autonomous decisions and is accountable for those decisions Treat patients with undifferentiated and undiagnosed issues Conduct assessments of healthcare needs Possess highly developed nursing knowledge and skills over and above those of practice nurses e.g., physical examination Screen for disease risk factors and early indicators of illness and orders investigations Work collaboratively with different healthcare professionals Some NPs have undertaken additional medical education to prescribe medication 	Royal College of Nursing, 2005
Advanced nurse practitioner (ANP)	 Educated at master's level and assessed as competent in clinical practice Possess an extended level of practice with expert clinical knowledge, skills and complex decision making Undertaken additional medical education to prescribe medication Possess freedom and authority to act, make autonomous decisions in assessment, diagnosis and treatment Work in collaboration with GPs to ascertain an individualised scope of practice based on qualifications, level of experience and the needs of the individual practice 	RCGP Wales, 2017

Clinical pharmacist	 Expertise in medicines – resolving medication issues e.g., following discharge from secondary care Triaging and managing common ailments Managing and prescribing chronic conditions Managing repeat prescriptions and day-to-day medication issues Resolving day-to-day medicines issues. Triaging and managing common ailments. Reconciling medicines following discharge from hospital. Conducting medication reviews Supporting quality assurance at the GP practice Managing clinical audits with the multidisciplinary team Enhancing clinical education within the practice 	RCGP Wales, 2017
Physician associate (PA)	 New members of the clinical team, providing a complimentary service to GPs Support GPs and the wider primary care team to provide integrated healthcare Help to reduce GP workload in order to free up GP time to focus on complex patients Help to reduce other primary care practitioners' workload to allow them to focus on their areas of expertise Help to free up GP time to complete training and continuing professional development (CPD) Do not have prescribing authority 	RCGP, 2017
Allied Health Professionals		
Physiotherapist	 Provide first contact, face-to-face consultations for patients with musculoskeletal (MSK) problems Help to reduce repeat attendance at primary care and referrals to secondary care 	RCGP Wales, 2017

	 Some physiotherapists have undertaken additional medical education to prescribe medication, order blood tests and other diagnostic investigations Some physiotherapists possess skills in injection therapy Help to reduce referrals to the GP Provide consultations with patients with long term conditions Offer advice to support self-management including advice for frail and elderly patients Provide rehabilitation Work as part of the falls team, pulmonary rehabilitation team and community resource team 	
Occupational therapist (OT)	 Support patients to manage their conditions and remain as active in their daily lives Work in collaboration with other professionals, services and agencies and respond to homes crises Help to avoid avoidable admissions to secondary care Work to promote patients' mental health and physical well-being 	RCGP, 2017

Full descriptions of roles are available at:

Queen's Nursing Institute, 2017. Transition to General Practice Nursing RCGP Wales, 2017. RCGP Wales update. RCGP Wales Information Sheet No. 32. April, 2017.

RCGP, 2017. Royal College of GPs position paper on physician associates working in general practice, October 2017.

Royal College of Nursing, 2005. Nurse practitioners – an RCN guide to the nurse practitioner role, competencies and programme approval.

There is little consensus in the definition of the different types of nursing roles; ambiguity exists surrounding the different types of nurse titles and subsequent roles which may vary between different general practices. For example, the role of an advanced nurse practitioner may differ greatly and involve different tasks in different practices across the country (Wray, 2020).

Utilising non-medical health professionals and AHPs could offer a potential solution to counteract the increasing shortage of human resources and to prevent future instability in health systems (van Schalkwyk et al., 2020). The General Practice Forward View published in 2016 pledged that NHS England would expand its non-GP workforce to include a minimum of 5,000 other staff members working in general practice by 2021 (NHS England, 2016). Following this, the NHS Long Term Plan then went on to pledge significant funding to support PCNs to employ 'additional roles' including social prescribers, PAs and paramedics (British Medical Association and NHS England, 2019). AHPs make up a quarter of the clinical workforce of NHS Wales and make a valuable contribution to service delivery through the diversity of roles in which they are employed (Welsh Government, 2016). It has been proposed that non-medical health professionals and AHPs could potentially reduce GPs' workload and free-up time for GPs to manage more difficult tasks, which could result in enhanced efficiency, service capacity, access to care, and reduced costs (Leong et al., 2021). Furthermore, additional benefits may be brought forward through the use role substitution as other healthcare professions such as physiotherapists, pharmacists and OTs bring their own unique skills and expertise to primary care.

General practices across the UK are using role substitution to help combat rising demands, with the hope of improving patient access and to make services more receptive to patient needs (Centre for Reviews and Dissemination, 2015). By transferring some parts of GPs' work to non-medical health professionals and AHPs, GPs may have more time to treat complex cases that require their expertise. It is also argued that AHPs bring forward a breadth of skills and expertise, making them ideally placed to support transformational change in general practice (Chief Allied Health Professions Officer's Team, 2017).

In tandem with this role substitution in many general practices across England and Wales, receptionists' roles are changing to that of 'care navigators' who are responsible for signposting patients to the most appropriate non-medical health professional or AHP (NHS Health Education England, 2016). According to NHS England, the use of receptionists and clerical team members as care navigators have the potential to free up demand for GP

consultations and reduce patient waiting times to get the most appropriate care (NHS England, 2018). In order to determine whether this innovative redesign of the primary care workforce is working well in practice, the perspectives of all staff members, including receptionists and clerical team members, regarding their choices when navigating patients to different health professionals should be explored.

What we already knew about role substitution in 2016

At the beginning of this Doctor of Philosophy (hereinafter referred to as a PhD) project in 2016, fifteen published review papers on the topic of role substitution involving nurses and pharmacists in primary care were identified. These reviews mainly reported on clinical outcomes, patient outcomes and quality of care, resource utilisation and workload (with findings synthesised below). There was significantly less evidence on costs and the barriers and facilitators of role substitution. Only one review explored other non-medical professionals working in primary care which included health educators, exercise development officers, exercise physiologists, exercise specialists, exercise consultants and nutritionists. Moreover, there were no review papers reporting on AHPs working in primary care to substitute for some GP roles.

Clinical outcomes: Previous reviews exploring the impact of nurse-led care on clinical outcomes have reported either equivalent care between nurses and physicians, or better outcomes for nurse-led care in areas such as the treatment of blood pressure, cholesterol, blood glucose, incontinence, cardiovascular disease, Parkinson's disease, and lung and kidney function (Martínez-González et al., 2014b; Martinez-Gonzalez et al., 2015a; Martinez-González et al., 2015c; Swan et al., 2015; Tan et al., 2013). For example, 84% of the study estimates in a systematic review reporting the effect of physician-nurse task shifting on the course of disease found no significant difference between nurse and physician-led care; however, results demonstrated that nurses were better at managing dyspepsia and reducing cardiovascular risk (Martinez-Gonzalez et al., 2015a). Nevertheless, nurse-led care has also been found to negatively impact clinical outcomes, as demonstrated in a systematic review by Martinez-Gonzalez and colleagues, who reported a significant decrease in functional exercise capacity with nurse-led care (Martinez-Gonzalez et al., 2014b). In a separate review exploring the impact of pharmacist-led care, Tan and colleagues reported

significant reductions in blood pressure and glycosylated haemoglobin, and significant improvements in cholesterol and Framingham risk scores (Tan et al., 2013).

Patient outcomes and quality of care: The results from five reviews on nurses (Horrocks et al., 2002; Laurant et al., 2005; Martinez-Gonzalez et al., 2014a; Martinez-Gonzalez et al., 2015c; Swan et al., 2015) reporting data for patient outcomes and quality of care generally found either no difference between nurses and physicians, or nurse-led care was associated with better outcomes compared to physician-led care. For example, in a review assessing role substitution of doctors by nurses in primary care, Laurant and colleagues (2005) reported data on patient outcomes, patient compliance and process of care outcomes. The results reported no difference in some trials or favourable results for nurses in all outcomes. This suggests that nurses can provide care that is at least as good as physicians, and in some instances better than physicians when nurses were compared to doctors providing similar primary health care services. In another review reporting the effects of physician-nurse substitution in primary care in chronic diseases, the authors concluded that nurses have the capacity to provide equal care to doctors with respect to process outcomes (Martinez-Gonzalez et al., 2015c). Equally, Horrocks and colleagues (2002) concluded that nurses could provide equivalent, or in some cases better, care than doctors with regards to quality of care outcomes including communication skills, accurate diagnosis, and advice on self-management and medication. Similarly, three other reviews reported either no difference or favourable results for nurse-led care in terms of patient outcomes and quality of care (Martinez-Gonzalez et al., 2014a; Martinez-Gonzalez et al., 2015c; Swan et al., 2015). The majority of evidence suggests that nurse-led care is associated with higher patient satisfaction (Horrocks et al., 2002; Laurant et al., 2005; Martinez-Gonzalez et al., 2014a; Swan et al., 2015).

In a review by Tan and colleagues (2013), pharmacist interventions showed positive outcomes in nineteen RCTs, mixed outcomes in six RCTs and no significant effect in thirteen RCTs. Positive outcomes for pharmacist-led care included medication adherence, resolution of medication-related problems and indicators of quality of care. However, the findings found limited or no effects on symptoms and patient satisfaction. In a review exploring the effectiveness of pharmacy-based minor ailment schemes (PMAS) as a substitute for other service providers, Paudyal and colleagues (2013) reported positive results for patient satisfaction, but none of the included studies reported data on quality of life. It is important to note that the PMAS in the review conducted by Paudyal and colleagues were conducted in

community pharmacies which differ from pharmacists who are employed in general practices to perform face-to-face consultations such as medication reviews (Paudyal et al., 2013).

Tulloch and colleagues (2006) assessed physical activity counselling in primary care and compared three interventions: physician-only interventions, AHP-only interventions and combined-provider interventions. In this review, AHPs were categorised as nurses, health educators, exercise development officers, exercise physiologists, exercise specialists, exercise consultants and nutritionists. The results showed that only 50% of the included studies reported short and long-term positive changes in physical activity in the physician-only group. The combined provider group reported short and long-term positive changes in physical activity in 67% of the included studies. Short and long-term positive changes in the AHP-only group were reported in 100% and 71% of the included studies, respectively. Nevertheless, the AHP studies tended to be more recent than the physician-only studies; therefore, advances in physical activity counselling may explain the favourable results for AHPs (Tulloch et al., 2006).

Resource utilisation and workload: Much of the evidence on nurses from the identified review papers suggested that nurse-led care negatively impacted resource utilisation. Nurses undertook more investigations and had longer consultations (Horrocks et al, 2002; Laurant et al., 2005; Martinez-Gonzalez, 2015b; Swan et al, 2015) and reported a higher mean number of visits compared with physicians (Martinez-Gonzalez, 2015b). Nevertheless, one review reported a reduction in physician workload (Martinez-Gonzalez, 2015b) and another found a reduction in hospital admissions with nurse-led care (Martinez-Gonzalez et al., 2014a). Other outcomes of resource utilisation, including referrals and prescriptions, demonstrated no differences between nurses and physicians. Martinez-Gonzalez et al. (2014a) suggested that the increased length of nurse consultations may explain the higher levels of patient satisfaction observed in previous studies. Similarly, it is possible that patients were more satisfied with nurse-led care as they carried out more investigations.

The evidence of pharmacists substituting for physicians or comparative services on resource utilisation and workload is positive (Paudyal et al., 2013; Royal, 2006). Paudyal and colleagues (2013) reported a decline in prescribing and a reduction in the number of minor illness consultations at general practice after community PMAS were introduced. There was no statistically significant difference found in re-consultation rates between patients using the PMAS and patients who attended general practice (Paudyal et al., 2013). Moreover, in a

review assessing the efficacy of three interventions in primary care to reduce medication related adverse events and hospital admissions, meta-analysis found that pharmacist-led interventions were successful at reducing hospital admissions (Royal, 2006).

Costs: The evidence from four reviews exploring the economic impact of role substitution between physicians to nurses is mixed. For example, a review conducted by Martinez-Gonzalez et al. (2015b) included an economic evaluation and a costing study. Firstly, a cost-minimisation analysis found that direct costs for consultations were lower with nurse-led care compared to doctor-led care, when salaries, length of follow-up and length of stay were considered (Martinez-Gonzalez et al., 2015b). The costing study concluded that nurse-led care costs were either the same or higher than doctor-led care (Martinez-Gonzalez et al., 2015b). Another review by Martinez-Gonzalez and colleagues (2014a) also reported mixed results for nurses substituting for physicians in terms of costs; it included six trials with data on costs and two comprehensive economic evaluations. Martinez-Gonzalez and colleagues (2014a) reported results reported lower direct costs which included resource use, follow-up consultations, length of consultations, and salary costs in nurse-led care, but the mean costs per quality-adjusted life year (QALY) and the costs of interventions were reported as significantly higher in one trial. Nevertheless, the paper cited in the review (Campbell et al., 1998) did not include details of mean costs per QALYs. Although Martinez-Gonzalez and colleagues cited mean costs per QALYs for nurse-led care in one of the included studies. The review also reported no significant differences in direct and productivity costs for consultations in all patients at study practices, in costs of care including both total time and face to face time, or in hospital admissions. The authors recommended that more research is needed on costs and future research should also consider the indirect costs of task shifting. The results of the remaining two reviews identified suggested that physician-nurse substitution is cost neutral (Laurant et al., 2005; Swan et al., 2015).

Two reviews published in 2013 explored the costs of pharmacist-led primary care (Paudyal et al., 2013; Tan et al., 2013). Firstly, findings from Paudyal and colleagues reported mean costs per pharmacy-based minor ailment scheme consultation of between £1.44 and £15.90. Moreover, they reported that the total number of consultations and prescribing for minor illnesses decreased after the introduction of pharmacy-based minor ailment schemes (Paudyal et al., 2013). However, no study in this review included a full economic evaluation, consequently, the authors of this review recommended that future research should include full economic analyses in order to fully establish the cost-

effectiveness of community pharmacist minor ailment schemes (Paudyal et al., 2013). The other review reported no significant changes in costs for pharmacist-led interventions (Tan et al, 2013).

Barriers and facilitators: McInnes (2015) reviewed qualitative evidence regarding the barriers and facilitators influencing the collaboration and teamwork between GPs and nurses working in general practice. Barriers included lack of clarity regarding nursing roles, scope of practice, GP territorialism, overlapping roles, nurses' education and the hierarchy of the business model found in general practice. Facilitators included clearly defined roles, shared leadership, respect and trust (McInnes, 2015). In a separate review paper, Rashid (2010) reviewed the evidence on the benefits and limitations of nurses taking on the clinical role of physicians in primary care. Of the eight studies that were identified in the review, most were qualitative studies. Three key themes emerged: studies exploring the impact on patients, studies addressing nurse competence, and studies addressing NHS policy (Rashid, 2010). Key findings from the review found that nurses felt pressurised to perform routine tasks. Additional findings highlighted that patients had higher levels of satisfaction with nurse-led care compared with GP-led care, as they valued the longer nurse-led consultations. One of the included qualitative studies in the review suggested that NP consultations was associated with repetition. Reasons behind longer nurse-led consultations included nurses' tendency to reiterate messages, ensuring that patients know how to use treatments and attempting to resolve problems (Rashid, 2010).

Evidence gaps: From the reviews on the topic of role substitution in primary care identified at the beginning of this PhD study in 2016, the majority of evidence was for nurses and pharmacists substituting for physicians on clinical outcomes, patient outcomes and quality of care. However, there was a lack of evidence for other non-medical roles and AHPs working in primary care. There was also a lack of evidence to demonstrate whether role substitution is cost-effective in practice. To further explore these evidence gaps, a systematic review of economic evaluations of role substitution by non-medical health professionals and AHPs was conducted and is presented in Chapter 2 of this thesis. There was also a shortage of evidence exploring the barriers and facilitators of role substitution, with reviews only including qualitative evidence for nurses. Consequently, a systematic review exploring the barriers and facilitators of role substitution was conducted to explore the evidence on patient and provider preferences for primary care medical services and is presented in Chapter 3 of this thesis.

Theories relating to role substitution

In this thesis, role substitution is broadly defined as some roles and tasks that were previously completed by a GP and are now completed by non-medical health professionals or AHPs. However, it is important to understand that the nature of shifting health care and treatment activities from doctors to non-doctors is not straightforward and may be characterised by several different means. Due to the complex nature of substituting tasks between professions working in general practice, and the different approaches by which this is achieved, concepts such as role substitution, skill mix and task shifting are difficult to define and measure (Jenkins-Clarke et al., 1997).

To compensate for the increasing shortage of finite healthcare resources, **task shifting** is an approach often used in general practice which refers to the process of shifting specific tasks, where appropriate, to other groups of professionals who possess fewer qualifications and shorter training (WHO, 2008). Task shifting can help to ease pressures placed on GPs through the delegation of some tasks to less senior professions. Task shifting may involve shifts in clinical roles but may also occur within administrative work. For example, GPs are faced with a high volume of administrative tasks, such as dealing with correspondence from secondary care and other agencies, checking test results and writing reports, some of which may be shifted to members of the practice's administration team (Apaydin, 2020).

Another concept that describes the analysis of workforce redesign in general practice is **skill mix** and a number of different definitions to describe this concept are presented in the literature. For example, skill mix may be used to describe a mix of professions, posts or grades within establishments such as general practices (Buchan and Dal Poz, 2002). It may also be used as a term to describe the combination of individual competencies and skills or the number of different types of health care professionals by occupation within a practice (Sibbald et al., 2004).

As proposed by Sibbald, Shen and McBride (2004) skill mix can occur through four modes: **enhancement, substitution, delegation, and innovation**. Sibbald and colleagues define **enhancement** as the increased depth within an occupation through the extension of roles and skills within a specific profession (Sibbald, Shen and McBride, 2004). An example of enhancement within the nursing profession has been nurse-led clinics for the management of chronic conditions such as asthma and diabetes.

Substitution refers to exchange of one group of professional for another (Laurant, 2007; Sibbald et al., 2004) and can involve enlarging and widening the scope of a job in particular where roles extend beyond traditional boundaries (Sibbald et al., 2004). For example, nurses working as substitutes for GPs to perform some roles that would otherwise be completed by the GP (Laurant, 2007). Laurant adds that nurses may work as substitutes where the main purpose is to reduce the demand for GPs, but they may also work to provide a supplementary role to GP care where their work complements or supplements GP activities with the intention of improving quality of care through increased access to a variety of patient services (Laurant, 2007). Role substitution that occurs between professions through substitution does not necessarily mean a complete transfer; it can also involve the sharing of tasks and responsibilities between professionals in order to bridge deficiencies in health care (Vrijhoef et al., 2002).

Delegation is often a word used to describe substitution, but delegation involves shifting care activities and tasks from a senior grade to a junior or lower grade individual within the same profession (Laurant, 2007). However, Sibbald and colleagues add to this definition and explain that delegation can involve moving tasks and activities up or down a uni-disciplinary ladder (Sibbald et al., 2004). An example of delegation may be GPs delegating tasks to GPs in training or advanced OTs delating activities to OTs (i.e., their lower status counterpart in terms of seniority). In terms of skill mix, **innovation** is the concept of creating a new job/occupation through the introduction of a new type of worker (Sibbald et al., 2004). The introduction of the physician associate within general practice is a good example of this (Drennan et al., 2017).

According to Sibbald and colleagues, there are potential harms that may be brought about by changing the skill mix of general practice teams. For example, increasing the number of different clinical and non-clinical roles means that more time needs to be spent discussing with one another in order to successfully coordinate patient care which reduces the time to perform direct patient activities (Sibbald et al., 2004). Moreover, fragmentation of care may result from increasing the size of general practice teams.

With general practice teams widening to include a number of different health care professionals within complex delivery models, it is important to consider how new groups of occupations coexist within an interdependent system and the shift in boundaries between health professionals (Richards et al., 2000). Each occupational group makes jurisdictional claims since they must undergo specialised training and education to be able to perform a

specific set of healthcare activities; however, professions often have domains which overlap whereby equivalent or comparable activities are carried out (Feyereisen and Goodrick, 2019; Abbott, 1988).

Professional boundaries: Andrew Abbott's thesis explores the notion of boundaries as barriers and indicators of difference between and within professions whereby different groups of occupations strive to maintain, defend, expand and change their professional boundaries (Abbott, 1988). The notion of boundaries is complex. There can be boundaries which are strong and robust, or weak and flexible, and they change in how they are built and what they encompass (Liljegren and Saks, 2016). Jurisdictional boundaries are what separate the working tasks and activities of different professions. Abbott defines the link between a profession and its work as 'jurisdiction' (Abbott, 1986). Within the construct of jurisdiction there are two factors that come in to play: the working tasks and activities performed, and the control a profession possesses over those tasks and activities (Abbott, 1988). Professions are constantly in conflict with one another, where they compete with each other for recognition of their cognitive claims and their rights to manage specific tasks. This results in professional boundary disputes in an effort to gain control, status and power, where more senior professionals such as GPs may endeavour to defend their boundaries, whereas less senior groups of health care professionals attempt to challenge these boundaries (Battilana, 2011). One example of this is provided in a qualitative study by Håland (2012) that demonstrated doctors' hesitancy of using new electronic record keeping as they did not view it to be in-line with their professional identity as physicians. Instead, they viewed this type of administrative work to be better suited for secretaries and felt that this type of work was taking time away from their medical role. In contrast, nurses felt that using the new patient record keeping system provided them with opportunities to increase their competency and to enter an area of work previously reserved for doctors. From the viewpoint of the nurses, by using the new system, they had gained new rights and responsibilities and therefore a new jurisdiction (Håland, 2012; Abbott, 1988). Consequently, changes in the activities and jurisdiction of one profession will impact on other professions (Nancarrow and Borthwick, 2005). The dynamic boundaries of individual professions and the different ways in which they can shift means that the activities of one profession can pre-empt the activities of another and subsequently results in an interrelationship between the components of a workforce (Abbot, 1988; Nancarrow and Borthwick, 2005). Freidson describes the division of labour as a social interaction where workers are constantly occupied in trying to "define, establish, maintain

and renew the tasks they perform and the relationship with others which their tasks presuppose" (Freidson, 1976, p.311). Jurisdictional boundary disputes between professions are often not resolved fully and therefore 'limited jurisdictional settlements' need to be made which mean that professions do no end up with full jurisdiction over a task or activity. Jurisdictional settlements mean that professions share the jurisdiction of a task where control is distributed between professions (Kroezen et al., 2013). One type of jurisdictional settlement is subordination, whereby a lower grade or less senior profession accedes to the authority of a more senior profession as a trade-off to gain limited control within their own scope of a task. In order to meet the increasing demands placed on general practice, GPs have delegated a significant proportion of tasks and activities to subordinate professions such as nurses who, as a profession, play a vital role in models of primary care (Contandriopoulos, Perroux and Duhoux, 2018). It is argued that the level of professional autonomy of subordinate groups is reliant on the level of subordination processes within a work setting (Liberati, 2017).

The boundaries of healthcare professionals may shift in general practice when they perform work in new areas or perform roles that were previously reserved for other groups of professions. In some instances, shifting may be due to consensual delegation of tasks, or in contrast be a response to protect against encroachment of professional boundaries (Witz, 1992). Nancarrow and Borthwick (2005) propose four directions in which disciplinary boundaries can change and adapt in the healthcare workforce: through diversification, specialisation, horizontal substitution and vertical substitution. Diversification and specialisation take place through **intra-disciplinary change** where boundaries expand within a particular profession and therefore can result in the generation of hierarchies within that discipline (Nancarrow and Borthwick, 2005; Abbott, 1988). In the concept of **diversification**, roles expand within a profession through the detection of new and novel ways of working that other disciplines have not yet gained 'ownership' of (Nancarrow and Borthwick, 2005). However, it is difficult for some professions such as AHPs to diversify as they are often obstructed by the authority of the medical profession (Larkin, 1983).

The concept of **specialisation** refers to the acquisition of an increasing degree of expertise within a particular area of a discipline. In the medical profession, increased specialisation attained through specialist training and limited selection criteria often results in better financial rewards, higher status and prestige, and an increased level of professional autonomy (Nacarrow and Borthwick, 2005). In contrast to this, some nurses and AHPs may

undergo formal or informal training to become specialised within a particular area but often do not experience the same privileges as physicians who become specialised (Nancarrow and Borthwick, 2005).

Nancarrow and Borthwick (2005) also describe how shifts in boundaries can occur by inter**disciplinary change** through role substitution. Role substitution has been defined as roles or work that was previously completed by one profession but is now taken on by another profession and this can take place either through vertical or horizontal substitution (King et al., 2015). Vertical substitution refers to the transfer of tasks and activities across professional boundaries from one occupation to another where one profession is considered superior on the hierarchy in terms of their expertise, training, power or professional autonomy (King et al., 2015; Vrijhoef et al., 2002). An example of vertical substitution withing general practice has been the expanding roles of some nurses and pharmacists to prescribe medications, a role previously reserved for the GP. Although they have been granted the authority to prescribe medication, it does not been that nurses and pharmacists hold the same status or receive the same financial rewards as physicians. Horizontal substitution can be defined as the transfer of tasks and activities between occupations from different disciplinary backgrounds but who possess similar levels of training and expertise (King et al., 2015; Vrijhoef et al., 2002). According to King and colleagues, horizontal substitution can only be effective when roles are flexible so that other professions can take on their roles (King et al., 2004). An example of horizontal substitution that may occur within general practices is the overlap of roles between physiotherapists and OTs who may complete the same activities e.g., when consulting with patients who experience difficulties completing activities of daily living (ADLs) or have mobility issues. Another example reported in the literature is the horizontal substitution of activities between ANPs and PAs (Drennan et al., 2017).

The theory of negotiated order first proposed by Anselm Strauss (1978) postulates that social interactions between professions represent a negotiated social order or structure which means that hierarchies between professions are not certain, instead they are subject to continuous negotiation in the social order of professions (Faberman, 1979; Strauss, 1978). Consequently, interprofessional relationships and status are arbitrated through negotiation between professions (Faberman, 1979) to 'get things accomplished' (Badejo et al., 2020). "The theory emphasises the nuanced, diverse and distributed characteristics of power, as being complex with multiple origins, in and outside the healthcare context, rather than the

static and unidirectional focus of the medical dominance theory. The negotiated order theory has also been extended to mean that interprofessional competition is a fundamental act of professional life and that professional groups are constantly engaged in a battle over work jurisdictions and role boundaries" (Bandejo et al., 2020, p.2). Inter-professional change in general practice therefore requires a teamworking approach to the provision of general medical services which is reliant on the extent to which occupational groups are willing to delegate tasks and accept changes to traditional professional boundaries and the consequence of blurring roles (Masterson et al., 2002).

Definition of role substitution, non-medical health professionals and AHPs in this thesis Role substitution in this thesis refers to the substitution of some GP roles by groups of nonmedical health professionals and AHPs. However, this thesis acknowledges the complex nature of role substitution in practice and the different concepts and approaches by which it may occur, for example through supplementation, diversification, delegation, task shifting and skill mix, all of which are discussed above in this chapter. In this thesis, when using the term 'non-medical health professionals' this refers to a definitive list of the following: nonmedical health professionals includes practice nurses, NPs, ANPs, pharmacists and physician associates. Physician assistants are a new development in the NHS and have also been presented as a solution to medical staff shortages as they can diagnose, treat, and refer patients autonomously within their professional boundaries but do not yet have prescribing authority (Drennan et al., 2015). Although PAs can work within the medical model, they are not GPs and therefore in this thesis, PAs will come under the term 'non-medical health professional'. AHP is an umbrella term used to categorise 13 individual professional groups that help individuals of all ages from cradle to grave to manage their own physical and mental wellbeing. Their work supports the Welsh Government's 'A Healthier Wales' 2018 strategy to prevent ill-health, maximise wellness and empower the people of Wales to live longer, healthier and happier lives (Welsh Government, 2020). A definitive list of the AHP groups working across the NHS in Wales are as follows: art therapists, music therapists, drama therapists, dietitians, OTs, orthoptists, orthotists, paramedics, physiotherapists, podiatrists, practitioner psychologists, prosthetists, and speech and language therapists. Nevertheless, this thesis is only concerned with the groups of AHPs that provide general medical services to patients in general practices, therefore I will use the term 'AHP' in this thesis to refer to OTs, physiotherapists, paramedics, practitioner psychologists, podiatrists and dieticians, but I

will also include *social prescribers* and *approved mental health professionals* within my definition of AHPs in this thesis as they are also professionals who are allied to health who now work in some general practices and work to support the Welsh Government 2018 'A Healthier Wales' strategy (Welsh Government, 2018b). The roles of many general practice receptionists have also expanded to perform a **care navigator** role who refer patients to the correct health care professional based on their reason for consultation. Care navigators do not come under the definition of 'non-medical health professionals' or 'AHPs' who work as substitutes to GP provided care; however, they are a role of interest in this thesis as they play an integral part in the process of role substitution.

Having a clear definition of roles and terms detailing different types of role substitution have important implications for measurement of outcomes and methods of analysis. For example, measuring shifts in resources due to role substitution requires both an assessment of the roles involved and an understanding of what has changed so that appropriate values can be applied to consider the extent of implications. Differing definitions of roles has the potential to impact on the range of staff to be considered within a study, the monetary value of their time (with varying salaries across different health professional roles) and could impact on the interpretation of findings. Excluding some roles due to limited scope of definitions (both in terms of roles and role substitution) may result in the omission of important data and limited confidence in results. The interpretation of the impact of role substitution requires outcomes to be clearly defined and valued to enable the assessment of whether shifts in resources lead to positive or negative outcomes, for example an increase in the number of consultations alone does not provide a comprehensive picture of impacts on effectiveness, patient outcomes or patient safety, however it can be used to consider variations in the cost of resources over time.

A conceptual framework to judge quality in health care

This thesis uses a conceptual framework that was first described by Avedis Donabedian (1980) and elaborated by Robert Maxwell (1984; 1992) to judge quality in healthcare. This thesis uses this conceptual framework as a lens to consider the findings that are presented in the systematic review and empirical chapters of this thesis (Chapters 2, 3, 4, 5 and 6). The conceptual framework is then revisited in the final chapter and used to reconsider the overall thesis findings (Chapter 7).

This thesis is concerned with the introduction of workforce innovation, therefore it is appropriate to consider conceptual models used to judge quality in health care and whether any health care innovation should be adopted. The population is continuously striving for high quality goods and quality of care in general practice has become an increasingly predominant issue for the NHS (Kruk et al., 2018). Better quality of care is associated with higher satisfaction among patients, healthcare providers and suppliers and better organisational performance (Peckham and Wallace, 2018; Mosadeghrad, 2012; Sollecito and Johnson, 2012). Quality in healthcare is multidimensional and subjective in nature, therefore making it difficult to define and measure (Quentin et al., 2019; McLaughlin and Kaluzny, 2004). Moreover, the complexity, intangibility and heterogeneity within general practices further adds to this complication (Mosadeghrad, 2012).

Donabedian defined quality in healthcare as the appliance of medical science and technology in a way that maximises its benefit to health without also increasing the risk (Donabedian, 1980). Other definitions of quality of care have incorporated the issues of patient expectations and financial implications within its explanation (Øvretveit, 2009). In a review exploring definitions of quality of healthcare in general practice concluded that patient centeredness is a consistent area that emerges within definitions (Gardner and Mazza, 2012). Patient centred care can be defined as a process that is people-focuses that endorses independence and choice, which is an important domain in health policy and strategy documents in the UK. For example, based on equity and fairness the principles of prudent healthcare in Wales are documented in the Planned Care Programme (2015) which outlines a central focus to empower patients to take control and responsibility of their own health which has also been shown to result in better outcomes and lower costs (Rix and Marrin, 2015). In the UK, policy makers have acknowledged the importance of quality measurement in order to successfully deliver high quality healthcare services (Quentin et al., 2019; NHS England, 2016). In Wales, quality improvement has been on the agenda for many years as part of a commitment to ensure safe patient care, improve access, reduce wasted NHS resources and ensuring equitable delivery of high-quality care services across Wales (1000 Lives Improvement, 2014).

An early conceptual model developed by Avedis Donabedian for examining health services and evaluating quality of care postulated that quality can be derived by three dimensions: derived from three dimensions: structure, process and outcomes (Donabedian, 1988). The framework proposes that when these three dimensions are brought together, they

cover all of the areas that we can observe quality issues within a healthcare setting (Donabedian, 1988). As stated by Donabedian, these dimensions should not be viewed as attributes of quality, instead they should be regarded as the classifications for the different types of information that can be acquired to make inferences about the quality of care (Donabedian, 2002).

In Donabedian's quality of care model, structure refers to all of the necessary resources that go into the provision of care and therefore signifies the attributes of the healthcare setting. **Structure**-related attributes include material resources, such as costs, physical facilities and equipment, and human resources (e.g., the number and qualifications of different general practice staff) and there also organisational characteristics such as the training and general practice organisation). The **process** dimension of the model can be defined as all of the actions and aspects of the patient provider interaction. Process includes both the patients' actions in seeking healthcare and the healthcare providers' activities when providing services including diagnoses, treatment, prevention and patient education (Donabedian, 1988). Donabedian proposes two components within the performance of practitioners: technical processes and interprofessional processes. Technical processes are concerned with how care is delivered and relies on the knowledge, judgement and skill of a healthcare professional to carry out appropriate activities (Donabedian, 1988). Interpersonal processes are integral processes that involves communication by the patient to exchange the necessary information to the healthcare professional in order to arrive at a diagnosis and also their preferences relating to their care. During a consultation, the healthcare professional exchanges information about the illness and its management. Donabedian argues that interpersonal processes are the means in which technical process are fulfilled and therefore the success of technical processes are dependent on the interpersonal relationships between patients and providers. Good interpersonal relationships should be based on privacy, confidentiality, informed choice, empathy, honesty and sensitivity (Donabedian, 1988). Finally, the **outcome** dimension refers to the effects of care on patients and populations and therefore demonstrate the end results. These may include outcomes relating to changes in health status, safety outcomes, patients' knowledge, behaviour and satisfaction (Donabedian, 1988). According to Donabedian, structure attributes influence process measures, which consequently impacts outcome measures i.e., good structure increases the chances of good processes, and good processes should promote the likelihood of good outcomes (Donabedian, 1988).

Donabedian recognised that quality in healthcare is multi-dimensional and requires not only technical aspects but also involves interpersonal aspects where the patient perspective is an equally important (Maxwell, 1984). It is therefore not appropriate to attempt to measure quality of care in a single dimension. Consequently, Maxwell proposed six dimensions of quality of care that should be considered separately, with each dimension requiring a different approach to its measurement and assessment. This thesis uses this conceptual model first described by Avedis Donabedian (1980) and later elaborated by Robert Maxwell (1984; 1992) to judge quality of care. The thesis findings will be considered in relation to the six dimensions proposed by Maxwell (1992) for assessing quality of health care services and is applied in this thesis to role substitution in general practice. The dimensions are: effectiveness (including safety), acceptability, efficiency (including costs), access, equity, and relevance (Maxwell, 1992). A description of each dimension is provided in Box 1.

Box 1: Maxwell's six dimensions of quality (Maxwell, 1992, p.171)

_	Is the treatment given the best available in a technical sense, according to those best equipped to judge? What is their evidence? What is the overall result of the treatment?
Acceptability:	How humanely and considerately is this treatment/service delivered? What does the patient think of it? What would/ does an observant third party think of it ("How would I feel if it were my nearest and dearest?") What is the setting like? Are privacy and confidentiality safeguarded?
Efficiency:	Is the output maximised for a given input or (conversely) is the input minimised for a given level of output? How does the unit cost compare with the unit cost elsewhere for the same treatment/service?
Access:	Can people get this treatment/service when they need it? Are there any identifiable barriers to service – for example, distance, inability to pay, waiting lists, and waiting times – or straightforward breakdowns in supply?
Equity:	Is this patient or group of patients being fairly treated relative to others? Are there any identifiable failings in equity – for example, are some people being dealt with less favourably or less appropriately in their own eyes than others?
Relevance:	Is the overall pattern and balance of services the best that could be achieved, taking account of the needs and wants of the population as a whole?

Introducing new roles to general practice is not a simple process (Drennan, 2019; Nelson et al., 2019). When considering the impact of role substitution on quality of care in terms of these six dimensions it is also important to note that the introduction of role substitution may have pose potential risks to both patients and healthcare staff. For example, the widening of general practice teams may result in better access to services in terms of increased numbers of general practice staff and by allowing patients to see the most appropriate type of healthcare practitioner based on their reason for consultation. Nevertheless, increased role substitution may also lead to negative consequences on the acceptability and access dimensions by obstructing patient choice and access to the GP, this is especially true for vulnerable patients with high complex needs who benefit from consulting with a known and trusted health professional (Palmer et al., 2018). The lack of consensus around new roles in general practice may also lead to increased workloads and stress, duplication of care, higher healthcare costs and reduced continuity of care (Sibbald, McBride and Birch, 2011). As discussed earlier in this chapter, GP wellbeing and appropriate workload and support systems have important patient safety and effectiveness implications, for example, reducing rates of 'near miss' incidences (Hall et al., 2019). Iacobacci further postulates that the deskilling of GPs due to nurses increased involvement in chronic disease management and the downfall in continuity of care and may also be adding to GP stress and reduced wellbeing (Iacobucci, 2021). There are also concerns for patient safety due to the increasing workload and complexity of nursing roles and responsibilities in general practice (Needleman, 2017; Ebright et al., 2003).

Thesis methodology

Methodology provides the theoretical perspective that connects a research problem with certain methods (research tools). Methodologies are stemmed from a researcher's assumptions about the nature of existence which is known as ontology. A researcher's ontology subsequently guides the philosophy on the nature of knowledge creation (known as epistemology) and is therefore important as it influences how research is framed in an attempt to uncover knowledge (Hesse-Biber, 2010).

This thesis is underpinned by epistemological foundations that knowledge can be generated through research and is written into literature as evidence. The candidate comes

from a science background, with a Bachelor of Science degree in Sports, Health and Physical Education, and a Master of Science degree in Exercise Rehabilitation. The candidate has worked part-time in the field of health economics as a Research Project Support Officer at the Centre for Health Economics and Medicines Evaluation (CHEME) at Bangor University since 2017. The candidate does not come from a clinical background and had no previous experience of working within a clinical setting before commencing this PhD project.

Due to the nature of the research questions a number of different methods were utilised in this PhD study. The first stages of the thesis involved undertaking two separate systematic reviews, followed by an online survey and then finally a mixed-methods study which comprised of a quantitative budget impact analysis (BIA) and a qualitative exploration. The mixed-methods study (including both the BIA and the qualitative exploration) was conducted at the same two practices and used as case studies in this thesis. Mixed-methods research allows the researcher to combine components of both qualitative and quantitative research methods, in order to achieve a broad breadth and depth of understanding and corroboration (Johnson, Onwuegbuzie and Turner, 2007).

Mixed-methods studies are in keeping with (but are not limited to) a pragmatist paradigm whereby research is constructed on the breadth of generalisation obtainable from quantitative methods with the depth of meticulous understanding provided from qualitative research (Tashakkori and Teddlie, 2008). As well as pragmatism, mixed-methods can also be underpinned by other philosophical approaches such as postpositivism, constructivism, and other participatory world views (Creswell, 2013; Creswell and Creswell, 2017). A pragmatic research paradigm accepts that there is not just a singular reality but provides an opportunity to consider multiple experiences and standpoints (Creswell and Planko Clark, 2011). Rather than a philosophical position, pragmatism provides a practical set of philosophical tools for exploring real work research (Biesta, 2010).

There is guidance around evaluating complex interventions and that they require careful methodological consideration (Skivington et al., 2021). However, health care systems are complex systems which provide challenges especially with respect to the evaluation of workforce redesign and planning required for the implementation of role substitution (Long et al., 2018). A pragmatic approach provides an opportunity to explore the views of patients and staff as well as exploring the cost implications of role substitution, in recognition of the rapidly changing and complex nature of health services implementation and evaluation (Long et al., 2018).

Mixed-method designs

Mixed methods research allows the researcher to combine components of both qualitative and quantitative research methods to achieve a broad breadth and depth of understanding and corroboration and allows the strengths of one approach to complement the restrictions of another (Regnault, Willgoss and Barbic, 2018; Johnson, Onwuegbuzie and Turner, 2007). Although common definitions of mixed-methods refer to the integration of both quantitative and qualitative research and data in a study (Creswell and Planko Clark, 2017; Tashakkori, 2009; Greene, 2007) other researchers acknowledge that mixed methods can apply in within-paradigm research and argue that mixed methods can be solely quantitative or qualitative (Morse, 2010). For example, a qualitative mixed methods study may consist of one core qualitative component that forms the theoretical basis of the study with another qualitative component that supplements the core component (Morse, 2010). Morse argues that in this type of mixed methods research, the supplementary qualitative component cannot be interpreted on its own for reasons such as an inadequate sample or it may be too limited to be of interest alone (Morse and Niehaus., 2009). Qualitative mixed methods may employ a combination of different qualitative methods such as interviews, diaries, emotion maps, observation and focus groups.

Although there are many study designs within the field of mixed methods, according to Creswell and Planko Clark there are three core types of mixed methods designs: convergent designs, exploratory designs and explanatory designs (Creswell and Planko Clark, 2017). Firstly, convergent (parallel) mixed methods designs are one stage parallel designs that involve collecting and analysing both quantitative and qualitative data at approximately the same time points and then the researcher integrates the data during the overall interpretation of the results in order to determine in what ways the data converges of diverges (Creswell and Creswell, 2017). Although this is a popular design for mixed methods studies, Creswell and Planko Clark warn that convergent mixed methods designs pose a number of challenges including issues relating to the two different sample sizes when merging the quantitative and qualitative data and the difficulties when attempting to resolve divergence when comparing the results (Creswell and Planko Clark, 2017). A convergent mixed methods design would not have been appropriate for this thesis, as the purpose was to use the first stage of the mixed methods study to inform the methods of the second stage.

The second core type of mixed methods design are sequential exploratory designs which is a two-stage approach whereby the researcher collects and analyses the qualitative

data and then moves on to collect and analyse the quantitative data. This type of design is helpful when the purpose is to use the qualitative findings to inform or be utilised in the quantitative phase for example, to build instruments, identify research areas or variables of interest, or to develop an intervention or experiment (Amir-Behghadami and Sadeghi-Bazarghani, 2021; Creswell and Creswell, 2017). The sequential exploratory design was not suitable as it did not fit with the aims of the PhD thesis (discussed below). This type of design was also not feasible as the qualitative data collection needed to come after the quantitative phase, due to the lengthy process of obtaining ethical approval to conduct the qualitative interviews.

The third core type of mixed methods design is the explanatory design, which is the reverse of exploratory designs and involves collecting and analysing the quantitative data first and then the qualitative data (Creswell and Creswell, 2017; Ivankova, Creswell and Stick, 2006; Tashakkori and Teddlie, 1998). The information gained from the quantitative analysis is then used to inform the qualitative phase of the study. This form of design in particularly useful when the purpose is to gain knowledge about participant characteristics to inform purposive sampling in the qualitative phase (Creswell and Planko Clark, 2017; Morgan, 2014; Tashakkori and Teddlie, 1998). Moreover, the sequential explanatory design allows the research to explain why the findings in the quantitative data occurred by exploring the mechanisms in the qualitative data. For these reasons, the sequential explanatory mixed design was the chosen design for this PhD study. The purpose of the mixed methods study in this thesis was to firstly explore the financial implications of the increased use of role substitution in two general practices used as case studies by conducting a quantitative BIA. The next stage was then to explore what this actually means in practice by conducting qualitative interviews at the same two general practices used as case studies in the BIA in order to gain the perspectives of both patients and general practice staff and to help provide context to the quantitative results. Moreover, by conducting and analysing the quantitative data first this provided information on the practice staff characteristics i.e., which types of professional groups were being employed at the practices, which then informed the purposive sampling strategy in the qualitative phase. This design was also advantageous for this PhD study as it follows a straightforward structure and involves collecting one type of data at a time making it manageable for a single researcher to implement (Creswell and Planko Clark, 2017).

Health economics – the quantitative phase of the sequential explanatory design

Economics is the study of allocation of limited resources to meet the infinite demands of society. Health economics applies the economic principles to the consumption and allocation of scarce health care resources (Edwards and McIntosh, 2019; McGuire, Henderson and Mooney, 1997). There are a limited number of GPs and nurses in primary care and health economics can help provide information on the best use of valuable resources to meet the health care needs of a specific patient population. There is an opportunity cost of not using resources to their best use, with forgone benefits from their alternative use (Drummond et al., 2015). While health budgets have increased over time, they have not kept pace with rising costs of ill-health and an aging population. Primary care budgets are reported to have been under-funded over the last decade and the case for a greater share of healthcare budgets is made (BMA, 2020b).

Primary care is the first point of access to healthcare for patients with ill-health. However, there are barriers to access and inefficiencies in service provision, and consequently there is an economic case for improving primary care on both equity and efficiency grounds. Economic evaluation of interventions and service design requires both benefits and costs to be considered (Drummond et al., 2015). There are various methods of economic evaluation, including cost-effectiveness analysis, cost-benefit analysis, cost-utility analysis and cost-minimisation analysis (see definitions for more detailed descriptions of these). Evaluating complex interventions and policy changes needs a pragmatic approach that recognises this is real world implementation issues (Long, McDermott and Meadows, 2018); therefore, full economic evaluations traditionally conducted in randomised-controlled trial (RCT) settings are challenging and impractical. Other economic tools such as programme budgeting and marginal analysis (PBMA) and Budget Impact Analysis (BIA) are useful methods to guide decision makers with regards to complex organisational or workforce changes (Brambleby and Fordham, 2003; Edwards et al., 2014; Soto-Gordoa et al., 2017; Sullivan et al., 2014). Role substitution has been rapidly implemented across general practices despite a lack of cost information reported in published role substitution literature; therefore, it is important to explore what the financial implications are. In consequence, this thesis used the BIA method to demonstrate the financial implications of increasing role substitution in two general practices in North Wales to provide real-world case study examples.

A BIA is an economic assessment that predicts the potential financial impact of the adoption of a new health technology or intervention into a health care system with finite resources (Mauskopf et al., 2007). While economic analyses assess the additional health benefit gained from the adoption of a new health intervention, a BIA assesses the affordability of the intervention and reports costs only. A BIA can be used to predict how the adoption of a new health technology or intervention for a given condition will impact the overall expenditure for that condition and can be used to help make decisions about the allocation or reallocation of resources in health care systems (Health Information and Quality Authority, 2014). The use of BIA in this thesis is justified as the purpose of this quantitative component was to uncover the cost implications and the affordability of increasing role substitution at two general practices between two time points. The intention was not to measure whether role substitution provides value for money which requires cost-effectiveness analysis (York Health Economics Consortium, 2016). This was beyond the scope of this PhD thesis as this would prove problematic due to a lack of resources and time constraints of this PhD study. Role substitution was already being implemented at both the practices; however, the affordability of this was not known. Consequently, the BIA served as a pragmatic tool to address the research question and to inform the sampling strategy for the qualitative component of this thesis.

Patient and provider perspectives – the qualitative phase of the sequential explanatory design

As part of the second phase of the sequential explanatory mixed methods design conducted in this PhD project, semi-structured qualitative interviews were conducted with patients and general practice staff to explore their views regarding role substitution at the same two general practices recruited in the BIA. The RCGP highlight the importance of patient understanding of different roles when considering the impact of widening the general practice team to include different types of non-medical health professionals and AHPs (RCGP, 2018). Qualitative evidence can augment understanding in a field and can unearth 'different' types of information and vision, offering richer and more in-depth insights (Davies et al., 2000; Popay and Williams, 1998). Qualitative research can provide answers to research questions about experiences, beliefs and preferences in order to gain in-depth knowledge of the area of interest (Murphy et al., 1998). Moreover, qualitative research is particularly beneficial when assessing complex multi-component interventions or systems of change

(Busetto, Wick and Gumbinger, 2020) and can be used to sought valuable information on the impact of implementing new health technologies and innovations on both patients and health professionals (Murphy et al., 1998). It can also be used to increase understanding of issues relating to intervention delivery and compliance, and the processes involved in achieving change in practice which is particularly important when implementing innovative models of general practice (Craig et al., 2017). The chosen method for qualitative data collection in this PhD study was semi-structured interviews as they provide an opportunity to obtain the indepth experiences of patients and staff on a one-to-one basis, as opposed to focus groups which are impacted by group dynamics and may not provide participants with a comfortable environment to voice their true views and perspectives on possibly sensitive topics (Nyumba et al., 2018). For example, when asking patients and staff about their perspectives of role substitution they may wish to discuss issues relating to their health or interactions with colleagues in order to provide context to their narrative. One-to-one interviews were the perfect choice of qualitative data collection method as it allows the researcher to ask openended questions and use probes to gain an in-depth understanding of patient and providers' experiences, opinions and knowledge of role substitution in practice (Rosenthal, 2016).

Health services research has historically been deep-rooted within the evidence-based medicine research paradigm focused on examining the effectiveness of interventions to improve clinical practice where RCTs are considered the 'gold' standard choice of study design (Clark, Draper and Taylor, 2018; Christ, 2014). This notion fits in with conventional hierarchies of evidence which content that some research designs are objectively superior to others (e.g., with observational study designs sitting at the bottom of the hierarchical pyramid), and that selecting an inferior study design is only appropriate when an RCT is unfeasible (Howick et al., 2011). Nevertheless, this belief has been contended by a number of researchers who dispute the existence of objective hierarchies of evidence in that research designs and methods should be selected on the basis that they can address the specific research questions of the study (Clark, Draper and Taylor, 2018; Petticrew and Roberts, 2013; Christ, 2014; Berwick, 2008). According to Berwick (2008), conducting RCTs to assess complex multi-component interventions that are impacted by a range of contextual factors such as organisation and leadership are an "impoverished way to learn", he argues that researchers should instead accept a broader variety of methods such as qualitative methods that are better suited to assess how to make improvements in practice and guide interventions (Berwick, 2008). Petticrew and Roberts (2003) agree that the notion of a

hierarchy of evidence is often unhelpful especially when assessing the evidence for social or public health interventions (Petticrew and Roberts, 2003). Instead, they propose the use of typologies to assess the strengths and weaknesses of different methodologies which should be used to match the study research questions to specific categories of research designs (Petticrew and Roberts, 2003). According to Petticrew and Roberts, qualitative research methods are particularly appropriate to utilise when the purpose of the study is to obtain evidence relating to processes (i.e., how does it work?), quality of implementing the intervention and the context in which it happened (Petticrew and Roberts, 2003). Qualitative research has a potentially influential role in evidence-based practice and systematic reviews of effectiveness (Long and Godfrey, 2004). In line with the matrix-based approach presented by Petticrew and Roberts, the choice to conduct a qualitative exploration was justified to address the research question in this thesis because the purpose to explore how both patients and staff feel about role substitution in order to unearth rich and insightful information such as the acceptability of role substitution in their practices, whether they deem the changes appropriate and whether they accepted by staff and patients.

Qualitative research methods were required as the research question could not be addressed using quantitative methods, as the purpose of the qualitative exploration was to uncover views and perspectives including their narratives of experiences and interactions. Qualitative methods allow researchers to investigate topics and innovations in their natural settings in order to make sense of and interpret phenomena with respect to the meaning individuals bring to them (Moen, 2006). Moreover, qualitative research is needed to explore patient and staff perspectives on the practice of role substitution to consider both provider perspectives (general practice team members) and recipient perspectives (patients).

Aims of the thesis

With some roles traditionally performed by the GP now being carried out by non-medical health professionals and AHPs, evaluation of this change in service design is needed. Early indicators suggest that the substitution of skills could potentially reduce GP workload and allow GPs more time to manage patients with more serious and complicated illnesses. Nevertheless, we do not know if this model of general practice delivery described as role substitution in this thesis is deemed as appropriate and acceptable to both the patients and the general practice workforce, or if it serves as a cost-effective use of NHS resources. In broad

terms, this thesis aims to explore the advantages, disadvantages and consequences of role substitution including beginning to explore the cost implications and the perspectives of both staff and patients. To answer the research questions outlined below, a number of different methods were adopted, namely systematic reviews, survey methodology and mixed methods (utilising health economics and qualitative data). This thesis includes a mixed-methods sequential explanatory design that involved collecting and analysing quantitative and then qualitative data (Creswell and Creswell, 2017; Ivankova, Creswell and Stick, 2006; Tashakkori and Teddlie, 1998). All data were gathered before the Covid-19 pandemic.

Thesis research questions

The research questions addressed by this PhD thesis are as follows:

- 1. What existing literature is there on the cost-effectiveness of role substitution in primary care? (Chapter 2)
- 2. What existing literature is there on the barriers and facilitators to role substitution in primary care? (Chapter 3)
- 3. To what extent is role substitution being implemented locally in general practices across Wales? (Chapter 4)
- 4. What are the cost implications of increasing the use of role substitution within general practice? (Chapter 5)
- 5. How do patients and general practice team members feel about role substitution within their practice? (Chapter 6)

Thesis structure

Following this first introduction chapter, the rest of this thesis is structured as a series of six chapters comprising of two review papers, followed by three empirical study chapters and finally the discussion chapter. Each chapter follows a logical sequence and informs the next chapter sequentially. Chapters 2 to 6 follow a typical journal article format with a view to future publication with the exception of Chapter 2, which a version of this has already been published (Anthony et al., 2019). Figure 1 provides a visual representation of the research questions, structure and layout of the thesis.

In this introductory chapter a brief presentation of the available literature (up to 2016) on the topic role substitution was presented. The rapid searches employed to uncover the evidence presented in this introductory chapter demonstrated a lack of information regarding both the costs relating to role substitution and a lack of evidence regarding peoples' views and perspectives of role substitution. These findings were used to inform two novel systematic reviews (Chapters 2 and 3). A systematic review of economic evaluations set out to uncover what evidence existed about the cost-effectiveness of role substitution in primary care (Chapter 2). A systematic review of qualitative studies set out to uncover what qualitative evidence existed on the views of patients and primary care staff and stakeholders regarding the barriers and facilitators of role substitution in primary care (Chapter 3).

The first empirical study (Chapter 4) set out to explore the extent to which role substitution was implemented in general practices in Wales and used online survey to gain responses from cluster leads. The survey also set out to explore perceptions relating to perceived workforce crises issues in general practices and what strategies practices were using to compensate for these pressures.

The second empirical study (Chapter 5) set out to assess the financial implications of increasing role substitution at a local level by assessing health service activity and associated costs at two general practices used as case studies. This BIA formed the quantitative component of the sequential explanatory mixed methods design described above. From a NHS perspective, and using national published unit costs of health and social care (Curtis and Burns, 2018) to cost the health service activity at two general practices between two time points, this chapter set out to assess any shifts in health service costs as a result of the increased use of non-medical health professionals and AHPs working to provide general medical services.

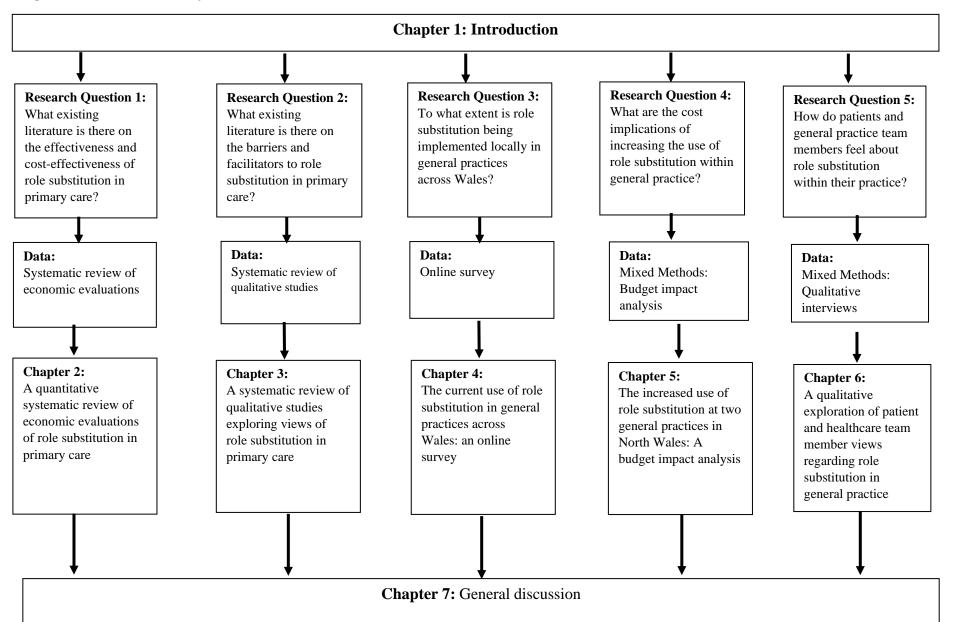
The third empirical study (Chapter 6), a qualitative exploration set out to unearth the views of patients and general practice team members from the same two general practices used as case studies in BIA. This study formed the qualitative component of the sequential explanatory mixed methods design described earlier in this chapter. The views of patients and general practice team members on the substitution of groups of non-medical professionals and AHPs providing general medical services instead of GPs were explored through individual, face-to-face semi-structured interviews. The interviews set out to explore the acceptability of role substitution among patients and staff and the advantages and disadvantages such as the impact on access and continuity of care.

This thesis is concluded with a general discussion chapter (Chapter 7) which provides a general discussion of the findings with respect to the conceptual framework of the thesis and the theoretical literature discussed in this introductory chapter. The chapter provides a discussion on the strengths and weaknesses of this research, and implications for practice, policy and future research directions. This chapter also considers the overall thesis findings in relation to the conceptual model of the thesis and theories relating to role substitution.

Original contribution of the thesis

This thesis provides unique insights into the implementation of role substitution in general practice in Wales. Previous research has tended to focus on the role substitution context in other parts of the UK, this PhD study fills important evidence gaps for the Welsh context. Novel findings across a wide range of roles are presented through the consideration of whole-practice team dynamics to explore the costs and acceptability of role substitution in real-world settings. This thesis offers findings in relation to less well researched roles and also provides a novel contribution to the field of health economics of role substitution.

Figure 1: Structure and layout of the thesis



CHAPTER 2: A QUANTITATIVE SYSTEMATIC REVIEW OF ECONOMIC EVALUATIONS OF ROLE SUBSTITUTION IN PRIMARY CARE

A version of this chapter has been published as:

Anthony, B.F., Surgey, A., Hiscock, J., Williams, N.H. and Charles, J.M., 2019. General medical services by non-medical health professionals: a systematic quantitative review of economic evaluations in primary care. *Br J Gen Pract*, 69(682), pp.e304-e313.

Introduction

Previous systematic reviews have found that nurses can provide equivalent, or in some instances higher, quality of care compared with GPs in primary care (Horrocks, Anderson and Salisbury, 2002; Kuethe et al., 2013; Laurant et al., 2005; Martínez-González et al., 2015). Furthermore, previous reviews have also reported positive results for pharmacists substituting for GPs in primary care (Chisholm-Burns et al., 2010; Paudyal et al., 2013). Previous reviews have explored the economic impact of task shifting in primary care (Horrocks, Anderson and Salisbury, 2002; Kuethe et al., 2013; Laurant et al., 2005; Martínez-González et al., 2015) but the majority of studies did not include full economic evaluations. A previous systematic review of economic evaluations explored the substitution of skills between healthcare professionals across a variety of settings including general practice, hospital, and the community (Dierick-van Daele et al., 2008) but most of the evidence included was of nurses substituting for GPs and only one study was in a general practice setting. Literature from review papers presented in Chapter 1 of this thesis identified a significant economic evidence gap for role substitution in primary care. Given the need to justify the use of sparce health care resources an update on the economic case for role substitution was warranted.

There are a range of different forms of economic evaluation, each with an established methodology to assess the value gained for resources used to implement an intervention or policy. The most common forms of economic evaluation are cost-benefit analysis (CBA), cost-effectiveness analysis (CEA), cost-utility analysis (CUA), cost-minimisation analysis (CMA) and cost-consequence analysis (CCA) (Drummond et al., 2015).

CBA compares costs and benefits of different interventions in monetary values. This form of evaluation only measures factors that can easily be assigned a monetary value (Drummond et al., 2015).

In CEA costs are compared with the therapeutic goal, commonly this will be the measure of clinical effectiveness. Health benefits are measured in natural units appropriate to the population included within the study. Typically, an incremental cost-effectiveness ratio will be produced to assess the cost per unit of benefit gained (Edwards and McIntosh, 2019).

CUA, a specific type of CEA, measures the effects an intervention with the primary outcome measured in terms of utility and a resulting cost per quality-adjusted life year (QALY) calculated. The QALY provides a generic measure of disease burden that incorporates both the quantity and quality of life lived. One QALY equates to one year lived in perfect health. Unlike other forms of economic evaluation where different units of benefits may be used across studies, QALYs offer the advantage of allowing for comparisons across economic evaluations. In the UK, a typical willingness to pay threshold of £20,000 to £30,000 per QALY has been applied by NICE to consider acceptable levels of spending on health benefits (National Institute for Health and Care Excellence, 2013).

In CMA where health outcomes have been established to be equal, only differences in costs are then considered with the evaluation focusing on identifying the least costly alternative (Drummond et al., 2015).

CCA measures a range of consequences and aims to provides information to decision maker in a simple disaggregated format to enable factors most relevant to the decision context to be considered (Drummond et al., 2015).

Economic evaluations are commonly conducted alongside RCTs, where there are concurrent aims to explore both the effectiveness of an intervention and the cost-effectiveness of the intervention (Petrou and Gray, 2011; Hughes et al., 2016). While clinical trials have been argued to provide a good opportunity to generate economic data, often within a methodologically rigorous study design, the conduct of economic evaluations is not limited to RCT study designs, with alternatives including economic evaluations alongside natural experiments (Deidda et al., 2019) or economic modelling studies which often utilise sources of data from previous literature in addition to or instead of collecting primary data (Brennan, Chick and Davies, 2006).

The aim of this systematic review was to review economic evaluations of non-medical health professionals and AHPs working in primary care as substitutes for some of the tasks performed by GPs.

This chapter aims to address the following research question:

1. What existing literature is there on the cost-effectiveness of role substitution in primary care?

Methods

Selection of studies

For this systematic review of economic evaluations exploring role substitution of non-medical health professionals and AHPs in primary care, role substitution was defined as 'the substitution of work that was previously completed by a GP in the past and is now completed by a non-medical health professional or AHP'. Studies were excluded if the authors did not explicitly state within the article that role substitution was taking place. The population assessed was patients consulting in primary care; the intervention was role substitution by the following non-medical health professionals: nurses, pharmacists and PAs, and also the following AHPs: physiotherapists, OTs, paramedics, practitioner psychologists, podiatrists, dieticians, social prescribers and approved mental health practitioners; the comparator was GP-led care; the outcomes were economic evaluations; and the setting was primary care. The form of economic evaluation had to be a full economic evaluation to be eligible for inclusion, and was limited to CEA, CBA, CUA, CMA, or CCA as defined in the introduction of this chapter.

Identification of studies

A comprehensive search was performed in Ovid MEDLINE, CINAHL, Cochrane Library, National Institute for Health and Care Excellence (NICE), and the Centre for Reviews and Dissemination database. Search dates were from 19 May 2017 to 31 July 2017. The search strategy performed in Ovid MEDLINE can be seen in Appendix 1. The search strategy focused on the 'intervention', including the terms 'role substitution', 'task shifting', 'general practice', and 'primary care'. The 'population', 'comparator', and 'outcome' elements were not included in the search strategy to avoid narrowing the strategy and subsequently limiting the search results. In order to recover a comprehensive set of relevant literature and to increase sensitivity, the searches were purposely broad. The search terms were not narrowed

to specify the professional groups and aimed to capture a comprehensive list of non-medical health professionals and AHP roles performing role substitution. In order to capture a full range of different forms of economic evaluation, there was no restriction on the study design in which the economic evaluation was embedded, and no filter was applied for example, to focus on RCTs alone. The search was not restricted by age, date, or country of origin. Additional studies were identified through hand searching the reference lists of included studies and relevant reviews. This review conformed to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidance (Moher et al., 2009) and the PRISMA checklist can be viewed in Appendix 2. Following the removal of duplicates, two reviewers (PhD candidate and AS) independently screened titles and abstracts for relevance, and full-article screening was subsequently conducted to retrieve eligible articles. Discrepancies were resolved through discussion. AS is an academic clinical Fellow at Bangor University.

Quality assessment

The 10-point Drummond checklist (Drummond et al., 2015) was used to assess whether the economic evaluation study methods were appropriate and whether the results were valid. The 10 questions covered the following items 1) the economic research question; 2) the intervention and competing alternative; 3) the effectiveness of the intervention(s); 4) the identification of relevant costs and consequences, 5) measurement of costs and consequences, and 6) valuation of costs and consequences; 7) discounting of cost consequences; 8) incremental analysis; 9) approach to dealing with uncertainty e.g. sensitivity analyses; and 10) discussion of results in the context of stakeholders.

For each of the ten questions included in the Drummond checklist, the reviewers answered either 'yes', 'no', 'can't tell' or 'not applicable'. The Drummond checklist does not include a standardised scoring system (Drummond et al., 2015; Gonzalez-Perez, 2002). For the purpose of this review each of the included papers were scored out of a possible ten points, with each question equally weighted and a score of 1 allocated where the answer was either 'yes' or 'not applicable'. A total score was used to provide an indication of the strength of quality across the included papers. For indicative purposes in this review, a quality rating based on the total scores were as follows: 0-5 poor quality, 6-8 moderate quality, 9 and over good quality (Table 3).

The same two reviewers (PhD candidate and AS) independently assessed the quality of the included studies using Drummond and colleagues (2015) checklist for economic evaluations (Table 3 and Appendix 3).

Data extraction

Key characteristics from the included study were extracted including: sample size of the intervention groups being compared, number and location of practices, type of economic evaluation and perspective, outcomes measured, and main findings.

Results

After the removal of duplicates, the search identified 10,261 studies (Figure 2). Most of these were excluded because they did not explicitly state that role substitution had occurred, were not conducted in a primary care setting, or were not full economic evaluations. Six studies were included in the review (N = 6), four studies were of good quality, and two were of moderate quality (Table 3), three used cost-minimisation, two cost-utility, and one cost-effectiveness analysis (Table 3). Three studies were economic evaluations of nurse-led care, two studies of pharmacist-led care and one study of community health practitioner-led care (Table 4). Despite being sought for inclusion, the systematic review did not identify full economic evaluations of role substitution for PAs or the following AHPs: occupational therapists, physiotherapists, paramedics, practitioner psychologists, podiatrists, dieticians, social prescribers or approved mental health professionals. Due to the heterogeneity of included studies, a narrative review is presented.

Table 3: Quality appraisal of economic evaluations of role substitution in primary care

Drummond question	The Community Pharmacy Medicines Management Project Evaluation Team, 2007	Dierick-van Daele et al. 2010	Lee et al. 2004	Neilson et al. 2015	Richardson et al. 2013	Turner et al. 2008
Was a well-defined question posed in an answerable form?	√	√	√	√	√	✓
Was a comprehensive description of the competing alternatives given	√	√	✓	-	-	√
Was the effectiveness of the programmes or services established?	√	√	√	√	√	√
Were all the important and relevant costs and consequences for each alternative identified?	-	√	√	x	√	✓
Were costs and consequences measured accurately in appropriate physical units?	-	√	√	✓	√	√
Were costs and consequences valued credibly?	√	√	√	√	√	√
Were costs and consequences adjusted for differential timing?	N/A	-	N/A	N/A	√	√
Was an incremental analysis of costs and consequences of alternatives performed?	N/A	N/A	N/A	✓	√	✓
Was allowance made for uncertainty in the establishments of costs and consequences?	x	√	x	√	√	×
Did the presentation and discussion of study results include all issues of concern to users?	√	√	√	√	√	√

Quality assessment score out of a	7	9	9	8	9	9
possible 10 (included questions						
answered N/A) ^a						

^aQuality rating based on the number of Drummond questions answered: $0-5 = poor \ quality$, $6-8 = moderate \ quality$, $9+ = good \ quality$. $\checkmark = yes$; $\times = no$; - = can't tell, $N/A = not \ applicable$.

Figure 2: Systematic review flow diagram

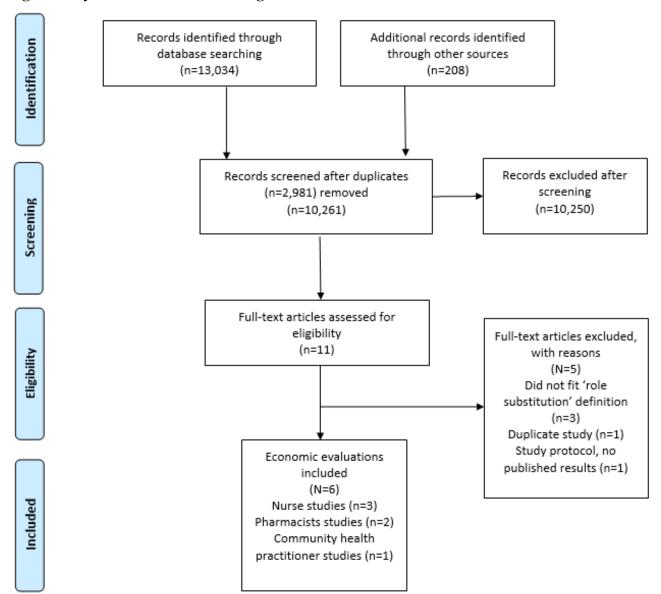


Table 4: Characteristics of included studies (n = 6)

Studies	The Community Pharmacy Medicines Management Project Evaluation Team, 2007	Dierick-van Daele et al. 2010	Lee et al. 2004	Neilson et al. 2015	Richardson et al. 2013	Turner et al. 2008
Country of origin	England	Netherlands	Korea	United Kingdom	England	United Kingdom
Study design	RCT	RCT	Retrospective, descriptive- correlational design	RCT	RCT	RCT
Aims	To assess the cost- effectiveness of a comprehensive community pharmacy medicines management (MEDMAN) service for patients with coronary heart disease.	To assess the difference in costs between GPs (GPs) and nurse practitioners (NPs) in treating common conditions.	To assess community health practitioner services in primary care, and to assess the economic impact of these services.	To measure the differences in mean costs and effects of a pharmacy-led service for the management of chronic pain in primary care.	To assess the cost- effectiveness of nurse- led self-help treatments for patients with chronic fatigue syndrome/ myalgic encephalitis in primary care.	To assess health service resource use of a nurse-led disease management for secondary prevention in patients with chronic heart disease and heart failure in primary care.
Type of non-medical health professional or AHP substituting	Pharmacists	Nurse practitioners	Community health practitioners (CHPs)	Pharmacists	Nurses	Nurses
Setting	Nine general practice sites	Fifteen general practices	Random sampling of CHPs working in community health posts	Six general practices	186 general practices	Twenty general practices
Length of follow-up	12 months	2 weeks	6 months	6 months	70 weeks	12 months
Type of economic evaluation conducted	Cost-minimisation analysis	Cost-minimisation analysis	Cost-minimisation analysis	Cost-utility analysis	Cost-effectiveness analysis	Cost-utility analysis

Primary economic outcome measure	Appropriate treatment and health status (measured using the SF-36 and EQ-5D).	Direct costs within the healthcare sector and costs outside the healthcare sector (productivity losses).	Activity measures e.g., consultations and cost measures.	Differences in mean total costs and effects (quality adjusted life years (QALYs)).	Costs and health related quality of life (HRQoL), measured using QALYs	QALYs measured using EQ-5D.
Quality	Moderate	Good	Good	Moderate	Good	Good
assessment	(7/10)	(9/10)	(9/10)	(8/10)	(9/10)	(9/10)
score ^a						

aQuality rating based on the number of Drummond questions answered: 0–5 = poor quality, 6–8 = moderate quality, >9 = good quality. CHPs = community health practitioners. EQ-5D = European Quality of Life-5 Dimensions measure. HRQoL = health-related quality of life. QALYs = quality-adjusted life years. SF-36 = Short Form-36 Health Survey.

Substitution by nurses

Three economic evaluations investigated the cost-effectiveness of nurses substituting for GPs with two evaluations examining nurses and one evaluation examining nurse practitioners (Dierick-van Daele et al., 2010; Richardson et al., 2013; Turner et al., 2008). A good-quality cost-utility analysis assessed health service resource use of a nurse-led disease management programme for secondary prevention in patients with chronic heart disease and heart failure in primary care, compared with usual GP care within a RCT study design (Turner et al., 2008). Length of follow-up was 12 months. The nurse-led group was associated with higher costs relating to all categories of resource use, compared with the usual care group (P<0.01). A difference of 0.03 quality-adjusted life years (QALY) value was reported between the nurse-led group and usual care, and the cost per QALY gained in the nurse-led group was £13,158 (£17,694 GBP, inflated to 2016/2017 prices) (Curtis and Burns, 2017). It is unclear whether there was a statistically significant difference in QALYs between the nurse-led disease management programme and usual care, as confidence intervals were not reported in the article (Table 5). In addition to the cost-utility analysis, the RCT included a concurrent clinical effectiveness evaluation (Khunti et al., 2007). The primary clinical outcomes focused on patient subgroups in terms of their clinical cardiac diagnosis who were receiving beta blockers and angiotensin-converting enzyme (ACE) inhibitor treatments, and levels of cholesterol recorded. There were no differences reported between the intervention and control group in terms of ACE inhibitor treatment rates; however, there were significant improvements observed in the intervention in terms of cholesterol management. The intervention group had significant more prescriptions for beta-blockers compared with the control group. The authors concluded that the nurse led care disease management programme had benefits in terms of diagnosis and appropriate treatment of patients with heart conditions and was valuable in the secondary prevention of heart disease and heart failure.

A good-quality CMA conducted alongside a randomised controlled trial (RCT) compared the differences in costs between GPs and nurse practitioners (NPs) in treating common minor health problems (Dierick-van Daele et al., 2010). Cost-minimisation was used because the RCT found no significant differences in effectiveness between GPs and NPs on outcomes of health status, burden of illness, patient concerns about illness, or patient consultation satisfaction levels (Dierick-van Daele et al., 2010). The economic evaluation study had a short follow-up period of 2 weeks to cost the interventions. The costs of NP consultations were significantly lower than with GPs (P = 0.01) with a mean difference of

&8.21, which equates to £7 inflated to 2016/2017 prices (Curtis and Burns, 2017). Sensitivity-analysis varying GP salary reported significantly lower costs of NP consultations when adjusting to the salary of an employed GP (P<0.007) or of a GP employed by other GPs in partnership (P = 0.02).

A good-quality CEA of nurse-led pragmatic rehabilitation (PR), and supportive listening (SL), for patients with chronic fatigue syndrome was compared with treatment as usual (TAU) by GPs within a RCT study design (Richardson et al., 2013). In the CEA, costs and outcomes were discounted at a rate of 3.5% per year; however, there was no further detail of how this discounting was performed (Richardson et a., 2013). Length of follow-up was 70 weeks and patients were asked to recall use of hospital services, day services, and contacts made with health professionals during this period. TAU was slightly more effective than PR and SL, at a lower cost, when baseline differences in European Quality of Life-5 Dimensions (EQ-5D) were adjusted. Richardson et al reported that all confidence intervals (CIs) for estimations of costs and effects crossed zero (Richardson et al., 2013). Imputed results showed that PR has a mean incremental cost-effectiveness ratio (ICER) QALY of -0.01 (95% CI = -0.09 to 0.07) and SL had a mean ICER QALY of -0.04 (95% CI = -0.12 to)0.04). SL was no more effective than PR or TAU, but costed more; therefore, SL was not found to be cost-effective. Complete case analysis as part of sensitivity analyses showed PR was associated with slightly higher QALYs than TAU, but confidence intervals crossed zero. Complete case results found that PR had a mean ICER QALY of -0.01 (95% CI = -0.08 to 0.10) and SR had a mean ICER QALY of -0.04 (95% CI = -0.13 to 0.05). The nurse-led PR intervention produced a cost per QALY of £39,583 GBP (£44,812 inflated to 2016/2017). It was concluded that the nurse-led PR intervention would not be deemed cost-effective in the UK at the current NICE threshold of £20,000 to £30,000 per QALY (Table 5).

In addition to the economic evaluation (Richardson et al., 2013), the RCT included a concurrent clinical effectiveness evaluation (Wearden et al., 2010). The primary clinical outcomes were fatigue and physical functioning. Results from the clinical effectiveness study found that nurse-led PR care led to a statistically significant improvement in patient fatigue compared with TAU, however there was no statistically significant difference in physical functioning (Wearden et al., 2010). The economic evaluation was a CEA which used QALYs as the primary economic outcome, there was no analysis conducted to assess the costs of any improvements in clinical outcomes.

Substitution by pharmacists

Two moderate-quality economic evaluations assessed the substitution of medicines management by pharmacists instead of GPs (Community Pharmacy Medicines Management Project Evaluation Team, 2007; Neilson et al., 2015) (Table 3). A CMA explored the costeffectiveness of a comprehensive community pharmacy medicines management project service for patients with coronary heart disease (Community Pharmacy Medicines Management Project Evaluation Team, 2007). The study design was a RCT which had a follow-up period of 12 months. There were no significant differences between GP led care and pharmacist led care on primary clinical outcomes including aspirin related management and lifestyle measures. The CMA focused on comparison of intervention costs. Total NHS costs at baseline were £852 and £738 for the intervention and control group, respectively. The difference in costs between groups at baseline was £114 (P<0.01) (£139 inflated to 2016/2017 prices) (Curtis and Burns, 2017). Total NHS costs at follow-up were £971 and £835 for the intervention and control groups, respectively. Total NHS costs at follow-up for the pharmacist group were significantly greater than the control group (P<0.01) with a mean difference in costs of £135 (164 GBP at 2016/2017 prices) (Curtis and Burns, 2017) (Table 5). This was due to the costs of providing the additional pharmacist training. The differences in QALYs between groups was 0.04 (95%, CI = -0.05 to 0.13); this was non-significant. An ICER was not presented in the article.

A CUA (conducted as part of a RCT) of a pharmacy-led service for the management of chronic pain (Neilson et al., 2015) as part of a three-arm RCT compared pharmacist-led medication review with face-to-face pharmacist prescribing, pharmacist-led medication review with feedback to GP, and TAU from the GP. Study follow-up was 6 months. After baseline costs were adjusted, both pharmacy-led interventions were more costly than TAU. Relative to TAU, the adjusted mean costs differences per patient was £78 (£87 inflated to 2016/2017 prices) (95% CI = -82 to 237) for prescribing and £54 (61 GBP inflated to 2016/2017 prices) (95% CI = -103 to 212) for medication review. Relative to TAU, the adjusted mean QALYs to 0.01 (95% CI = -0.01 to 0.02) for prescribing and 0.01 (95% CI = -0.01 to 0.02) for medication review (Table 5). The authors did not report an adjusted mean cost for TAU in the paper. In the clinical effectiveness study, the three primary outcomes focused on general health and functioning using the SF-12 (Ware et al., 2009), chronic pain, and anxiety and depression (Bruhn et al., 2013). This exploratory stage study considered both within group differences over the 6-month study period, and between group differences

across all arms of the study. The physical component of the SF-12 improved in the TAU group over time and remained the same in the intervention arms and there were no significant differences between groups. The mental component of the SF-12 indicated a significant reduction in functioning in the TAU group and no change over time in the intervention arms. There was a significant difference reported between groups on the mental component of the SF-12 (Bruhn et al., 2013). The authors concluded that there were indicators of significant benefit for the pharmacist-led intervention arms on the anxiety and depression scores outcome compared with TAU. For the chronic pain outcomes, both intervention arms had a significant improvement over time while TAU remained the same, however this was not considered significant between groups. The authors highlighted that a larger trial was required to assess their findings definitively.

Community health practitioners

A good-quality CMA from South Korea compared the delivery of primary care services by community health practitioners (CHPs) in remote communities with equivalent care delivered by physicians in inner-city clinics (no CHP services) (Lee et al., 2004) (Table 3). CHPs were described as registered nurses responsible for the delivery of primary care, who had received 6 months of special training. The length of study follow-up was 6 months. The mean total cost of CHP services per month was \$2,424 USD (£2,520 GBP inflated to 2016/2017) (Curtis and Burns, 2017). The total mean costs of no CHP services was \$5,188 USD (£5394 in 2016/2017). Total mean costs were significantly lower for CHP services (P<0.01) with a cost ratio of 2.16 (SD 1.24, range 0.09 to 9.63). Indirect costs were also lower for the CHP services group, due to travel costs and loss of earnings for patients in the physician group, who had to travel to inner-city clinics to see a physician (Table 5).

The authors deemed CMA to be appropriate based on previous literature that suggests that a model of care involving CHPs was as effective than one that required physicians to deliver all services. As the study was not embedded within a RCT study design and a CMA form of economic evaluation employed, effectiveness data was not collected. The authors did not consider effectiveness within the economic evaluation other than to highlight previous literature which informed their assumption that interventions were equally effective "in terms of client satisfaction, health status, health education and counselling, and access (Kim et al. 1985, 1991, Song et al. 1988, Kim 1992, 1999)" (Lee et al., 2004, p.472).

Table 5: Results of included studies (n=6)

The Community Pharmacy Medicines Management Project Evaluation Team, 2007	Dierick-van Daele et al. 2010	Lee et al. 2004	Neilson et al. 2015	Richardson on et al. 2013	Turner et al. 2008
2007; England	2010; Netherlands	2004; Korea	2015; United Kingdom	2013; England	2008; United Kingdom
Intervention: pharmacist (n=62) Control: GPs (n=164); Pharmacist- led medicines management vs. standard care from the GP in nine general practices.	Intervention: nurse practitioners (n=12) Control: GPs (n=15); Role substitution of nurse practitioners by GPs in 15 general practices.	Intervention: community health practitioner (CHP) (n=600) Control: care delivered by physician; CHP services vs. no-CHP services in primary health care. Postal survey questionnaire sent to a sample of CHPs nationwide.	Intervention 1: pharmacists medication review with pharmacist prescribing (n=70); Intervention 2: pharmacist review only (n=63). Control: treatment as usual from GP (n=63); Pharmacy-led care vs. treatment as usual for the management of chronic pain in six general practices.	Intervention 1: nurse-led pragmatic rehabilitation (PR) (n=85), Intervention 2: nurse-led supportive listening (SL) (n=97). Control: Treatment as usual (TAU) from GP (n=92); Nurse-led supported selfmanagement compared with treatment as usual in 186 general practices.	Intervention: nurse- led care (n=505) Control: usual GP care (n=658); Nurse- led disease management vs. standard GP care in 20 general practices.
Cost-minimisation analysis	Cost-minimisation analysis	Cost-minimisation analysis	Cost-utility analysis	Cost-effectiveness analysis	Cost-utility analysis
Total NHS costs; Direct costs of delivering the intervention and NHS treatment costs (e.g., cost of medicines) and indirect costs of training (e.g., attendance fees);	Costs of GP vs. nurse practitioner consultation; Direct costs within the healthcare sector and costs outside of the healthcare sector (productivity losses); Process outcomes and	Total costs of care between CHP services model and no-CHP services model of care; Direct costs (e.g., personnel costs, materials) and indirect costs (operational and	Differences in mean total costs and effects of pharmacist-led management vs. GP-led management of chronic pain; Direct costs, other costs borne by patients and productivity losses;	Quality Adjusted Life Years (QALYs) derived from the EQ5D; Cost to the NHS (e.g., resource use and unit costs), private expenditures, informal care costs and loss of	Quality Adjusted Life Years (QALYs) derived from the EQ- 5D; Direct costs (including travel costs); Health utility measured with EQ- 5D.
	Pharmacy Medicines Management Project Evaluation Team, 2007 2007; England Intervention: pharmacist (n=62) Control: GPs (n=164); Pharmacist- led medicines management vs. standard care from the GP in nine general practices. Cost-minimisation analysis Total NHS costs; Direct costs of delivering the intervention and NHS treatment costs (e.g., cost of medicines) and indirect costs of training (e.g.,	Medicines Management Project Evaluation Team, 2007 2007; England Intervention: pharmacist (n=62) Control: GPs (n=164); Pharmacist- led medicines management vs. standard care from the GP in nine general practices. Cost-minimisation analysis Total NHS costs; Direct costs of delivering the intervention and NHS treatment costs (e.g., cost of medicines) and indirect costs of training (e.g., Medicines Management Project Evaluation Intervention: nurse practitioners (n=12) Control: GPs (n=15); Role substitution of nurse practitioners by GPs in 15 general practices. Cost-minimisation analysis Costs of GP vs. nurse practitioner consultation; Direct costs within the healthcare sector and costs outside of the healthcare sector (productivity losses);	Medicines Management Project Evaluation Team, 2007 2007; England Intervention: pharmacist (n=62) Control: GPs (n=164); Pharmacist- led medicines management vs. standard care from the GP in nine general practices. Cost-minimisation analysis Total NHS costs; Direct costs of delivering the intervention and NHS treatment costs (e.g., cost of medicines) and indirect costs of training (e.g., Management Project Evaluation Team, 2007 2010; Netherlands 2004; Korea Intervention: community health practitioner (CHP) (n=600) Control: care delivered by physician; CHP services vs. no-CHP services vs. no-CHP services in primary health care. Postal survey questionnaire sent to a sample of CHPs nationwide. Cost-minimisation analysis Total NHS costs; Direct costs of delivering the intervention and NHS treatment costs (e.g., cost of medicines) and indirect costs of training (e.g.,	Management Project Evaluation Team, 2007 2007; England Intervention: pharmacist (n=62) Control: GPs (n=164); Pharmacist- led medicines management vs. standard care from the GP in nine general practices. Cost-minimisation analysis Cost-minimisation analysis Total NHS costs; Direct costs of delivering the incost of medicines) and indirect costs of training (e.g., Melication 2010; Netherlands 2004; Korea 2015; United Kingdom Intervention: Inte	Pharmacy Medicines Management Project Evaluation Team, 2007

	and health status (SF-36 and EQ-5D).		CHP services. Direct costs (e.g., outpatient costs) and indirect costs (travel and loss of earnings) of no CHP services; Outcomes not assessed. The efficacy of the intervention was based on previous findings.	Health utility derived from SF-6D.	Health-utility measured using EQ-5D.	
Perspective of analysis	Not stated	Practice and societal	Not stated	NHS	NHS and personal social services	Patient and NHS
Currency and Cost Year	Pounds sterling derived from general practice –held records. Cost year not reported.	Euros (€) derived using the price index of Statistics Netherlands for cost year 2006.	Korean won (\(\foat\)) converted to US dollars (\(\foat\)) derived from national unit costs for cost year 1999	Pounds sterling (£) derived from Personal Social Services Research Unit (PSSRU) and British National Formulary for prices at cost year 2009/10.	Pounds sterling (£) derived from NHS reference costs and PSSRU at 2008/09 prices.	Pounds Sterling (£) derived from healthcare resource groups (HGRs) for cost year 2003-03 and inflated to 2003/04 prices.
Discounting and sensitivity analysis	Follow-up period 12 months, no discounting, no sensitivity analysis	Sensitivity analysis varying GP salary. No discounting.	6-month time horizon; no discounting, no Sensitivity analysis	6-month time horizon; no discounting. Three sensitivity analyses were conducted with imputed values for SF-36 scores.	Costs and outcomes were discounted at a rate of 3.5% per year. A complete case analysis as part of sensitivity analyses was conducted.	Follow-up period 12 months no discounting discount rate of 6% for equipment and training that would have an expected lifespan of more than one year. No sensitivity analysis
Intervention costs and main findings	Total NHS costs at baseline: intervention group £852.4, control group £737.8. Total	Cost per NP consultation €31.94. Cost per GP consultation €40.15;	Mean direct costs CHP \$2423.7, SD: \$565.6 (£252 inflated to 2016/17 prices ¹⁵).	Unadjusted total mean costs: prescribing group £452 (£509 in	Excluding intervention costs of SL and PR, at 70-week follow-up, total	Total mean NHS delivery costs nurse £1107.81 and GP £660.57, (p=0.001);

	NHS costs at follow-up: intervention £970.5, control £835.2; Statistically significant difference (p<0.0001) in total NHS costs, due to the costs of providing pharmacists' training. Mean difference in costs of £135.3 (£164 inflated to 2016/17 prices ¹⁵).	Lower direct consultation costs for NP compared with GP ($p = 0.001$) mean difference $\in 8.21$ (£7 inflated to $2016/17$ prices ¹⁵).	Physician \$5187.7, SD: \$3262.5 (£5394 inflated to 2016/17 prices ¹⁵). Mean indirect costs CHP (\$499.9, SD: \$257.8) Physician (\$1268.6, SD: \$951.7); t-test found a significant difference in the average costs of care between the groups (p<0.001 cost ratio of 2.16, with a range of 0.09 to 9.63).	2016/17 ¹⁵), medication review group £570 (£642 in 2016/17 ¹⁵), TAU group £1333 (£1500 in 2016/17 ¹⁵); Both pharmacy-led interventions were more costly, with slightly higher QALY gains than TAU.	NHS cost of chronic fatigue syndrome £789 for PR, £916 for SL and £710 for TAU; TAU was slightly more effective than PR and SL, at a lower cost, when baseline differences in EQ-5D were adjusted. The nurse-led PR intervention produced a cost per QALY ratio of £39,583 (inflated to £44,812 in 2016/17 ¹⁵).	A difference of 0.03 QALY value was reported between the nurse-led group and usual care, and the cost per QALY gained in the nurse-led group was £13,158 (£17,694 inflated to 2016/17 prices ¹⁵).
Conclusions	No change in numbers of patients receiving appropriate treatment. Pharmacy- led group more costly than standard care.	Direct costs of consultations were lower for nurse practitioners than GPs. The differences in costs were mainly due to differences in salary.	Care provided by a physician was twice as costly as the CHP services due to travel costs and loss of earnings for patients who would have had to travel to inner city clinics to see a physician.	Pharmacy-led management is more costly than usual treatment and produce similar QALYs compared with usual treatment.	The nurse-led PR intervention was not cost-effective.	Nurse-led disease management programme was cost- effective.

Discussion

Summary of main findings

Nurse-led care for common, minor health conditions was as effective as and less costly than GP care. Nurse-led preventive care for secondary prevention of heart disease and heart failure was more costly and similar in effectiveness as usual GP care. It is uncertain whether there was a statistically significant difference in the QALY value reported between groups as confidence intervals were not reported in the article. Nurse-led interventions for chronic fatigue syndrome were more costly and less effective. Pharmacy-led services for the medicines management of coronary heart disease were as effective as, but more costly than, GP care. For managing chronic pain, pharmacy-led care was slightly more effective than GP care for increased cost. In South Korea, community health nurse practitioners delivered primary care services for half the cost of physicians. There was a lack of economic evidence for role substitution by AHPs.

Findings in relation to the conceptual framework of the thesis and theories of role substitution

This thesis used an evaluative framework with dimensions proposed by Maxwell for evaluating quality of care and was applied in this thesis to role substitution in primary care (Maxwell, 1992). This systematic review of economic evaluations presented findings in relation to the two of the six dimensions of quality: costs (efficiency domain) and effectiveness. The economic evaluations included in this systematic review presented evidence of the costs and outcomes of role substitution in primary care settings.

The findings from this thesis were also framed by an awareness of theories concerning role substitution and the system of professions (Abbott, 1988). Role substitution is a complex system change however the economic evaluations to date have focused on a narrow range of professional groups and types of substitution. The findings presented in this systematic review of economic evaluations were interventions of vertical substitution between GPs and the following non-medical health professionals: nurses, pharmacists, and community health practitioners. This systematic review did not focus on the wider factors important to role substitution which have been discussed in more detail in other chapters of this thesis, for example, theories of professional boundaries and jurisdiction which by their nature are more likely to be considered within the findings other types of study design e.g., qualitative methods. This highlights the need for consideration of the value of different study

fields and methods to explore the full range of role substitution theories and the domains of the conceptual framework. Consideration of the findings from each of the thesis chapters in relation to the conceptual framework and theories of role substitution are discussed in detail in the overall discussion chapter of this thesis (Chapter 7).

Strengths and limitations

To the authors' knowledge, this was the first systematic review that identified full economic evaluations of the substitution of GPs by non-medical health professionals and AHPs in a primary care setting. This review undertook extensive literature searches using a well-developed search strategy and robust methodology, and adhered to the PRISMA guidelines (Moher et al., 2009). There were no restrictions on date of publication or country of origin for the included studies. Economic evaluations conducted alongside RCTs are important as they produce reliable estimates of cost-effectiveness at low marginal cost (Petrou and Gray, 2011). Of the six studies included in the review, five were concurrent economic evaluations alongside RCTs (Community Pharmacy Medicines Management Project Evaluation Team, 2007; Dierick-van Daele, 2010; Neilson et al., 2015; Richardson et al., 2013; Turner et al., 2008), while the one remaining paper was a retrospective descriptive-correlational design study (Lee et al., 2004).

The Drummond checklist offers a brief quality appraisal tool to assess the quality of included studies within this systematic review of economic evaluations. The checklist itself does not provide a full assessment of the study design in which the economic evaluation is embedded, for example, to consider risk of bias within clinical trial design. Instead, the Drummond criteria focuses on elements specific to the economic evaluation including the measurement and valuation of costs and benefits and is widely used in the assessment of economic evidence.

The Drummond checklist does not consider the quality of the economic evaluation by reflecting on the quality of the underlying clinical-effectiveness study from which the health economic study is based. An economic evaluation is only as valid as its underlying measures of effectiveness (Weintraub and Cohen, 2009). "The choice of clinical effectiveness data, particularly the estimates of clinical effect size, is crucial to the outcomes of the study, and findings may be distorted if the underlying data are not adequately represented" (Hanratty et al., 2007, p.139). Other appraisal tools may be useful to consider wider factors which contribute to areas of uncertainty in the data and may impact on the quality of the economic

study. For example, inclusion of a risk of bias tool to help appraise the source study in cases where a RCT study design is employed (e.g., Higgins et al., 2011) may help increase the confidence in the estimates of costs and benefits used within the economic evaluation. Where non-randomised studies are employed or other sources of data utilised to establish the effectiveness of the intervention then alternative tools may be warranted to appraise their quality (see Higgins et al., 2013). The Drummond checklist requires areas of uncertainty in the economic analysis to be identified and for studies to address these using methods such as sensitivity analysis to report on whether variations to key parameters effect the conclusions drawn in the study, however the assessment of whether this is sufficient is a subjective process. In addition, there is no agreed upon method for the scoring of the Drummond checklist (Gonzalez-Perez, 2002), as such the methods applied within this study were only indicative of study quality.

As an alternative to the 10 question Drummond checklist there are a range of economic evaluation quality appraisal tools that can be employed to provide a comprehensive assessment of the quality of the economic evaluation methods and reporting. These include a previous version of the Drummond checklist (Drummond and Jefferson, 1996), prepared for the assessment of economic evaluations for publication in the British Medical Journal, consisting of 35 questions which highlights the need to report study conclusions with appropriate caveats. In addition, the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement (Husereau et al., 2022) provides a further tool which aims to increase the quality of reporting of economic evaluations, consisting of 28 items it provides recommendations for the transparent reporting of all economic evaluations in peer-reviewed journal articles.

There were a number of limitations in the included studies. Consultation length was not considered in two of the economic evaluations that found role substitution to be costeffective (Lee et al., 2004; Turner et al., 2008). Although the results reported lower unit costs in these studies, nurse and CHP consultations may have been significantly longer than GP consultations, so actual costs may have been higher for the non-medical health professional groups. Only one of the included studies explicitly provided information on patient recall (i.e., re-consulting for the same condition, as the issue was not resolved during a patient's first appointment) including contacts made with healthcare professionals over the study period (Richardson et al., 2013). There was a lack of information regarding patient recall in the other included studies, making it difficult to ascertain how information on services used

by patients was gathered, whether the appropriate perspective was chosen to include all relevant costs, and whether the length of time horizon patients was asked to recall was appropriate. The South Korean study may not be directly comparable with the UK and other countries with highly developed primary care services. There was a lack of explanatory detail when describing the intervention and control treatments, which might be improved by the inclusion of a concurrent process evaluation. For example, two studies provided only minimal information about usual GP care (Community Pharmacy Medicines Management Project Evaluation Team, 2007; Richardson et al., 2013).

The economic evaluation method can be criticised where assumptions are made without clear supporting evidence provided, for example in the case of Lee and colleagues (2004) cost-minimisation was used with outcomes reported to be equal and only costs were considered, however, there was no one definitive piece of supporting evidence provided on clinical effectiveness (Lee et al., 2004), instead a range of outcomes published in previous studies were considered and reported to be equal. In addition, one of the other included economic evaluations where no significant differences in outcomes were found between groups, and a cost-minimisation analysis was also conducted (Community Pharmacy Medicines Management Project Evaluation Team, 2007). Given the lack of a statistically significant effect, a cost-consequence analysis may have been more appropriate. There were inconsistencies in the reporting of findings of the included studies, for example, ICER calculations and CIs around small differences in QALYs that make interpretation of results difficult. In one study authors' conclusions are not supported by their findings (Turner et al., 2008). Despite the higher service use costs reported substituting nurses for GPs, the authors concluded that the nurse-led disease management programme was cost-effective as it fell below the NICE cost-effectiveness threshold of £20,000 to £30,000 GBP per QALY (National Institute for Health and Care Excellence, 2013). However, this finding does not provide clear evidence of cost-effectiveness for this intervention given it was more costly than GP-led care. Furthermore, there was a lack of clarity about the perspective adopted, with two studies not providing this information (economic evaluation appraisal tool responses are available from the authors on request). This lack of clarity makes it difficult to ascertain whether all pertinent costs and outcomes were included in the analysis. Additionally, only two of the included studies (Richardson et al., 2013; Turner et al., 2008) produced a costeffectiveness acceptability curve.

There were disparities between the country and the type of role substitution that took place in the included studies. This review used a specific definition of role substitution; however, there were difficulties distinguishing true role substitution in the included studies, which makes generalisability difficult. The majority of the included studies assessed novel non-medical health professional-led interventions; these studies represent a different kind of role substitution whereby non-medical health professionals are used to replace GP-led care. When reviewing the literature, the definition of role substitution was used to uncover economic literature of non-medical health professionals and AHPs performing care in place of a GP. In order to better inform current policy with regards to increasing the involvement of non-medical health professionals and AHPs in primary care, future studies should assess the cost-effectiveness of all forms of role substitution to better understand the impact of such workforce redesign. From the included studies, generalisability of results is difficult as each study assessed different non-medical health professionals, and used different interventions, outcome measures, and time horizons. There is a larger evidence base for role substitution with nurses; in order to improve the generalisability of role substitution with other nonmedical health professionals and AHPs further evidence is needed. Finally, the majority of articles were within a 1-year time horizon (70-week time horizon in one study); none of the studies extrapolated beyond this. Given the range of interventions, it would have been useful for the authors to justify their chosen time horizon in order to assess if this was appropriate and relevant for expected outcomes resulting from the intervention. A new, innovative service redesign such as role substitution in primary care may not necessarily show changes in the immediate term; therefore, future studies with longer time horizons are recommended.

Comparison with existing literature

The evidence reported by previous systematic reviews only reported the economic impact of role substitution of GPs by nurses and pharmacists in terms of their costs. These are not considered full economic evaluations as they do not synthesise costs and outcomes (Chisholm-Burns et al., 2010; Horrocks et al., 2002; Kuethe et al., 2013; Laurant et al., 2005; Martínez-González et al., 2015; Paudyal et al., 2013).

In 2008, Dierick-van Daele et al reviewed economic evaluations of the substitution of skills between health professionals in a variety of settings including general practice, hospital, and community settings. However, the majority of the evidence looked at nurses and only one of the included studies took place in general practices (Dierick–van Daele et al., 2008).

Dierick-van Daele and colleagues stated that this article was an economic evaluation, but did not compare costs and outcomes, and therefore it would not be considered a full economic evaluation. The current systematic review serves as a timely update of the evidence and identifies full economic evaluations of role substitution in primary care.

Implications for research and practice

There is only limited evidence that nurses can provide a cost-effective alternative to GPs. This evidence is most convincing for the management of common, minor health problems by nurses. However, it is worth acknowledging the majority of included studies in this review assessed novel interventions using non-medical health professionals to replace GP-led care. This broadens the use of role substitution, which could have implications on evidence as workforce redesign continues to grow. Role substitution is becoming commonplace throughout primary care but there is a lack of economic evidence. This systematic review did not identify full economic evaluations for PAs or AHPs (physiotherapists, OTs, paramedics, practitioner psychologists, podiatrists, dieticians, social prescribers and approved mental health practitioners). High-quality economic evaluations are needed for all of the different roles that non-medical health professionals and AHPs could perform in primary care instead of GPs.

The substitution of GPs by non-medical health professionals and AHPs may have the potential to reduce costs, but this is greatly reliant on salary differences. Furthermore, consultation length and patient recall must also be considered. Though it may seem less costly to employ non-medical health professionals and AHPs in general practice in terms of their unit costs, their consultation lengths may be longer, and they also might be associated with higher patient recall to general practice. Patient recall can be defined as patients returning to general practice to re-consult for the same condition/issue that they initially presented with because the issue was not resolved following their first consultation. For example, a patient may consult with a non-medical health professional or AHP but may then return to general practice and request a GP appointment. Consequently, employing non-medical health professionals and AHPs to perform roles and duties normally completed by GPs may prove more costly overall.

Conclusion

Previous systematic reviews have found that nurses can provide equivalent, or higher, quality of care for some tasks performed by GPs' however, evidence is lacking for role substitution

by AHP groups. There is also a lack of economic evidence for this role substitution, and a number of reviews have concluded that future research should address this. Despite the shortage of evidence, role substitution is becoming commonplace in primary care.

Evidence presented in the introduction chapter of this thesis highlighted evidence gaps in terms of economic evidence and the barriers and facilitators of role substitution. Chapter 2 of this thesis concluded a need for greater exploration into the economic and qualitative evidence of role substitution. This chapter identified the existing literature on the effectiveness and cost-effectiveness of role substitution in primary care. Therefore, the purpose of the next chapter of this thesis (Chapter 3) was to systematically review the qualitative evidence on this topic.

CHAPTER 3: A SYSTEMATIC REVIEW OF QUALITATIVE STUDIES EXPLORING ROLE SUBSITUTION IN PRIMARY CARE

Introduction

Previous reviews identified in the introduction chapter of this thesis (Chapter 1) have provided qualitative evidence in relation to nurses substituting for GPs in primary care settings (McInness, 2015; Rashid, 2010), but there was a lack of evidence on the barriers and facilitators for other groups of non-medical roles and AHPs substituting for GPs in primary care. As previously explained in Chapter 1 of this thesis, general practices are increasing the use of non-medical health professionals and AHPs to substitute for GPs to provide medical services, however, it is not known whether patients or clinicians views these changes as appropriate or acceptable. In order for role substitution to be successfully implemented within practice, both patient and provider perspectives must be considered. In consequence, the aim of this chapter was to systematically review the qualitative literature on the barriers and facilitators concerning the substitution of GPs by non-medical health professionals (excluding nurses) and AHPs.

This chapter presents a systematic review of qualitative studies which can be defined as a systematic review where meta-analysis is not technically possible (Booth et al., 2016). The term qualitative evidence synthesis (QES) is used as an umbrella term to describe over twenty diverse methods of qualitative synthesis, some of which are implemented with the intention of developing new theory (such as meta-ethnography), while other methods (such as framework synthesis) may be used to present findings at a descriptive level when the purpose is to inform practice and policy (Booth et al., 2016). The diversity of methods of QES can be explained in terms of their epistemological positions and are generally categorised as either 'realist' (e.g., thematic and framework synthesis) or 'idealist' standpoints (Barnett-Page and Thomas, 2009).

Booth and colleagues developed a criteria-based approach for reviewers to use when considering the most appropriate methods of QES for use in health technology assessments of complex interventions (Booth et al., 2016). Their RETREAT framework outlines seven criteria for choosing a QES approach: Review question; Time/Timescale; Resources; Expertise; and Audience/purpose (Booth et al., 2016). Moreover, Noyes and colleagues also offer guidance when selecting an appropriate QES method for intervention reviews, defined as systematic reviews of evidence from health research exploring the impact of an

intervention in a specified population or setting. They recommend three QES methods for intervention reviews: thematic synthesis, meta-ethnography and framework synthesis (Noyes et al., 2019). The purpose of this systematic review presented in this chapter was to explore the barriers and facilitators of role substitution in primary care settings. In order to choose the most appropriate QES method for this systematic review, both the RETREAT framework (Booth et al., 2016) and the guidance provided in by Noyes and Colleagues in the Cochrane Handbook for Systematic Reviews of Interventions was considered and used to reflect on the three methods of QES recommended for intervention reviews.

Meta-ethnography was not deemed as an appropriate method of QES for this systematic review. Although meta-ethnography provides a clear and accessible approach (Noyes et al., 2019), this method was not suitable for a number of factors. Meta-ethnography is suitable when the research question is more negotiable and emerges over time through exploration of the data in the initial review process (Booth et al., 2016). In the systematic review presented in this chapter, the research question was fixed and followed a clear PICOC (Population, Intervention, Comparison, Outcome, and Context) framework and therefore more suited to thematic or framework synthesis methods. Moreover, meta-ethnography is deep rooted within epistemological considerations and carries a strong philosophical component, whereas in contrast, thematic and framework approaches are considered more epistemology-neutral and are particularly useful when the purpose is to simply map the barriers and facilitators of an intervention to produce a model in order to describe the findings across the included studies (Booth et al., 2016). Meta-ethnography also requires a large number of resources (including time and qualitative research expertise) and therefore was not appropriate for this PhD project due to limited time constraints and because the PhD candidate undertaking the review was new to qualitative research. With respect to the 'Audience/Purpose' domain of the RETREAT framework, meta-ethnography synthesis is a type of interpretive approach which is generally more complex and conceptual that "requires practitioners to interpret relevance and applicability to their own context" (Booth et al., 2016). The purpose of this systematic review was to identify barriers and facilitators which can then be considered in relation to their implications to practice and policy. According to Barnett-Page and Thomas, more realist methods of QES such as thematic and framework synthesis produce outputs that are more directly relevant to policy makers and are consequently better suited for the purpose of this systematic review, as they enable easily translatable findings to policy makers and practitioners (Booth et al., 2016; Barnett-Page and

Thomas, 2009). In terms of the type of data that can be incorporated, meta-ethnography does not have the capacity to synthesis evidence from a large number of studies, as opposed to framework synthesis and thematic synthesis which can handle a large number of studies (Booth et al., 2016).

Based on some of the RETREAT criteria reflected on in terms of the suitability of the three methods of QES described above, both thematic and framework synthesis would have been suitable QES methods in this systematic review. Nevertheless, thematic synthesis is a complex process that requires an experienced team (Noyes et al., 2016). In contrast, Framework synthesis follows a clear and simple process which is particularly useful for novice qualitative researchers (Dixon-Woods, 2011). Moreover, framework synthesis is also useful when there is a broad agreement about the nature of the intervention and its potential impacts. Before conducting the systematic review, the PhD candidate was already aware of some of the potential impacts of role substitution based on background reading of the topic, for example the potential impact of role substitution on factors such as access, workload and continuity of care which is highlighted in Chapter 1 of this thesis. Framework analysis was particularly useful as it allowed the PhD candidate to test existing theory relating to role substitution. By using Framework synthesis for both the literature synthesis (presented in this chapter) and also for the empirical data synthesis (presented in Chapter 6 of this thesis) this allowed for consistency and to map and compare findings across both chapters.

Framework synthesis was further justified as it fits in with the overarching theoretical approach of this thesis as it allowed for a later stage consideration of theory. Framework synthesis allows for both bottom-up and top-down analysis, and therefore the top-down capability allowed for interpretation of the data in light of the theories relating to role substitution and the conceptual model by which the findings of this thesis are framed (described in Chapter 1 of this thesis).

This chapter aimed to answer the following research question:

2. What existing literature is there on the barriers and facilitators to role substitution in primary care?

Methods

Selection of studies

Role substitution was defined as 'the substitution of work that was previously completed by a general medical practitioner in the past and is now completed by a non-medical health professional (other than a nurse) or AHP. The justification to exclude nurses is because this area has already been reviewed in 2019. Karimi-Shahanjarini and colleagues (2019) have published a systematic review of qualitative studies in the Cochrane Review Group that explores the barriers and facilitators to the effectiveness and implementation of doctor-nurse substitution in primary care settings. This high calibre Cochrane review has already filled this literature gap; therefore, it was decided to exclude nurses from this review. Consequently, this systematic review explored the barriers and facilitators of role substitution between GPs and other groups of non-medical health professionals (excluding nurses), namely pharmacists and physician associates and also the following AHPs: physiotherapists, OTs, paramedics, practitioner psychologists, podiatrists, dieticians, social prescribers and approved mental health practitioners.

Studies were excluded if role substitution (i.e., work completed by a non-medical health professional or AHP instead of a GP) was not discussed in the findings of the paper. Studies were also excluded if they explored the substitution of GPs by nurses. To be included in the review, the study design of the included papers had to be a qualitative study with no restrictions on the types of qualitative study design sought. The population assessed was patients, service providers and primary care stakeholders; the intervention was role substitution by non-medical health professionals (pharmacist and physician associates) and AHPs (physiotherapists, OTs, paramedics, practitioner psychologists, podiatrists, dieticians, social prescribers or approved mental health professionals); the comparator was GP-led care; the outcomes were barriers and facilitators uncovered from qualitative findings; and the context that role substitution was taking place was within primary care settings. The search terms were not narrowed to specify the professional groups and aimed to capture a comprehensive list of non-medical health professionals and AHP roles performing role substitution.

Identification of studies

A comprehensive search was performed in OVID Medline, CINAHL, Cochrane Library, NICE, and the Centre for Reviews and Dissemination (DARE & NHS EED databases). Search dates were from inception to July 31st 2017. The search strategy performed in OVID Medline can be seen in Appendix 4. In order to recover a comprehensive set of relevant

literature and to increase sensitivity, the searches were purposely broad. The search strategy included the terms 'role substitution', 'task shifting', 'general practice' and 'primary care'. The 'population', 'comparator' and 'outcome' elements were not included in the search strategy to avoid narrowing the strategy and subsequently limiting the search results. The search was not restricted by age, date or country of origin. Additional studies were identified through hand searching the reference lists of included studies and relevant reviews. This review conformed to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidance (Moher et al., 2009) (Appendix 5 PRISMA checklist). The review protocol was registered at the PROSPERO international prospective register of systematic reviews, registration number CRD42018093668.

Quality assessment

Following the removal of duplicates, two reviewers independently screened titles and abstracts for relevance, subsequently full-paper screening was conducted to retrieve eligible papers (PhD candidate, AS). AS is an academic clinical Fellow at Bangor University. Discrepancies were resolved through discussion between the PhD candidate and AS. The same two reviewers independently assessed the quality of the included studies using the Critical Appraisal Skills Programme (CASP) qualitative checklist (Public Health Resource Unit, 2006) (see Table 6 and Appendix 6). For each of the ten questions included in the CASP tool, the reviewers answered either 'yes', 'no', 'can't tell' or 'not applicable'. Although the CASP checklist was designed to be used as an educational pedagogic tool and does not include a scoring system (Public Health Resource Unit, 2006), for the purpose of this review each of the included papers were scored out of a possible ten points with each question equally weighted and a score of 1 allocated when the answer was either 'yes' or 'not applicable'. This scoring system was used to provide an indication of the strength of quality across the included papers. For indicative purposes in this review, a quality rating based on the number of CASP questions answered were as follows: 0-5 poor quality, 6-8 moderate quality, 9 and over good quality (Table 6).

The selection of the most appropriate tool for appraising qualitative research is under much debate (Miller, 2010; Noyes et al., 2008; Reid et al., 2009). In a systematic exploring the content of critical appraisal tools for both quantitative and qualitative research, Katrak and colleagues (2004) concluded that the selection of an appraisal tool should depend on the needs of the research, arguing a 'one size fits all' approach does not exist (Katrak et al.,

2004). According to Barbour and Barbour (2003) an appraisal tool's trustworthiness is something that changes over time and that knowledge is dependent on paradigm influence (Barbour and Barbour, 2003). Additionally, Dixon-Woods and colleagues (2004) state that the search for a universal 'gold standard' appraisal tool is impractical and would not support the diverse nature of qualitative methods, thus one method may not necessarily be suitable when evaluating another (Dixon-Woods et al., 2004). Consequently, much thought and consideration are necessary when selecting the most suitable method to fit the purpose of the research.

There are a number of different tools that can be used to appraise qualitative evidence; some of which include the QARI Critical Appraisal Instrument (Joanna Briggs Institute, 2007), the Quality in Qualitative Evaluation (QQE) report and tool (Spencer et al., 2003) and the Critical Appraisal Program (CASP) tool (Public Health Resource Unit, 2006). The QARI Critical Appraisal tool contains 10 items where reviewers must respond with either a yes, no, or unclear answer. Each statement is concerned with congruity, for example, the congruity between the stated philosophical perspective and the research methodology, the congruity between the research methodology and the research aims, methods of data collection, data analysis etc. Unlike the CASP and QARI, the responses to the questions can be scored to determine whether or not the study will be included in the review. In a study measuring the extent to which different qualitative quality appraisal tools assessed the validity of qualitative research, the results found the QARI instrument to be the most sensitive to validity, and the Critical Appraisal Program (CASP) tool to be the least (Hannes et al., 2010).

The QQE is a 7-page report followed by an 18-item quality appraisal tool. The report provides information on the framework of the tool and the appraisal questions. Of the 18 questions included in the QQE; five are concerned with the research findings, two are concerned with the sample, one concerns the study design, another question relates to data collection, four relate to data analysis, two items concern the reporting of results, and the final three questions take into account reflexivity, ethics and audibility. Following the completion of the 18 questions, there is a section for reviewers to add comments. Despite drawing on 29 existing frameworks in the area of qualitative research, the QQE has the potential to be unwieldy and unnecessarily complex (Dixon-Woods et al., 2004).

Similar to the QARI, the CASP tool also includes 10 questions, which are used to assess the rigour, credibility and relevance of the research, where the first two questions serve

as screening questions and invite a yes or no response. These two screening questions are concerned with the aims and appropriateness of the research and allow the researcher to decide whether or not to answer the remaining eight questions. Anchors are provided with each item to assist the researcher in answering the questions accurately. These anchors are particularly helpful for inexperienced reviewers as they assist in minimizing ambiguity surrounding the questions, allowing for a similar representation of the questions between reviewers (Newton et al., 2012).

Although previous research has found the CASP tool to be the least sensitive to validity and the QARI the most sensitive to validity (Hannes et al., 2010), for the purpose of this review we decided to use the CASP tool to appraise the quality of the included studies. Before the decision was made to use CASP, two reviewers (BA, AS) put all three qualitative appraisal tools discussed above (QARI, QQE and CASP) into practice. The reviewers felt that the QQE was too cumbersome and complex which made the quality appraisal process difficult and dawn out. The reviewers felt that the CASP tool offered some middle ground and offered a coherent framework for appraising the literature. Unlike the CASP tool, the QARI offers no guidance on answering each of its statements. As stated by Hannes and colleagues (2010) CASP is easily accessible and clearly describes what is meant by each individual criterion. Consequently, the CASP tool was deemed the most appropriate method of quality appraisal for this review.

Data extraction

In order to avoid misinterpretation, results of the included studies were extracted verbatim and direct quotes were excluded, and the authors' findings were regarding as the primary data in the review (Major and Savin-Baden, 2012). Data was extracted into Microsoft Excel spreadsheets in order to provide a clear visual representation of the data. The data was extracted by the PhD candidate and was checked by the PhD supervisory team.

Data synthesis

Review of participant views was conducted using the Framework approach (Richie and Spencer, 1994). The Framework method of qualitative analysis is a systematic, five-stage matrix that allowed the option for both theme-based and case-based analysis (Dixon-Woods, 2011). Framework analysis is an established method of qualitative analysis that has been used since the 1980s (Ritchie and Lewis, 2003) and its use has become increasingly prevalent in the field of medical and health research (Gale et al., 2013). This method of analysis was

chosen as it is valued for its transparency and clarity, and its suitability to policy and applied research (Ward et al., 2013). The Framework analysis was applied using Microsoft Excel spreadsheets, which providing a clear visual matrix structure that facilitated the generation of themes by making comparisons within and between cases (Gale et al., 2003).

The first stage of the analysis involved familiarisation of the data from the results sections of each of the included studies. The second stage involved constructing a thematic framework where key themes, categories, and issues/discussion points from results of the studies identified where used to form a coding structure (Richie and Lewis, 2003). The purpose of this stage was to produce a detailed index of the data to categorise the data into manageable chunks of information which could later be retrieved and explored during the later stages of analysis (Pope, Zieband and Mays, 2000). As stated by Gale and colleagues, the framework approach holds no allegiance to either inductive or deductive thematic analysis and may sit on a continuum between bottom-up or top-down interpretation depending on the type of research question (Gale et al., 2013). Consequently, both a mix of deductive and inductive approached were implemented to generate the framework. Firstly, as the purpose of the systematic review was to explore barriers and facilitators of role substitution, the data was approached with a priori structure based on the research question and on previous existing knowledge of role substitution through the candidates' awareness of the topic (some of which included literature presented in the introduction chapter of this thesis). This deductive process allowed the PhD candidate to approach the data with some pre-selected themes (e.g., access, workload, continuity of care) in order to generate the index (Gale et al., 2013). The PhD candidate also used an inductive approach which allowed for the discovery of unexpected themes to emerge from the data in order to generate additional index categories (Gale et al., 2013).

The third stage involved applying the index to the results of the included studies by annotating (or tagging) the data with the numerical codes from the index. The fourth stage of analysis was charting, which involved synthesising the data and thematic framework to form charts (Ritchie and Lewis, 2003). The final stage of the Framework analysis was the interpretation stage which involved deep exploration of the charts in order to generate concepts, unearth phenomena and identify links between themes (Pope et al., 2000).

Conceptual and theoretical framework

Following the primary analysis, the systematic review findings were considered in relation to Maxwell's six dimensions used to judge quality in health care (Maxwell, 1992). The contribution of non-medical medical professions and AHPs in primary care was explored through the dimensions of effectiveness (including safety), acceptability, efficiency (including costs), access, equity and relevance. Moreover, an awareness of theories concerning role substitution and potential contests between professional groups (described in Abbott' theory of a dynamic system of health professions) were also considered in relation to the findings of this systematic review (Abbott, 1988). The systematic review findings relating to the dimensions of quality of care assessment and theories of role substitution are presented as topic points in the discussion section of this chapter and are then re-considered in the final discussion chapter of this thesis.

Results

After the removal of duplicates, the search identified 10,261 studies (Figure 3). Most of these were excluded because they were concerned with nurses substituting for GPs, did not discuss role substitution within the findings, were not conducted in a primary care setting, or did not report qualitative findings. Eleven studies were included in the review; four studies discussed pharmacists substituting for GPs (Gidman, Ward and McGregor, 2012; Hatah et al., 2013; Lamberts, Bouvy and van Hulten, 2010; Stewart et al., 2009), six studies discussed physician associates substituting for GPs (Drennan et al., 2011: Drennan et al., 2017; Halter et al., 2017; Jackson, Marshall and Schofield, 2017; Taylor et al., 2013; van der Biezen et al., 2017), and one paper discussed physiotherapists within primary care (Dufour, Brown and Lucy, 2014). Despite being sought for inclusion, the systematic review did not identify evidence for the following groups of AHPs: OTs, paramedics, practitioner psychologists, podiatrists, dieticians, social prescribers or approved mental health professionals.

Quality assessment of the included studies are detailed in Table 6 and the study characteristics are given in Table 7. Across the eleven studies, a range of views and experiences were presented from the following types of participants: patients, doctors, nurses, pharmacists, PAs, receptionists, senior members of national medical and nursing organisations, managers and specialists (Table 7). In terms of the study designs employed across the eleven studies, all studies either conducted interviews or focus groups, with one study employing a combination of both (Table 7). One study also conducted document and text analysis (in addition to semi-structured interviews) and another study used a qualitative

case study approach using questionnaires and video recordings in addition to interviews (Table 7). All eleven studies were found to be of good or moderately good quality (Table 6). However, item 6 of the CASP tool which considers researcher reflexivity was poorly reported across the studies, with only three studies out of the 11 included studies that adequately reported on the relationship between researcher and participants.

The qualitative studies were set in five different countries: four in England (Drennan et al. 2011; Drennan et al., 2017; Halter et al., 2017; Jackson et al., 2017); two in Scotland (Gidman et al., 2012; Stewart et al., 2009); two in Canada (Dufour et al., 2014; Taylor et al., 2013); two in the Netherlands (Lamberts et al., 2010; van der Biezen et al. 2017); and one in New Zealand (Hatah et al., 2013).

Table 6: Quality appraisal of qualitative studies of role substitution in primary care

CASP question:	Drennan et al. 2011	Drennan et al. 2017	Dufour et al. 2014	Gidman et al. 2012	Halter et al. 2017	Hatah et al. 2013	Jackson et al. 2017	Lamberts et al. 2010	Stewart et al. 2009	Taylor et al. 2013	van der Biezen et al. 2017
1. Was there a clear statement of the aims of the research?	√	√	√	√	√	√	√	√	√	√	√
2. Is a qualitative methodology appropriate?	√	√	√	✓	√	√	√	√	√	√	√
3. Was the research design appropriate to address the aims of the research?	√	√	√	√	√	√	√	√	√	√	√
4. Was the recruitment strategy appropriate to the aims of the research?	√	√	√	√	√	√	√	✓	√	√	√
5. Was the data collected in a way that addressed the research issue?	√	√	√	√	✓	√	√	√	√	√	√
6. Has the relationship between researcher and participants been adequately considered?	x	x	√	x	x	√	√	x	x	x	-
7. Have ethical issues been taken into consideration?	√	√	√	√	√	√	√	×	√	√	√

8. Was the data analysis sufficiently rigorous?	√	√	√	√	-	√	√	√	√	√	√
9. Is there a clear statement of findings?	√	✓	√	√	√						
10. How valuable is the research?	√	√	✓	√							
Quality assessment score out of a possible 10 (including questions answered n/a)	9	9	10	9	8	10	10	8	9	9	9

Note: \checkmark = yes; \times = no; - = can't tell, N/A = not applicable.

Quality rating based on the number of CASP questions answered: 0-5 = poor quality, 6-8 = moderate quality, 9+ = good quality

Figure 3: Identification and screening of relevant studies.

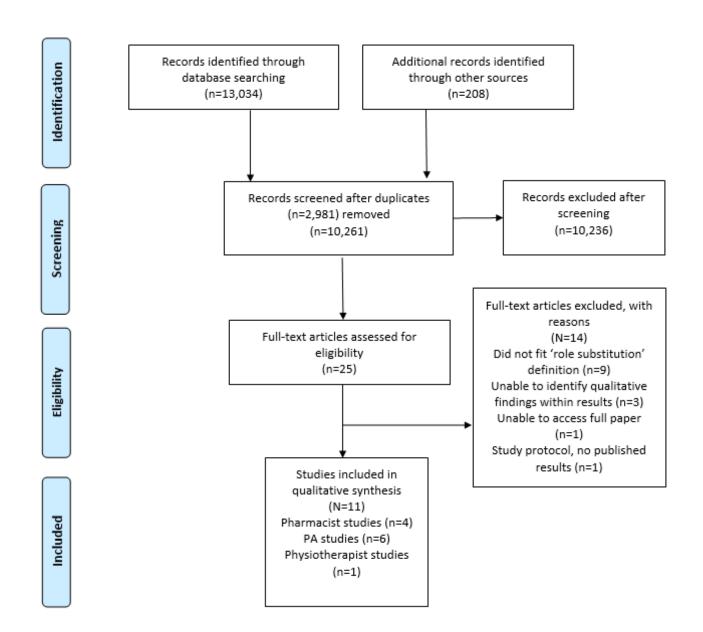


Table 7: Characteristics of included studies (n=11)

Author and year of publication	Country of origin	Type of non-medical health professional or AHP substituting	Study aims	Setting and participants	Study methods
Drennan et al. 2011	England	Physician associates	To understand the motivation of GPs and practice managers to employ physician assistants and the factors that sustained their employment.	15 general practices; 16 participants (GPs=13, practice managers=3).	Semi-structured interviews
Drennan et al. 2017	England	Physician associates	To explore perceived effects on professional boundaries and relationships of introducing physician associates in primary care.	Macro and meso level data - policy documents, interviews with civil servants, senior members of national medical and nursing organisations and regional level NHS managers (n=25). Micro level data - interviews with GPs, nurse practitioners, nurses, PAs and receptionists (n=30) working in 11 general practices, and observations of clinical and professional meetings.	Semi-structures interviews and document and text analysis
Dufour et al. 2014	Canada	Physiotherapists	To explore the perspectives of GPs and nurse practitioners regarding the integration of physiotherapists within primary care.	Number of general practices not stated in paper; 20 participants (GPs=11, nurse practitioners=9)	Semi-structured in-depth interviews
Gidman et al. 2012	Scotland	Community pharmacists	To explore the trust of members of the public regarding services provided by the	26 participants (members of the public=26)	Five focus groups

			pharmacists compared to those provided by the GP.		
Halter et al. 2017	England	Physician associates	To explore patients' views about consulting with physician associates in primary care.	Six general practices; 30 participants (patients=30)	Semi-structured interviews
Hatah et al. 2013	New Zealand	Pharmacists	The views of GPs regarding the current and potential contributions pharmacists make to medication reviews	18 participants (GPs=18) from two localities in New Zealand	Semi-structured interviews
Jackson et al. 2017	England	Physician associates	To explore the barriers and facilitators to the integration of physician associates in primary care	Number of general practices not stated in paper; 51 participants (GPs=30, ANPs=11, Patients=10).	Eight focus groups
Lamberts et al. 2010	The Netherlands	Community pharmacists	To explore patients views about the opportunities for pharmacists regarding the provision of information for patients with type 2 diabetes mellitus.	Six community pharmacies in central part of the Netherlands; 42 participants (patients with type 2 diabetes=42)	42 Semi-structured telephone interviews and two focus groups
Stewart et al. 2009	Scotland	Pharmacists	To explore pharmacist, GP and patient views on pharmacist prescribing.	Primary and secondary care settings in six NHS Health Board areas in Scotland; 35 participants (pharmacist prescribers=9, GPs=8, patients=18)	Qualitative case study approach including interviews, video recordings and questionnaires
Taylor et al. 2013	Canada	Physician associates	To explore the views of physician assistant employers regarding the benefits and barriers of hiring a physician assistant.	Number of general practices not stated in paper; 14 physicians (family physicians=7, other specialists=7).	Semi-structured interviews
van der Biezen et al. 2017	The Netherlands	Physicians associates	To uncover the factors influencing the decision	39 participants (GP out of hours managers=7, GPs	Face-to-face and telephone interviews

of GPs and managers to	who owned a general
train and employ	practice=32)
physician assistants in	
primary care.	

Findings of included studies

Four major themes were identified from the eleven studies: relationships with the non-medical health professional or AHP; the role of the non-medical health professionals or AHP; factors relating to the patient; and factors relating to the healthcare system, general practice and general practice team. Sub-themes within each major theme differed between the pharmacist, physician associate and physiotherapist papers.

Pharmacists

The systematic review identified four studies exploring the contribution of pharmacists to general medical services (Gidman et al., 2012; Hatah et al., 2013; Lamberts et al., 2010; Stewart et al., 2009). Of these, three studies investigated the role of community pharmacists (Gidman et al., 2012; Hatah et al., 2013; Lamberts et al., 2010). One study explored views regarding both community pharmacists and the roles of pharmacists who are employed in general practices (Stewart et al., 2009).

Relationship with the community pharmacist

In one paper, patients reported higher levels of trust in GPs compared with community pharmacists and some patients felt that trusting the community pharmacist could be a threat to their health (Gidman et al., 2012). In two of the studies, patients expressed that they did trust community pharmacist interventions (Lamberts et al., 2010) and also pharmacists working in general practices (Stewart et al., 2009). Some patients reported that they did not feel the need for personal contact with the community pharmacist (Lamberts et al., 2010). GPs stated that they were more likely to accept community pharmacist services if they trusted the pharmacist and if they knew them well or had already developed good working relationships with the pharmacist (Hatah et al., 2013). Patients' trust in the community pharmacist is undermined by a lack of familiarity with the pharmacist, and relationships were described as less consistent and more distant compared with relationships with the GP (Gidman et al., 2012). Patients stated that it was difficult to develop strong relationships with the community pharmacist due to shortages and changes in personnel and they felt that it was important for the community pharmacist to invest time in building relationships with patients (Lamberts et al., 2010).

Both GPs and patients felt that the GP knows their medical conditions and history well (Gidman et al., 2012; Hatah et al., 2013). In contrast, patients expressed concerns about pharmacists' lack of knowledge about their medical history and clinical conditions (Hatah et

al., 2013). This in turn was associated with patients feeling less likely to be able to discuss sensitive and confidential issues with the pharmacist (Gidman et al., 2012). The community pharmacy setting was also deemed as a barrier to discussing sensitive topics (Gidman et al., 2012; Hatah et al., 2012). Patients said that they felt like they were able to have open and honest discussions with the GP (Gidman et al., 2012). Nevertheless, GPs expressed that patients may not feel confident discussing their medications with a GP, as they may not be happy with the prescribed treatment (Hatah et al., 2013). Despite GPs' concern that community pharmacist prescribing may contest with GPs' own work they did not deem it as too much of an issue due to the current GP shortage crisis (Hatah et al., 2013). GPs were seen to be at the top of the pecking order by patients who would 'tell pharmacists what to do' (Gidman et al., 2012). More cooperation between GPs, nurse practitioners and community pharmacists were considered important to patients (Lamberts et al., 2010).

Role of the pharmacist

Community pharmacists were viewed by patients to provide 'low risk' care such as treating patients with minor illnesses and providing advice on smoking cessation (Gidman et al., 2012). Patients lacked full awareness of the community pharmacist role and primarily viewed them as suppliers of medicine (Gidman et al., 2012; Lamberts et al., 2010). Patients associated seeing the GP for more serious, higher risk conditions and those with long-term medical conditions preferred to see GPs in every instance (Gidman et al., 2012). Patients preferred to receive medication information by the GP but accepted that GPs lacked time, and also noted that the GP does not deliver all patient information needs (Lamberts et al., 2010).

Training and expertise were emerging themes in all of the included pharmacist studies (Gidman et al., 2012; Hatah et al., 2013; Lamberts et al., 2010; Stewart et al., 2009). Pharmacists' knowledge and expertise in pharmacotherapy, dosage forms, drug interactions and adverse drug reactions were noted by GPs (Hatah et al., 2013; Lamberts et al., 2010; Stewart et al., 2009). However, some patients were uncertain about pharmacists' level of education (Gidman et al., 2012) while others, despite feeling apprehensive, accepted that pharmacists were trained professionals (Stewart et al., 2009). In contrast, patients were confident in GPs level of training and education and believed that GPs are not capable of making errors (Gidman et al., 2012). Furthermore, GPs perceived their own strengths to be their superior skills and training in diagnosing and treating patients (Hatah et al., 2013).

Views regarding pharmacists' competency and knowledge in completing medication reviews and independent prescribing were mixed. Some GPs were concerned that community pharmacists who work in general practice may have a lack of appropriate skills and training to prescribe and review medications clinically, and expressed worry that they were not trained in diagnosis and treatment (Hatah et al., 2013), which could in turn threaten patient safety (Hatah et al., 2013).

Some patients' unfavourable experiences with pharmacists' advice on over the counter medications raised GPs' doubts about pharmacists' clinical skills (GP views of community pharmacists, New Zealand) (Hatah et al., 2013).

Apprehensions about prescribing outside their areas of competence were reiterated by community pharmacists and pharmacists who were employed in general practices (Stewart et al., 2009). Despite this, pharmacists expressed enthusiasm to take on independent prescriber after further training and felt that GPs would support them in their decision to undertake independent prescribing (Stewart et al., 2009). Prescribing by pharmacists was deemed as acceptable to GPs, so long as it was completed under agreed protocols and under close supervision, preferably within the GP practice to prevent miscommunication and fragmented care (Hatah et al., 2013). GPs believed that medication reviews performed by the community pharmacist may reduce prescribing errors and provide support of correct prescribing, and their ability to obtain detailed information on medications from patients was noted (Hatah et al., 2013). Patients also expressed strengths of consulting with a pharmacist prescriber (both community pharmacists and pharmacists employed in general practices) and valued the degree and quality of discussions regarding their medications with the pharmacist (Stewart et al., 2009). On the other hand, some GPs voiced concerns regarding the current and potential contributions of pharmacist medication reviews in general practices as outlined in the following quote:

Some GPs thought that pharmacists' contributions to medication reviews might be a threat to patient care, as the advice provided could conflict with that given by the GP (e.g. about a clinically irrelevant drug interaction) and hence might confuse patients and harm GP-patient relationships (GPs, New Zealand) (Hatah et al., 2013).

Factors relating to the patient

Conflicting information received from GPs and pharmacists was a concern; consequently, multi-disciplinary cooperation between healthcare professionals was viewed as key to improving quality of care (Hatah et al., 2013; Lamberts et al., 2010). In order to ensure continuity of care, GPs stated that pharmacist prescribing should take place within the practice in order to avoid fragmented care and to ensure that the GP could discuss other health concerns with their patients (Hatah et al., 2013). Facilitators to community pharmacist services included convenience, quick access and availability to medications (Gidman et al., 2012; Lamberts et al., 2010). Difficulty in accessing GP appointments were voiced among patients (Gidman et al., 2012). Pharmacists believed that they could provide good patient services, quicker access to healthcare and longer consultations (Stewart et al., 2009). Additional benefits to community pharmacist services included uncharged minor illness services for children (Gidman et al., 2012), increased information needs and medication adherence (Hatah et al., 2013; Lamberts et al., 2010) and improved patient care (Stewart et al., 2009). Moreover, it emerged that GPs do not fulfil all information needs; therefore, opening up opportunities for pharmacists (Lamberts et al., 2010).

The confrontation matrix shows a clear opportunity for pharmacists as patients feel a need for information about medicines and like to discuss drug-related issues, such as adherence (GPs, The Netherlands) (Lamberts et al., 2010).

Following the consultation [with a pharmacist] they reflected positively on the treatment they had received (Patients, Scotland) (Stewart et al., 2009).

Benefits were reiterated by doctors who praised the improvement in patients care (GPs, Scotland) (Stewart et al., 2009).

Furthermore, patients thought GPs provided a safer and a more complete package of care compared to community pharmacists (Gidman et al., 2012). Some patients were also unsure of community pharmacists' motives, were unsure as to what to expect when consulting with a pharmacist prescriber and were worried that health screening completed by the community pharmacist would not lead to results being recorded or treatment being prescribed (Gidman et al., 2012; Stewart et al., 2009). Moreover, GPs expressed concerns regarding patient safety due to pharmacists' lack of appropriate skills and training (Hatah et al., 2013). Conversely, in the same study some GPs felt that pharmacists' superior knowledge of medicines could be valuable to ensuring patient safety (Hatah et al., 2013).

The community pharmacy setting was an emerging theme across all the studies (Gidman et al., 2012; Hatah et al., 2013; Lamberts et al., 2010; Stewart et al., 2009). Some patients reported that the community pharmacy setting was often busy resulting in long waiting times and felt unclear and confused about the activities that were taking place in the background (Stewart et al., 2009). Both patients and GPs described the community pharmacy setting as being unsuitable for confidential consultations and discussions due to a lack of privacy (Gidman et al., 2012; Hatah et al., 2013). Some patients were unwilling to use the community pharmacy consultation rooms as they are often associated with consultations for substance abusers (Gidman et al., 2012).

Interestingly, patients and GPs expressed concerns about the commercial aspects of community pharmacist services and were unsure if community pharmacists place financial incentives above patient care (Gidman et al., 2012; Hatah et al., 2013).

Our data suggest that participants question whether pharmacists prioritise profits or patient care and they distrust pharmacists' motives (Patients, Scotland) (Gidman et al., 2012).

GPs were also worried that those services [prescribing outside of the GP practice] could conflict with pharmacists' business interests (GPs, New Zealand) (Hatah et al., 2013).

Factors relating to the healthcare system, general practice and the general practice team

GP time constraints were voiced in two of the pharmacist studies (Hatah et al., 2013; Lamberts et al., 2010). GPs felt that their heavy workloads and limited time gave pharmacists the upper hand when conducting medication reviews (Hatah et al., 2013).

They thought it was quite difficult to talk about medication issued or do a detailed check for drug interactions during a 15-minute consultation (GPs, New Zealand) (Hatah et al., 2013).

Although patients primarily would like to receive this information from their GP and perceive the GP as the primary health care provider who decides about the drug regimen, they also realize that their GP does not have enough time to give attention to their needs (Patients, The Netherlands) (Lamberts et al., 2010).

GPs felt that in some instances, the community pharmacist prescriber could have the capacity to reduce GP and nurses' workloads (Hatah et al., 2013). Moreover, GPs felt that pharmacists, including both community pharmacists and pharmacists working in primary care could potentially free up time to allow GPs to treat acute conditions (Stewart et al., 2009). Conversely, some GPs felt that the pharmacist prescriber may in fact add to the GP workload due to the completion of additional work such as following-up on pharmacist's recommendations (Hatah et al., 2013). Pharmacists expressed benefits such as increased job satisfaction, responsibility and autonomy in response to their prescribing role and deeper sense of integration within the general practice team (Stewart et al., 2009). GPs also felt that the inclusion of the pharmacist prescriber within the healthcare team was also associated with enhanced teamwork (Stewart et al., 2009). Nevertheless, most pharmacists in this study stated that there were no formal support structures in place for pharmacists and would frequently depend on informal advice given by other members of the healthcare team (Stewart et al., 2009).

Physician associates

The systematic review identified six studies exploring physician associates (PAs) in primary care (Drennan et al., 2011; Drennan et al., 2017; Halter et al., 2017; Jackson et al., 2017; Taylor et al., 2013; van Der Biezen et al., 2017).

Relationship with the physician associate

Three studies brought up the issue of trust (or mistrust) in the PA (Drennan et al., 2011; Drennan et al., 2017; Halter et al., 2017). PAs, GPs and practice managers stated that trust in the PA was earned through competence gained over time which resulted in the expansion of their roles and types of patient care (Drennan et al., 2017). Once trust in PAs clinical competence and safety was established, GPs and PAs would agree on putting light touch supervision strategies in place (Drennan et al., 2017). GPs admitted that they were cautious of the PA role, which verged on feelings of resistance and opposition to the PA (Drennan et al., 2011). Interestingly, according to some GPs and practice managers, some GPs mistrusted the PA as they felt that they might be in competition for their own work (Drennan et al., 2011). In another study, nurses were concerned for their jobs when PAs first started working in their practices despite this, good working relationships between nurses and PA were reported thereafter (Drennan et al., 2017).

Patients had mixed feelings with respect to trusting the PA (Halter et al., 2017). On the most part, patients expressed trust and confidence in the PA role, but this trust was not established straight away and some patients were less trusting in the PA initially as they were not familiar with the PA role. Trust was built on positive consultations with the GP for example, experiences of the PA knowing when to seek assistance from the GP (Halter et al., 2017). Additionally, patients trusted the GP to employ competent members of the health care team (Halter et al., 2017). Other patients were more wary of the PA role (Halter et al., 2917). Trust and confidence in the PA seemed to rely on a mix of factors relating to the general practice, the wider healthcare system and patient-level consultation dynamics (Halter et al., 2017). Trust varied depending on the type of consultation experience they had with the PA and also prior judgments of the PA role.

Despite a high level of trust being expressed by many participants, this was not universal and was certainly not the immediate response of everyone beginning a consultation with a PA (Patients, England) (Halter et al., 2017).

There was some uncertainty among GPs, advanced nurse practitioners (ANPs) and patients about whether the PA would function in the primary care setting due to a lack of familiarity with the PA role (Jackson et al., 2017). GP familiarity with the PA role was associated with positive attitudes towards the potential contributions of the PA in general practice (Taylor et al., 2013).

Physicians who had previous experience training or practicing in the United States were already familiar with the PA role, and therefore were more enthusiastic about the potential for PAs to have a positive effect on their practices (GPs, Canada) (Taylor et al., 2013).

Role of the physician associate

In two of the studies, it was explicitly stated that PAs were employed to act as substitutes for GPs (Drennan et al., 2017; van Der Biezen et al., 2017). The issue of complexity of tasks performed by PAs was discussed in all of the studies (Drennan et al., 2011; Drennan et al., 2017; Halter et al., 2017; Jackson et al., 2017; Taylor et al., 2013; van Der Biezen et al., 2017). Patients and GPs stated that the role of the GP was to treat complex conditions (Drennan et al., 2017; Halter et al., 2017). GPs had concerns about the safety of the PA in dealing with complexity (Jackson et al., 2017); these concerns seemed to be reiterated by patients who felt the need to consult with doctors for more complex problems (Halter et al.,

2017). GPs, practice managers and out-of-hours managers believed that the introduction of PAs could potentially allow GPs more time to complete acute and complex cases (Drennan et al., 2011; Taylor et al., 2013; van Der Biezen et al., 2017).

Acceptable roles of the PA included: minor ailments/conditions (Drennan et al., 2011; Halter et al., 2017; van Der Biezen et al., 2017); minor procedures (Taylor et al., 2013); home visits (Drennan et al., 2011; van Der Biezen et al., 2017); post-operative consultations (Taylor et al., 2013; van Der Biezen et al., 2017); and administrative tasks (Taylor et al., 2013). Some GPs and managers were divided as to whether PAs should be treat patients with chronic and acute conditions, palliative care, children and the elderly (van Der Biezen et al., 2017). Patients felt that consultations with a PA were very similar to what they would expect from a GP, the only difference being that prescribing by the PA was prohibited (Halter et al., 2017). PAs roles were limited due to their lack of prescribing authority (Drennan et al., 2011; Drennan et al., 2017; Halter et al., 2017; Jackson et al., 2017).

Many of the GPs and practice managers commented that the lack of authority to prescribe potentially made the PAs less efficient and therefore more costly than nurse practitioners with prescribing authority (GPs and practice managers, England) (Drennan et al., 2017).

Comparisons between the roles of PAs and nurses were discussed in three of the studies (Drennan et al., 2011; Drennan et al., 2017; van Der Biezen et al., 2017). Benefits of the PA role in comparison to the nursing role included an ability to work within a medical model and to deal with uncertainties (Drennan et al., 2011). PAs were also believed to possess a wider range of competencies compared with nurses (Drennan et al., 2017) and were able to complete a greater volume of work (Drennan et al., 2011) whilst requiring less supervision (Drennan et al., 2011; Drennan et al., 2017).

There was a wide variation in understanding of the PA role among patients (Halter et al., 2017). Patients knowledge and understanding of the PA role ranged from being 'certain and accurate', 'certain and inaccurate' and 'uncertain' of the PA role (Halter et al., 2017).

The first group was certain they understood the role of the PA and expressed this understanding accurately in terms of it being a close relationship to doctors, but correctly realising that it was a different role, one which meant they had a recognized education but could not do everything a doctor could do (Patients, England) (Halter et al., 2017).

Patients were considered by GPs and practice managers to lack full understanding of the PA role and how they differ from a GP (Halter et al., 2011). GPs, ANPs and practice managers also expressed a lack of full understanding in exactly what the PA role was (Halter et al., 2017; Jackson et al., 2017; van Der Biezen et al., 2017), and the specific roles they were able to complete (Halter et al., 2017). This led to doubts about whether they would be able to function within the general practice (Jackson et al., 2017). Interestingly, in one study GPs admitted not fully understanding the differences between nurse practitioners (NPs) and PAs (van Der Biezen et al., 2017). Despite common uncertainties of the PA role, the findings of one study suggests that nurses and ANPs already complete the same work that the PA can offer to general practice in the UK (Drennan et al., 2017).

Other reasons found in published commentaries for opposing the introduction of PAs included a viewpoint that nurses and ANPs fulfilled this role in the UK healthcare workforce and offered greater value to patients (Published commentaries, England) (Drennan et al., 2017).

Factors relating to the patient

In one study, doubts were raised by GPs, clinical commissioning group (CCG) leaders and PA educators about whether patients would deem the new PA role as acceptable in general practice (Jackson et al., 2017). Nevertheless, in two separate studies, patients expressed acceptance towards the PA role; this acceptance was evidenced by some patients' preference to see a PA (Drennan et al., 2011; Drennan et al., 2017). Some patients felt like they did not have a choice about seeing a GP or a PA and reported instances when they did not know which type of practitioner they were consulting with (Halter et al., 2017).

There were mixed views as to whether this lack of clarity was appropriate for patients. One participant considered it to be "the right way to go about it" to avoid patients having concerns about not seeing a doctor, while others expressed puzzlement and a little disquiet about not understanding at the time they had seen a PA rather than a doctor, with a sense of having been misled (Patients, England) (Halter et al., 2017).

Continuity of care was an emerging theme in four of the included studies (Halter et al., 2017; Jackson et al., 2017; Taylor et al., 2013; van Der Biezen et al., 2017). Maintaining continuity of care was important to patients (Halter et al., 2017). GPs had reservations about how the introduction of PA into general practice may impact continuity of care, but these

concerns were not reciprocated by patients and ANPs (Jackson et al., 2017). Some GPs felt that the PA role may improve quality and continuity of care (Taylor et al., 2013; van Der Biezen et al., 2017), through tasks such as post-operative and inter-visit telephone calls (Taylor et al., 2013). Some GPs noted better continuity of care when employing a PA over a young doctor (van Der Biezen et al., 2017).

The issue of patient access to healthcare was discussed in four studies (Halter et al., 2017; Jackson et al., 2017; Taylor et al., 2013; van Der Biezen et al., 2017). GPs, ANPs and patients acknowledged the difficulty in accessing healthcare services due to high patient demand for care (Jackson et al., 2017).

Patients reflected the other side of the workforce-access equation, describing how difficult it was sometimes to get care, but showed sympathy for practitioners, explaining that they thought the system as a whole was at fault (Patients, England) (Jackson et al., 2013).

Some of the main motivators behind GPs' reasons to employ PAs were to meet patient demand and improve access (Drennan et al., 2011; Drennan et al., 2017; Taylor et al., 2013). Some GPs stated that they were able to see more patients per hour (Taylor et al., 2013) and noted a reduction in waiting times for minor ailments through the employment of PAs (van Der Biezen et al., 2017). Moreover, in two studies, GPs believed that employing PAs would result in better quality of care (Taylor et al., 2013; van Der Biezen et al., 2017).

Factors relating to the healthcare system, general practice and the general practice team

Concerns about staff shortages to meet increasing demands on primary care were raised in four studies (Drennan et al., 2011; Drennan et al., 2017; Jackson et al., van Der Biezen et al., 2017). Due to significant shortages of, and difficulties in recruiting GPs and nurses in the UK (Drennan et al., 2011; Drennan et al., 2017), the Department of Health introduced PAs into UK general practice as part of its Changing Work Force Programme, basing the role on the American model of physician assistants (Drennan et al., 2017). In Canada, some GPs reported difficulties recruiting PAs due to their geographic location and a limited number of available PAs (Taylor et al., 2013). PAs stated that they actively moved to areas left vacant as a result of staffing shortages (Drennan et al., 2017). In one study, GPs and practice managers stated that some Primary Care Trusts in the UK actively supported the recruitment of USA trained PAs (Drennan et al., 2017). Nevertheless, issues where raised with respect to the transferability of the American model of PA to the UK setting (Drennan et al., 2017).

GPs and practice managers raised concerns about the level of supervision required to support PAs (Drennan et al., 2011; Jackson et al., 2017; Taylor et al., 2013). Nevertheless, some felt that the time supervising PAs would take no longer than the time taken to supervise other members of staff (Drennan et al., 2011). Moreover, some GPs and practice managers suggested that nurse practitioners require more supervision than PAs (Drennan et al., 2017).

There was considerable variation in how the PAs were used and the type of supervision expected. Some physicians believed they had to see every patient before turning the patient visit over to the PAs (GPs, Canada) (Taylor et al., 2013).

Some GPs and nurses thought that introducing the PA might allow them time to complete more tasks that require their expertise (Drennan et al., 2011; Drennan et al., 2017; Taylor et al., 2013). On the other hand, some GPs were doubtful that hiring a PA would have any effect on their own profession or workload; however, these GPs has no previous experience of working PAs (van Der Biezen et al., 2017). These concerns were not backed-up by GPs who had hired PAs to work within their practices as they reported benefits such as improved targets for preventative measures such as blood pressure check and vaccinations, increased working flexibility and an overall reduction in working hours (Taylor et al., 2013). Some GPs also believed that their own quality of life would improve through working with a PA (Taylor et al., 2013).

Identified barriers to the inclusion of the PA within general practice teams included resistance and hostility from other health professionals (Drennan et al., 2011; Drennan et al., 2017; Jackson et al., 2017; Taylor et al., 2013) particularly from nursing staff (Drennan et al., 2011; Drennan et al., 2017). Some GPs and practice managers recounted some instances were PA referrals were refused by secondary care consultants and ambulance transport services (Drennan et al., 2017). Other concerns were that the PA role could threaten GPs' jobs (Drennan et al., 2011; Drennan et al., 2017) and undermine the GP role (Drennan et al., 2017; Jackson et al., 2017).

There were mixed views regarding the cost-effectiveness of PAs in primary care (Drennan et al., 2011; Drennan et al., 2017; Jackson et al., Taylor et al., 2013). Some GPs and practice managers thought PAs would be cheaper alternative to GPs for some of tasks performed in general practice, while others were in disagreement due to the costs associated with lower levels of productivity and more time supervising PAs (Drennan et al., 2011; Taylor et al., 2013). Another issue was that PAs lack prescribing authority, which may make

them less efficient and consequently more costly compared to nurse practitioners and pharmacists (Drennan et al., 2017). GPs also raised concerns about the cost-effectiveness of hiring PAs in comparison to other advanced clinical professionals (Jackson et al., 2017). Additionally, managers expressed the need for more evidence on the cost-effectiveness of hiring PAs instead of other advanced practice clinicians who might work as GP substitutes (Drennan et al., 2017). Nurses deemed themselves as being the best option to work as substitutes for GPs and the best use of NHS spending on professional development (Drennan et al., 2017).

They argued that nurses were the best occupational group to provide vertical substitution for doctors. They contended that NHS finance for professional development would most effectively be used in skilling up nurses as an existing workforce for whom there was evidence to support their value in general practice rather than an untried, untested new occupational group (Nurses, England) (Drennan et al., 2017).

Physiotherapists

One study explored the role of physiotherapists within primary care (Dufour et al., 2014).

Relationship with the physiotherapist

Interviewees in the study did not discuss relationships with the physiotherapist.

Role of the physiotherapist

All GPs and NPs in the study felt that physiotherapists had a lot to offer to musculoskeletal health in roles such as triage, assessment and management (Dufour et al., 2014). Interestingly, GPs and NPs believed that physiotherapists were better placed in chronic disease management and self-management compared to other health professionals who were already providing services in these areas. Both GPs and NPs stated that without a physiotherapist on their team, they did not feel that they could offer the most appropriate care to patients (Dufour et al., 2014). Moreover, GPs and NPs who have already worked with physiotherapists felt that the healthcare team would not be able to function appropriately without them (Dufour et al., 2014).

In connection with other themes, participants who worked with PTs [physiotherapists] described how they could not envision functioning properly without them, particularly

given physiotherapists' expertise in MSK health and thus assisting with this particular portion of the caseload (GPs and NPs, Canada) (Dufour et al., 2014).

Factors relating to the patient

GPs and NPs believed that having a physiotherapist on their team would lead to better use of healthcare providers, which in turn would enhance patient care (Dufour et al., 2014). Additionally, impairment due to a lack of primary prevention approaches was associated with not having a physiotherapist working within the healthcare team. GPs and NPs believed that self-management strategies delivered by the physiotherapist could significantly improve patients' quality of life (Dufour et al., 2014).

Another theme that emerged related to the potential outcomes participants felt would transpire if physiotherapists were integrated into Ontario PHC teams. Possible improved outcomes were articulated at three levels: individual, health care system, societal (GPs and NPs, Canada) (Dufour et al., 2014).

Factors relating to the healthcare system, general practice and the general practice team

The absence of physiotherapists within Canadian general practices was deemed as a major gap in health care provision.

The current lack of physiotherapists within PHC teams was articulated as a critical gap in current care provision. In fact, participants described experiencing this perceived gap on a daily basis (GPs and NPs, Canada) (Dufour et al., 2014).

GPs and NPs believed that having a physiotherapist on their team would result in better use of other healthcare professionals and would allow them to focus on areas that require their expertise (Dufour et al., 2014). In turn, this would allow them to take on more patients and would lead to improved efficiency within the healthcare system (Dufour et al., 2014). Moreover, GPs and NPs felt that the integration of physiotherapists within the team could reduce the number of unwarranted diagnostic test and inappropriate referrals (Dufour et al., 2014). This notion was supported by other GPs and NPs who had already worked with a physiotherapist in the past, who described less follow-up appointments with complicated patients after the physiotherapist was managing their care (Dufour et al., 2014).

Discussion

Summary of main findings

Four descriptive themes were identified: relationships with the non-medical health professionals or AHP; role of the non-medical health professionals or AHP; factors relating to the patient; and factors relating to the healthcare system, general practice and general practice team. the integration of pharmacists and PAs within general practice teams.

A number of barriers and facilitators emerged from the included qualitative studies. Pharmacists' superior knowledge and expertise in pharmacotherapy was a facilitator that was acknowledged among participants, but views regarding their knowledge and competency to carry out medication reviews and independent prescribing were mixed. Another facilitator with regards to the contribution of pharmacists within primary care was GPs acceptance of pharmacist prescribing. In terms of their prescribing role, pharmacists revealed further selfreported facilitators including increased autonomy, responsibility and job satisfaction. Moreover, the qualitative findings suggested that there are clear opportunities for pharmacists in primary care, as GPs do not fulfil all information needs. Doctors and managers in some studies felt that pharmacists could potentially reduce workload and free-up GPs time to complete tasks within their areas of expertise such as treating acute conditions, but concerns were raised regarding levels of supervision. Some of the identified barriers that emerged from the qualitative evidence synthesis, were concerns about pharmacists' lower levels of knowledge about patients' medical history and their lack of training in diagnosis and treatment. In addition, another barrier that emerged was the possibility that patients may receive conflicting information from pharmacists and GPs. Barriers were also raised with respect to the community pharmacist role. Some patients lacked trust in the community pharmacist role which was undermined by a lack of familiarity with the role. Moreover, in one study a lack of trust in pharmacists working in general practices was reported by some patients.

Additional findings revealed that patients preferred to consult with a doctor for more serious, complex conditions and are happy to consult with a pharmacist or physician associate for 'low risk' problems such as minor ailments. This opinion was mirrored by doctors who felt that complex cases should be reserved for GPs. Additionally, factors such as trust, continuity of care and patient access were important when considering on medications.

A number of barriers and facilitators were identified regarding the role of PAs. The main facilitators identified were that PAs can work within the medical model and have the ability to deal with uncertainty. They may also require less supervision and be able to complete a greater volume of work compared with nurses. It was also noted that PAs may help to meet patient demand, improve access to services and free up GP time. Physician associates were employed in general practices to provide vertical substitution to GPs in response to the increasing demands placed on general practice and staff shortages. GP and PA consultations were viewed to be similar by some patients, but the PAs lack of prescribing authority was a notable difference. A notable barrier was that there were variations and uncertainties regarding the PA role, which was associated with unfamiliarity with the PA. Further barriers included resistance towards the PA role from GPs and NPs and concerns that the PA may be a threat to the work of GPs and NPs. There were mixed reviews regarding the cost-effectiveness of PAs working in primary care.

Only one physiotherapist study was identified in this systematic review and no barriers were identified from the paper; however, this study only explored the views of GPs and nurses and did not consider patient perspectives. The main facilitators identified were that physiotherapists have a major role to play in musculoskeletal health and were considered an integral part of the general practice team. Moreover, further facilitators were that physiotherapists can deal with a large proportion of the general practice workload and their integration within teams may result in better use of other practitioners.

Findings in relation to the conceptual framework of the thesis and theories of role substitution

This thesis used an evaluative framework with dimensions proposed by Maxwell for judging quality of healthcare and has been applied in this thesis to role substitution in primary care. The six dimensions of quality are effectiveness (including safety), acceptability, efficiency (including costs), access, equity and relevance (Maxwell, 1992). This systematic review presented findings in relation to the following dimensions: acceptability, access and costs. Moreover, some views and perspectives were voiced regarding issues relating to perceived relevance, equity and safety of role substitution. Discussion of how the findings of this chapter can be considered in relation to each of these domains is presented in Chapter 7 of this thesis.

The findings of this systematic review were also framed by an awareness of theories concerning role substitution and the potential conflict between groups of professions. The findings of this systematic review can be explained and considered in relation to the following topics and are discussed in detail in the final discussion chapter of this thesis (Chapter 7):

- The acceptability of expanding roles of non-medical health professionals and AHPs to provide vertical substitution to GPs.
- Complementary, supplementary and enhanced roles through the use of non-medical and AHP consultations
- The PA as an innovation in practice
- Contested professional role boundaries
- Defending roles
- Hierarchies and status within practice teams
- Horizontal substitution and role conflict resistance and hostility

Strengths and weaknesses

This review undertook extensive literature searches using a well-developed search strategy and robust methodology, and adhered to the PRISMA guidelines (Moher et al., 2009). There were no restrictions on date of publication, or country of origin for the included studies.

A range of views and experiences were presented from patients, doctors, nurses, pharmacists, CCG leaders, managers and PA educators on the topic of role substitution in primary care. The review only identified one study about physiotherapy, which presented positive views and opinions relating to the integration of physiotherapists into primary care in Canada. This paper did not identify any barriers to the integration of physiotherapists into primary care. The review failed to identify qualitative evidence on barriers and facilitators for other groups of AHPs providing general medical services instead of GPs, such as OTs and advanced scope paramedics.

This systematic review is limited by the low number of qualitative studies for each type of health care professional; the review uncovered six PA papers, four pharmacist papers, and only one physiotherapist paper. One study looked at PAs and NPs in primary care (Lamberts et al., 2010), hence it was difficult to tease out the findings relating to just the PAs.

Likewise, a separate study explored the perspectives of pharmacist prescribers across both primary care, secondary care and community pharmacy settings (Stewart et al., 2009). This made it difficult to extract the findings just relating to primary care, and it was also difficult to distinguish between findings relating to community pharmacists and pharmacists working in general practices. Most of the perspectives across the eleven included studies in this review were from patients and staff; there were fewer views from CCG leaders and managers.

In general, this research is limited by the limited evidence-base from which to draw on to help inform policy and practice. More research from the UK NHS, and policy that addresses role substitution is needed.

Comparison with previous literature

Previous reviews have provided qualitative evidence in relation to nurses substituting for GPs in primary care settings (Rashid, 2010; Creedon et al., 2015; Karimi-Shahanjarini et al., 2019). In reviews conducted by Rashid (2010) and Karimi-Shahanjarini and colleagues (2019), an increase in workload was identified as a driving factor for the implementation of doctor-nurse substitution. Similarly, an increasing workload due to rising demands for general practice was also highlighted in our review as a motivating factor for the use of pharmacists and PAs to complete roles previously undertaken by the general practitioner. Moreover, both of the previous systematic reviews found that patients were happy to consult with a nurse for simple reasons, but preferred seeing a GP if they felt it was essential. Our finding also show that patients prefer to consult with a GP for more complex cases but accepted pharmacists or PAs to provide consultations for 'low risk' conditions.

In 2015, Creedon and colleagues conducted a systematic review to assess the impact of nurse prescribing on the clinical setting. Comparable to our review, key emerging themes included factors relating to the patient, factors relating to the organisation and factors relating to the health professional.

Implications for research and practice

There is a significant evidence gap for the acceptance of other groups of AHPs. Although this systematic review sought to uncover evidence on other groups of AHPs, the search did not

identify evidence for OTs, paramedics, practitioner psychologists, podiatrists, dieticians, social prescribers or approved mental health professionals. Research on the barriers and facilitators of these other AHP groups who may be working as GP substitutes in primary care should be considered. Little is known about the full impact of pharmacists working in primary care on factors such as GP workload and whether these practitioners' effectiveness is equivalent to GPs. This review uncovered qualitative evidence in relation to the comparison between PAs and NPs, future research should progress on this and should assess the evidence comparing the effectiveness and also the cost-effectiveness of PAs compared with different types of nurses such as NPs and ANPs.

Clear information needs to be communicated to patients to ensure that they are fully aware of the roles and tasks that can be delivered by non-medical health professionals and AHPs instead of GPs. Suitable supervision strategies are needed for non-medical health professionals and AHPs taking on new roles in primary care. In addition to clear communication about the different roles available in primary care, good care navigation is essential to the successful implementation of role substitution. Future research should therefore explore perspectives regarding the developing role of care navigators responsible for signposting patients to the appropriate practitioner based on their reason for consultation. The evidence gaps highlighted in this systematic review of qualitative studies helped to inform the topic guides used in the qualitative interviews (Chapter 6 of this thesis).

Conclusion

There were a number of barriers and facilitators to pharmacists and PAs providing general medical services instead of GPs. Four descriptive themes were identified: relationships with the non-medical health professional and AHP; role of the non-medical health professional and AHP; factors relating to the patient; and factors relating to the healthcare system, general practice and general practice team. The integration of physiotherapists within general practice teams were accepted among GPs and NPs; nevertheless, this notion was only supported in one study. Chapters 2 and 3 of this thesis assessed the current evidence-base of role substitution in primary care. Findings from the reviews indicated that role substitution is being implemented in general practices in the UK and in other parts of the world; however, consideration of how role substitution was being used as a strategy to compensate for workforce pressures in general practice at a national level was needed. The following Chapter

set out to explore the extent to which role substitution was being implemented locally in general practices in Wales as self-reported by primary care cluster leads.

CHAPTER 4: THE CURRENT USE OF ROLE SUBSTITUTION IN GENERAL PRACTICES ACROSS WALES: AN ONLINE SURVEY

Introduction

As explained in Chapter 1 of this thesis, non-medical health professionals and AHPs are being employed in general practice to compensate for the increasing demands placed on practices in tandem with workforce shortages. Due to the significant pressures placed on primary care, it is likely that role substitution is taking place in most, if not all, general practices across Wales.

Background literature presented in Chapter 1 and the findings from the systematic reviews presented in Chapters 2 and 3 uncovered evidence of role substitution being used in general practice in the UK and in other parts of the world, but it is not known how practices are increasing their use of role substitution in Wales, UK. A previous survey conducted between 2016 and 2018 revealed that most GPs in Wales stated that they have access to a wide range of healthcare professionals (RCGP, 2018). However, this survey did not uncover the extent to which role substitution is happening in Wales. Routinely collected data from NHS digital and the Wales National Workforce and Reporting System (WNWRS) provides statistics on the general practice workforce in England and Wales, respectively. Chapter 1 of this thesis presents data from these sources on the changes in general practice staff in England and Wales over time. In Wales, between 2013 and 2018, the number of GPs (headcount figures) decreased from 2,026 to 1,964 (Welsh Government, 2022). Over the same period, the total number of nurses has increased from 1,296 to 1,408, and the number of direct patient care staff increased from 885 to 1,038 (Welsh Government, 2022). Direct patient care staff are defined as 'anyone who is directly involved in delivering patient care but who is not a nurse or GP (Statistics for Wales, 2019). This includes health care assistants (HCAs), physiotherapists, pharmacists, phlebotomists, chiropodists, dispensers, counsellors, and complementary therapists (Statistics for Wales, 2019, p.20). The routinely collected data collected for Wales does not provide any publicly available data for the year 2019. Moreover, a breakdown of the different types of direct patient care staff was not available until 2020.

Despite the availability of routinely collected data on general practice staff statistics in Wales, information on how clusters were using role substitution in general practices in Wales, including any future plans or strategies to increase role substitution was not known. Data collection for the survey presented in this chapter took place between November 2018

and January 2019 and therefore provides information for a very small window in 2019 where data on general practice teams staff statistics was not available from national sources. As mentioned above, a breakdown of the different types of direct patient care staff was not available until 2020. Although it is acknowledged that the present survey does not directly measure the number of staff employed in general practices in Wales, it does however provide some further insight at cluster level of the different types of direct patient care roles that were being employed during the time of this survey.

Primary care clusters were first introduced in Wales in 2010. There are 64 clusters across the seven Local Health Boards, each serving patient populations of between 30,000 and 50,000 (NHS Wales, 2019) and each health board is responsible for the delegation of funding to their clusters (Auditor General for Wales, 2018). There is variation in the number of general practices in Wales reported on in different sources, which may be due to continuous changes to general practice such as practice mergers. Welsh Government statistics reported that the number of general practices in Wales reduced from 416 in 2018, to 407 general practices in 2019; however, these statistics did not account for branch practices (Statistics for Wales, 2019). In 2019, Public Health Wales published a report with details on the breakdown of clusters and the number of general practices within each cluster.

Nevertheless, this document only provided a list of 61 clusters across Wales and cited 420 active general practices across these clusters (Public Health Wales, 2019). There is wide variation in the number of general practices across clusters; the highest number of practices within a cluster in 2019 was 13 practices, and the lowest number in a cluster was 3 practices (Table 8). The median number of general practices across clusters in 2019 was 7 (Table 8).

The aim of this current survey was to assess the current use of role substitution within general practices in Wales at cluster level.

This chapter addresses the following research question:

3. To what extent is role substitution being implemented locally in general practices across Wales?

The specific objectives were:

• To determine whether there was a perceived workforce crisis in primary care among cluster leads in Wales.

- To identify the general attitudes of cluster leads with regard to the use of role substitution in primary care, and to assess whether cluster leads had a strategy for increasing role substitution within their cluster.
- To determine the percentage of practices within each cluster using role substitution.
- To determine the percentage of practices within each cluster employing different health care professionals to provide face-to-face consultations with patients.

Table 8: Number of general practices across clusters in Wales in 2019

Aneurin Bevan University Health Board clusters	Number of general
(n=12):	practices:
Blaenau Gwent East	5
Blaenau Gwent West	6
Caerphilly East	7
Caerphilly North	9
Caerphilly South	7
Monmouth North	8
Monmouth South	5
Newport East	7
Newport North	6
Newport West	5
Torfaen North	6
Torfaen South	7
Total number of general practices in health board:	78
Betsi Cadwaladr University Health Board clusters	
(n=14)	
Anglesey	11
Arfon	10
Central & South Denbighshire	8
Central Wrexham	7
Conwy East	5
Conwy West	12
Dwyfor	5
Meirionnydd	6
North Denbighshire	6
North East Flintshire	7
North West Flintshire	7
South Flintshire	7
South Wrexham	10
North West Wrexham	6
Total number of general practices in health board:	107
Cardiff & Vale University Health Board clusters (n=9)	
Cardiff City & South	7
Cardiff East	5
Cardiff North	11

Cardiff South East	8
Cardiff South West	11
Cardiff West	8
Central Vale	7
Eastern Vale	4
Western Vale	3
Total number of general practices in health board:	64
Cwm Taf Morgannwg University Health Board clusters	
(n=8)	
Bridgend East	5
Bridgend North	8
Bridgend West	3
Merthyr (previously two clusters: North and South)	9
North Cynon	4
Rhondda (previously two clusters: North and South)	13
South Cynon	6
Taff Ely (two clusters: North and South)	7
Total number of general practices in health board:	55
Hywel Dda University Health Board clusters (n=7)	0
Amman/Gwendraeth Llanelli	8 7
North Ceredigion	7
North Pembrokeshire	9
South Ceredigion & Teifi Valley	7
South Pembrokeshire	6
Tywi Taf	8
Total number of general practices in health board:	52
Powys Teaching Health Board clusters (n=3)	
Mid Powys	5
North Powys	7
South Powys	4
Total number of general practices in health board:	16
Swansea Bay University Health Board clusters (n=8)	
Afan	8
Bay Health	8
City Health	8
Cwmtawe	3
Llwchwr	4
Neath Central	8
Penderi	5
Upper Valleys	4
Total number of general practices in health board:	48
Total number of general practices in Wales across all health boards (N=61)	420
Mean	6.89
Median	7
Mode	7
Mode	1

Source: Public Health Wales, 2019. Primary care clusters 2019. Available at: http://www.primarycareone.wales.nhs.uk/sitesplus/documents/1191/PHW Yearbook2019-20 s3.pdf

Methods

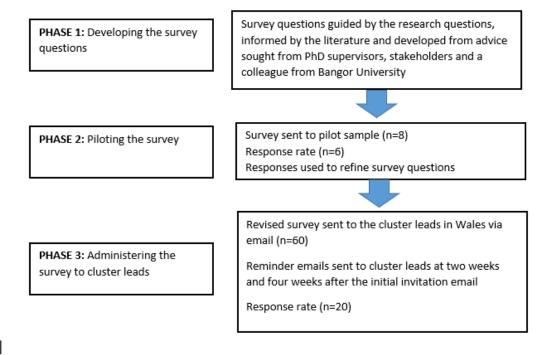
An electronic anonymous online, survey was administered to primary care cluster leads in Wales using the 'Online Surveys' platform (formerly Bristol Online Survey)

https://www.onlinesurveys.ac.uk/. According to the RCGP Wales, primary care clusters play a key role in allocating resources and facilitating multidisciplinary working between GPs and other health care professionals within practices (RCGP Wales, 2018b). Primary care clusters are groupings of GPs working with other health and care professionals to plan and provide services locally (National Assembly for Wales, 2017).

An online survey methodology was chosen in order to determine the extent to which role substitution was used in practices across Wales and the general attitudes of cluster leads regarding role substitution and potential strategies to increase role substitution within their clusters. Online survey designs are valuable methods for exploring attitudes, beliefs and knowledge-based areas (Gerrish and Lacey, 2010), and serve as practical, cost-effective methods to conduct research when it is difficult or unfeasible to access certain populations (Couper, 2000). Surveys on the topic of non-medical health professionals and AHPs working in primary care have been conducted previously (Drennan et al., 2012; RCGP, 2018).

The survey methodology comprised of three phases (Figure 4): developing the survey questions; piloting the survey; and administrating the survey to cluster leads.

Figure 4: Flow chart of the phases of the development and administration of the survey.



Phase 1 – Developing the survey questions

The survey questions were guided by the study research questions and informed by the literature identified in previous chapter of this thesis. Advice was sought from supervisors, stakeholders (two GPs and an Assistant Area Director of Primary Care and Commissioning) and a Research Officer at Bangor University working in primary care research with previous experience in survey design, to assist in the development of the survey questions. Feedback was used to determine the content and format of the questions. The pilot survey consisted of five sections: introduction page, background questions, role substitution in your cluster, piloting questions and feedback.

Phase 2 – Piloting the survey

Permission to pilot the survey was given by the Chair on behalf of the Healthcare and Medical Sciences Academic Ethics Committee, Bangor University. The purpose of the pilot phase was to test the veracity of the instrument and to refine the survey questions.

"Survey piloting is the process of conceptualizing and re-conceptualizing the key aims of the study and making preparations for the fieldwork and analysis so that not too much will go wrong and nothing will have been left out" (Oppenheim, 1992, p. 64).

The survey was pilot tested with a sample of eight stakeholders including members of the supervisory team and colleagues from Bangor University (who were aware of role substitution). No data were collected during this pilot phase of the study. The pilot sample was sent two invitations emails; firstly, an initial pilot survey invitation e-mail, followed by another e-mail invitation containing the link to the survey. A web method was used to administer the pilot survey (Online Surveys, formally known as Bristol Online Survey) www.onlinesurveys.ac.uk/). The response rate during this phase was 75% of the pilot sample (n=6). The pilot survey contained a section asking respondents to comment on the comprehension and clarity of the survey; whether or not the survey questions were difficult to answer; and if the length of the survey, and the time it took to complete the survey was appropriate. The responses from pilot survey were used to refine the survey questions and develop the final revised survey (Appendix 7).

Phase 3 – Administering the survey to cluster leads

Before administering the survey, ethical approval was obtained from the Bangor University Healthcare and Medical Sciences Academic Ethics Committee and from the Health Research Authority (HRA) and Health and Care Research Wales (HCRW) (Appendix 8). Participation in the survey was voluntary and answers to the survey questions were anonymous and confidential. In accordance with the ethical approval granted for this study, identifiable information about the clusters was not collected, therefore it was not possible to compare the sample characteristics of cluster lead respondents versus the non-respondents. No personal data was collected during the study and local health boards could not be identified from the data.

The survey targeted the primary care cluster leads in Wales. Primary care clusters are groupings of GPs working with other health and care professionals to plan and provide services locally (National Assembly for Wales, 2017). The decision to survey cluster leads was because they play a vital role in supporting local health needs assessments, allocating appropriate resources and estimating the potential future demand on primary care (Auditor General for Wales, 2018). There are 64 clusters across the seven local health boards in Wales; however, it was not possible to obtain full details of all the cluster leads working across Wales due to some leaving their positions and new cluster lead positions waiting to be filled. Consequently, 57 primary care cluster leads from six of the local health boards in Wales were invited to take part in the survey by email, most of whom were GPs and others were primary care managers. Names of the cluster leads were obtained online (http://www.gpone.wales.nhs.uk/clusters) and the NHS email addresses of the cluster leads were provided by the local collaborators (Research and Development contacts) identified through the ethical procedure process. Cluster leads were sent an invitation e-mail with information about the purpose of the survey and a link to the online survey platform (Appendix 9). By clicking on the survey link, participants were directed to the introduction page on the survey platform. The introduction page stated that by clicking 'next' they were providing informed consent to take part in the study. Two email reminders (Appendix 10) were sent to cluster leads, 2 weeks and 4 weeks after the initial survey invitation was emailed. The online survey platform was open for a duration of 8 weeks between November 2018 and January 2019.

Survey instrument

The unit of reporting was at cluster level. The study was a self-report survey of cluster leads; the data was not collected at practice level and therefore only provides an indication of the utilisation of role substitution at practices based on the answers provided by cluster leads.

The survey included both open and close-ended questions (Appendix 7). The survey comprised of 11 closed-ended questions relating to: the practice management of the practices within each cluster; the perceived workforce crisis in primary care; whether cluster leads had a strategy for increasing role substitution, the percentage of practices within each cluster using role substitution; and the percentage of practices employing different non-medical health professionals and AHPs to provide face-to-face consultations with patients.

The first two closed-ended questions related to the types of general practices within clusters and asked respondents to provide a numerical response in a free text box. The next two closed-ended questions asked whether there was a perceived workforce crisis in primary care, and whether cluster leads had a strategy for increasing role substitution within their cluster and required a categorical response (i.e., "definitely", "somewhat", "not at all" and "yes", "no", "don't know"). The final seven closed-ended questions asked cluster leads to give details of the percentage of practices within their cluster for each question relating to role substitution uptake, where respondents were required to provide the 'percentage of practices within their cluster' answer in a free text box.

The survey also included two optional open-ended questions. Firstly, a question to explore the general attitudes of cluster leads regarding role substitution and their potential strategies to increase role substitution within their cluster; and secondly, a question asking respondents to provide details of other AHPs that may be employed within their cluster that were not given in the previous survey questions. Surveys should include one or two openended questions as they can be motivating for respondents and will allow researchers to investigate the unknown and unexpected (Gillham, 2008).

The time taken to complete the survey was approximately 10 minutes; the survey was intended to be relatively brief, as surveys that take longer than 13 minutes are associated with lower response rates (Handwerk, Carson and Blackwell, 2000).

Data analysis

Descriptive statistics were calculated for the closed-ended responses using the Statistical Package for Social Sciences (SPSS) statistics software and a narrative approach was used to describe and summarise the responses to the open-ended questions. In order to preserve anonymity and confidentiality of the clusters, details of the clusters that the cluster leads were managing were not collected and was therefore not reported on in the analysis. Moreover, the

survey did not capture information on the total number of practices within each cluster or any information on the approximate size of the patient populations that the clusters serve.

Frequencies were calculated for the first two closed-ended questions that asked respondents to provide a numerical response for the types of general practices within each cluster. The total number of practices that were directly managed by the health board and the total number of practices that were commissioned/contracted were then calculated. This information was then aggregated and reported at a whole sample level. The number of respondents who answered 'don't know' to these questions was also quantified in the results.

Frequencies were calculated from the two survey questions that required categorical responses and then the percentage of responses for each categorical option was calculated. For the final seven closed-ended questions, for those practices that reported a percentage of practices within their cluster using role substitution, the mean percentage of responses and standard deviations were calculated. The mean percentage for each question was calculated as the sum of all of the percentages provided by each cluster divided by the number of cluster leads that reported percentage data.

The open-ended responses were analysed using a multi-stage approach where the responses were first read out in order to become familiarised with the content of the data and then categorised by role substitution criterion e.g., types of roles being utilised in clusters. The number of cluster leads reporting the use of different groups of professions and strategies to increase role substitution was then presented narratively.

Results

Response rate

Twenty cluster leads from six of the local health boards in Wales completed the survey out of 52 cluster leads that were invited to take part, giving a response rate of 38%.

Management of the practices

Survey responses revealed that between November 2018 and January 2019, there were 22 general practices that were directly managed by the NHS health board, and there were 70 general practices that were contracted/commissioned. Three respondents did not know the percentage of practices within their cluster that were contracted/commissioned.

Attitudes to the primary care workforce crisis and strategies to increase role substitution

One hundred percent of respondents (N=20) reported that there was 'definitely' a workforce crisis within primary care. Of these, 95% (n=19) stated that they had a strategy for increasing role substitution within their cluster. Additional comments in the subsequent, optional, openended question offered insight into how cluster leads were trying to increase the use of role substitution within their cluster, and their rationale for doing so.

A number of cluster leads reported that they were using cluster funds to expand the workforce in order to help with increasing pressures and the GP workload. For example, one cluster lead stated that they were working to bring in alternative clinicians into the practices to ease the issues of being unable to recruit GPs and the inability to afford the rising cost of GP locum cover. Another cluster lead reported that they had recently appointed a cluster funded mental health counsellor to provide active monitoring of patients with low-grade mental health problems, in order to free up GP time to deal with patients that are more complicated. Two cluster leads indicated that they employ physiotherapists within their cluster to avoid GP consultations. One of whom stated the following:

"Estimates suggest 15% GP consults are musculoskeletal - I feel my own experience of day to day GP work is consistent with this. We are hoping to develop systems where patients automatically consider first contact with a physiotherapist rather than GP".

Three cluster leads said that they have supported the employment and training of alternative practitioners including advanced nurses and pharmacists to become independent prescribers. One cluster lead felt that the majority of chronic disease work could be managed by clinical pharmacists and stated that they are currently developing pharmacist skills in different areas within their cluster including hypertension, diabetes and respiratory.

Ongoing work to increase social prescribing was noted among a number of cluster leads with the purpose of linking patients with non-medical activities to improve health and wellbeing. Moreover, one cluster lead stated that their goal was to direct patients who attend frequently with various issues towards local area co-ordinators, who were being slowly integrated within their practices.

Within one cluster, it was reported that independent contractors who run the practices have different opinions regarding who should be part of the primary care workforce and how

general medical services should be delivered. Another cluster lead stated that they were encouraging a wider skill mix in different sized practices and were exploring ways to share non-medical health professionals and AHPs between practices. One cluster lead expressed difficulty in expanding the workforce within their cluster due to a lack of availability of alternative professionals. The role of receptionists as system navigators was mentioned by one cluster lead.

Current uptake of role substitution within primary care clusters

The cluster leads who completed the survey reported that on average, 97% of the practices across the represented primary care clusters were using role substitution (Table 9). With respect to the different non-medical health professionals and AHPs employed across the clusters to provide face-to-face consultations with patients, cluster leads surveyed reported that on average 64% of the practices that were covered by the participating clusters employed nurse practitioners and on average 66% of these clusters employed pharmacists. Four respondents did not know the extent to which nurse practitioners were employed in their respective clusters (n=16, Table 9). They reported that on average, 66% of practices across the clusters employed pharmacists, and 46% employed physiotherapists to provide face-to-face consultations with pharmacists. Moreover, cluster leads reported a mean employment rate of 2% and 12% for OTs and paramedics, respectively. Finally, cluster leads stated that 47% of the practices employed other groups of AHPs.

Table 9: Use of role substitution across general practices in Wales (%)

Role substitution activities across general practices in	Mean percentage of practices (%)	n	
Wales			
Using role substitution	96.6 (SD: 7.45)	20	
Employing nurse practitioners	64.2 (SD: 30.99)	16	
Employing pharmacists	65.6 (SD: 34.12)	20	
Employing physiotherapists	45.7 (SD: 42.77)	20	
Employing OTs	2 (SD: 6.16)	20	
Employing paramedics	11.8 (SD: 23.43)	20	
Employing other allied	47.3 (SD: 44.61)	20	
healthcare professionals			

SD = Standard Deviation. SDs are given to two decimal places

Responses to the subsequent open-ended question on other groups of AHPs employed in the practices within clusters revealed that six primary care clusters employed mental health practitioners. In two of the clusters, the mental health practitioner was a community psychiatric nurse. One cluster lead gave additional information regarding the role of the mental health practitioner stating that they were employed to provide six sessions of cognitive behavioural therapy (CBT) for patients with anxiety and depression. The same cluster lead also stated that each practice had lowered the employment of the mental health practitioner from one day per week, to half a day per week due to funding pressures. Moreover, one cluster lead stated that they employed GP support officers within their cluster to provide mental health support.

Two cluster leads stated that they employed social prescribers within their cluster. One of whom stated that the role of the social prescriber was to see patients presenting with low grade mental health problems and to provide low level coaching/counselling, as well as signposting patients on to other services. Two cluster leads stated that they employed physician associates within their cluster, but no further information regarding their role was given. Two cluster leads reported that they employed paramedics within their cluster to carry out home visits. One cluster lead reported that they employed a family wellbeing practitioner to see early intervention Child & Adolescence Mental Health Services (CAMHS). Another cluster lead stated that they employed a paediatric advanced nurse practitioner who could treat and prescribe. One cluster lead stated that they employed a palliative care nurse who saw palliative and frail patients. Each of the following types of healthcare professionals were also reported to be employed within a primary care cluster, with no additional information regarding their roles: emergency care practitioners, audiologists, social workers and emergency care practitioner.

Discussion

Summary of findings

This study provides an indication of the different types of groups of healthcare professionals providing general medical services within clusters in Wales. There is evidently a workforce crisis in primary care in Wales and this was reported by cluster leads who responded to this survey. The survey findings indicated the widespread use of role substitution in clusters in Wales, as self-reported by the cluster leads who participated in the study. Cluster lead

respondents also provided additional comments regarding possible strategies to increased role substitution within their clusters. As reported at cluster level, the results of this survey provided an indication of a wide range of different healthcare professionals being employed in general practices in Wales to provide face-to-face consultations with patients. Cluster leads provided information on a variety of strategies to increase the uptake of role substitution including the ongoing support to employ and train AHPs and increase the uptake of independent prescribing by nurses and pharmacists. Mental health and social issues appear to take up a large portion of general practice demands, demonstrated by the increased employment of mental health practitioners and the development of social prescribing in Wales as reported by the cluster lead respondents.

Strengths and limitations

This survey provides novel findings of cluster lead views of strategies to implement role substitution in clusters in Wales. At the time of the survey, data in relation to primary care workforce planning in Wales was already routinely collected through the NWSSP; nevertheless, no data was available for the year 2019. Data collection for the survey presented in this chapter took place between November 2018 and 2019 and therefore provides information for a small window in 2019 where data on general practice staff was not publicly available from National sources. Moreover, routinely collected data in Wales did not provide a breakdown of the different types of direct patient care staff until 2020. Although this survey did not directly measure employment rates of staff at practice level, the findings provide some indication of the types of practitioners that are being utilised in practices, as reported by cluster leads who play an important role in supporting local health needs in terms of allocating appropriate resources within their clusters (Auditor General for Wales, 2018).

Nevertheless, the study has a number of limitations that impact the validity and reliability of the study findings. A major limitation is that this study was a self-report survey which relied on cluster leads' knowledge of the practices within their cluster. The cluster leads who completed the survey reported that on average, 97% of the practices across the represented primary care clusters were using role substitution. These findings may be down to the fact that cluster leads who responded did so because role substitution was already being implemented within their cluster. Consequently, it is likely that the non-responder cluster leads would have provided very different answers to the survey questions; this is known as non-response bias and is a common problem in surveys.

Self-selection bias is also an issue that impacts the interpretation of the results and is a common type of bias in survey studies in that the individuals that complete the survey are the types of people that complete surveys and therefore are not fully representative of the target population (Bethlehem, 2010). For example, cluster leads with strong opinions or those who have a large degree of knowledge on role substitution may be more likely to take the time to participate in the study than cluster leads who are impartial or have less knowledge.

Findings of self-reported measures must be handled with caution, as respondents are often biased when they report on their own experiences and their answers can often be influenced consciously or unconsciously through 'social desirability bias' (Mondal and Mondal, 2018). For example, cluster lead respondents may not have answered truthfully when asked about strategies to increase role substitution. They may only have offered potential solutions in order to provide a more socially acceptable answer, especially in light of the increasing pressures placed on the health service and the perceived workforce crisis in primary care (a question that was asked to cluster leads earlier on in the survey). The data collected in this survey was at a cluster level which may significantly contrast to information that would have been reported at practice level, this consequently has significant implications on the validity and reliability of the survey findings.

This survey did not capture information at a practice level to validate the information provided by cluster leads. In some cases, cluster leads reported that they 'did not know' the answer to the survey questions. Factors that might influence cluster lead knowledge might be the number of practices within their number i.e., cluster leads with a higher number of practices within their cluster may have found it more challenging to report on the innovations that were taking place within their practices. Furthermore, variability within clusters may have limited the ability of cluster leads to report answers to survey questions which were narrow in their scope. However, the survey did not capture information on the total number of practices within each cluster or any information on the approximate size of the patient populations that the clusters serve. Consequently, the findings of this survey are limited by the inability to determine whether or not the response rate by clusters were impacted by the sample characteristics of the clusters. The findings of this survey could have been strengthened by capturing this type of information to explore whether cluster lead respondents more likely to be from larger or smaller clusters. This lack of information required to compare the characteristics of respondents versus non respondents is a major limitation of this study that significantly impacts the generalisability of the survey results.

Out of a possible 58 cluster leads that were able to be contacted to participate in the study, the survey received a response rate of 38%; and therefore, suffers from a non-response bias of 62% which impacts the reliability and validity of the survey findings (Fincham, 2008). Nevertheless, according to Creswell (2008) a typical response rate for a survey is 30-35% (Creswell, 2008). This study surveyed cluster leads from six of the seven local health boards in Wales; and therefore, does not provide a complete picture of Wales as a whole. The findings could be strengthened by conducting a UK wide survey; unfortunately, this was not possible in this current study due to limited timescales and resources, and difficulty in obtaining local collaborators outside of Wales, which were required for ethical approval of the study.

There was inconsistency in the wording of the survey questions with mixing of denominator between primary care and general practice. One of the survey questions asked respondents whether there was a perceived workforce crisis in primary care, but all other survey questions specifically asked respondents to report on the practices within their cluster. The wording of this question may be confusing or have different meanings to different respondents; therefore, the interpretation of this question must be handled with caution. Moreover, this question required a closed answer response i.e., "definitely", "somewhat" or "not at all" which restricted the respondent to expand on or clarify their response, and some cluster leads may have felt that none of these responses adequately addressed their opinion or the situation within their cluster. There were seven worded responses in the data (e.g., 'don't know') to questions that requested a numerical response. Rather than using free-text box options, this issue could have been avoided through alternative response options which require a numerical response; nevertheless, this would not have captured the required information when the cluster leads said that they did not know the extent of role substitution within their cluster. Further piloting of the survey directly with cluster leads would likely have helped improve the design of the questions and aided the interpretation of the responses.

Previous literature

In 2018, the Royal College of GPs published a survey showing the percentage of GPs in Wales that said they have access to a variety of different healthcare professionals such as ANPs, pharmacists, physiotherapists and OTs (RCGP, 2018). Nevertheless, the RCGP survey did not provide information on the actual employment of different healthcare professionals. The RCGP survey findings reported that general practice is changing and becoming more

multidisciplinary by widening services. Our current survey expands on this by asking the cluster lead participants (who have important roles in service redesign in Wales) about role substitution strategies to combat to increasing demands and GP shortages.

Moreover, a previous online survey conducted in 2012 investigated the employment of physician associates (PAs) in primary care teams in England (Drennan et al., 2012). During the period of the survey, it was estimated that there were 25 PAs working in primary practices in England, of these, 16 PAs returned the survey. Results of the survey conducted by Drennan and colleagues found that PAs working in primary care in England contribute to a range of patient care, but their main roles were same day and urgent consultations (Drennan et al., 2012). The current survey presented in this chapter provides an indication of some of the roles that are being utilised in general practice in Wales i.e., the expansion of independent prescribing by nurses and pharmacists and the increased employment of mental health practitioners and social prescribers. Mental health and social issues appear to take up a large portion of general practice demands, demonstrated by the increased employment of mental health practitioners and the development of social prescribing in Wales as reported by the cluster lead respondents.

Since 2020, information on primary care networks (PCNs) on the number of clinical directors, direct patient care staff and admin/non-clinical staff is collected directly by each PCN in England (NHS Digital, 2020). Additional roles working in general practice teams are manged by PCNs, which are groupings of general practices in England, similar to primary care clusters which are the Welsh equivalent. This new source of information post-dates the survey work presented in this chapter but provides the most comparable data to my findings as it provides information on the workforce composition in England at a PCN level.

Nevertheless, these findings provide information on workforce compositions in England and are therefore not directly comparable to Wales, where workforce planning, and management may be vastly different in clusters compared with PCNs in England.

Implications for practice and policy

At a cluster level, this self-report survey suggested a high uptake of role substitution in the practices that that were covered by the clusters in Wales that took part in this study. Nevertheless, more information on the specifics of how practices are using role substitution would be useful, such as information on the models of service delivery and configuration that work best to ensure that general medical services are delivered in the best possible manner to

patients. In order to facilitate better policy making and practice, more understanding of how practices are utilising their funding and resources to provide general medical services by non-medical health professionals and AHPs is needed.

Findings in relation to the conceptual framework of the thesis and theories of role substitution

This thesis used an overarching framework for evaluating quality of care and is applied in this thesis to role substitution in primary care (Maxwell, 1992). While this survey did not directly measure the impact of role substitution on any of the six dimensions of quality of care (Maxwell, 1992), some of the survey findings can be considered in relation to the access, acceptability and cost dimensions. Although the survey did not directly ask whether role substitution was acceptable to respondents, it did provide information on cluster leads' strategies to increase role substitution within their cluster which could possibly be interpreted as their acceptability of using role substitution within their cluster. Nevertheless, this inference is only based on the responses of the clusters leads that were represented in this survey; therefore, the findings are not representative of the whole cluster lead population. Consequently, non-respondent views may have been vastly different and may have reported less role substitution use and/or may have been opposed to strategies to increase role substitution within their cluster.

The findings of the survey can also be interpreted in relation to the access dimension as the study provided some information on the types of practitioners that are available to patients in the clusters that were represented in the survey. Moreover, one cluster lead stated that they were working to bring in alternative clinicians into the practices to ease the issues of being unable to recruit GPs and the inability to afford the rising cost of GP locum cover.

The findings presented in this survey indicated that clusters were employing non-medical health professionals and AHPs to provide vertical substitution to GPs. Nevertheless, it did not provide any further information on how these innovations may impact on professional boundaries or whether the increased use of different practitioners had resulted in disputes between or across professions.

Conclusion

This survey suggested the widespread use of different groups of non-medical health professionals and AHPs providing face-to-face consultations with patients across practices in Wales as reported by the cluster leads who participated in this study. Nevertheless, this information was captured at cluster level and relied on cluster lead knowledge of the use of role substitution in the practices within their cluster. Future methodologically robust studies that ask more detailed questions are needed to uncover specific information of how role substitution is being implemented, including the best models of service delivery, and the decisions/rationale behind the allocation of funding and resources to deliver role substitution in general practice.

This Chapter indicated (as self-reported by cluster leads) that role substitution was being implemented widely across the clusters that were represented in this study, but the budgetary impact of these resource allocations is not known. The following chapter (Chapter 5) set out to assess the cost implications of increasing the use of role substitution at a local level.

CHAPTER 5: THE INCREASED USE OF ROLE SUBSTITUTION IN TWO GENERAL PRACTICES IN NORTH WALES: A BUDGET IMPACT ANALYSIS

Introduction

Between 2016 and 2017, NHS healthcare expenditure on primary care in Wales was £1.39 billion which was approximately 20% of the total NHS expenditure in Wales (Wales Audit Office, 2018). Chapter 4 of this thesis provided an indication of how role substitution was being implemented across some general practices in Wales and explored some of the strategies that some clusters were using to increase the use of role substitution. The budgetary impact of increasing role substitution at a national and local level is not well understood with few publications considering the costs of role substitution (see Chapter 2). This chapter sets out to explore the budget impact of increasing role substitution at a local level in North Wales.

As introduced in Chapter 1 of this thesis, budget impact analysis (BIA) can be used to predict how the adoption of a new health technology or intervention for a given condition will impact the overall expenditure for that condition and can be used to help make decisions about the allocation or reallocation of resources in health care systems (Health Information and Quality Authority, 2014). In the UK a budget impact test is used by NICE following a detailed technology appraisal to explore the costs of implementation, typically over the first three to five years of intervention roll-out (National Institute for Health and Care Excellence, 2021; Craig et al., 2019). BIAs are widely used in healthcare decision making when the purpose is to understand the affordability of an intervention in terms of costs gained or saved from implementing an intervention (Chugh, De Francesco and Prinja, 2021).

BIAs cannot determine whether an intervention is good value for money, nor do they include the costs of changes in outcomes that cannot be so easily monetised such as clinical effectiveness data (Trueman, Drummond and Hutton, 2001). Due to pressures on healthcare expenditure in the NHS, healthcare interventions must be proven to be both clinically effective and also cost-effective (Trueman et al., 2001). It must be noted that BIAs are not full economic evaluations, they only assess costs and do not consider the impact of interventions on wider resource use or patient safety. Cost-effectiveness analysis (CEA) is a method that combines both costs and clinical effectiveness outcomes in order to demonstrate

gains in health compared to the costs of adopting a new healthcare intervention and therefore allows researchers to highlight ways of allocating resources to achieve maximum health outputs (Edwards and McIntosh, 2019). In contrast to CEA that requires a longer time horizon and large amount of researcher resources, BIAs provides a different perspective through the estimation of short-term affordability on budgets, by comparing the cost difference of two scenarios occurring at different timepoints over a short time horizon (Petrou, 2021). BIAs are valuable when the aim it to assess changes in annual budgets and aid financial planning of services prospectively, but they are limited by their inability to consider the consequences of adopting a new intervention on clinical effectiveness and safety. Decisions about whether to invest, continue investment or disinvest in healthcare interventions should not be made on cost alone but instead a full range of evidence is needed relating to both the costs and benefits (National Institute for Health and Care Excellence, 2014).

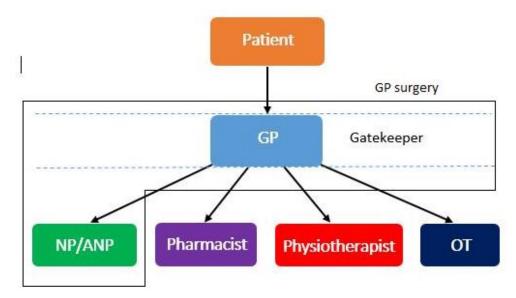
The BIA presented in this chapter is narrow in its scope as it is restricted to the general practice budget and does not extend to include resource allocation shifts such as prescriptions or shift in other health care services outside of the practice e.g., through referrals or diagnostic tests. In order to gain greater understanding of the impacts of role substitution, evaluations of interventions would need to make use of consultation and patient clinical record data to obtain information on process outcomes (including lengths of consultations, examinations, prescriptions, referral and re-consultations rates) as well as clinical effectiveness, health status and safety outcomes. Previous studies conducted in the UK have been successful in comparing the costs as well as the clinical and wider service impacts of role substitution. For example, in England Drennan and colleagues compared the processes and outcomes between PAs and GPs for same-day consultations (Drennan et al., 2015). Their findings revealed that PA appointment may be longer in time when compared with GP appointments; however, costs were found to be lower overall. There was no evidence of PA appointments resulting in higher incidences of re-consultation compared with GPs (Drennan et al., 2015). In another UK example of a study of general practices in England and Wales, clinical care and costs of consultation processes were found to be comparable for GP and NP (Venning et al., 2000).

Role substitution in the general practices

For the purpose of this study, role substitution is defined as roles that were previously completed by a GP and are now being completed by a non-medical professional or AHP. In a previous model of general practice, before role substitution was implemented, patients would see the GP as their first point of contact at the practice and the GP would serve as the gatekeeper for referral to other groups of non-medical health professionals and AHPs if and when needed (see Figure 5). After the implementation of role substitution within practices, patients were able to either self-refer themselves to a healthcare professional or the care navigator (formally the receptionist) could refer patients to the correct health care professional based on their reason for consultation (see Figure 6).

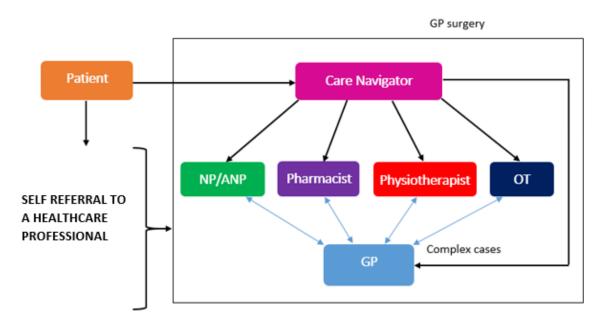
This new innovative system redesign of the primary care workforce enables patients to access the correct health care professional during their first point of contact at general practice based on their need for consultation, and also allowed GP consultations to be reserved for patients with complex conditions and consultations that require the expertise of the GP. It was expected that role substitution improved patient access to primary care services by removing the bottle-neck system in general practice (see Figure 6); however, opportunity costs must also be considered. Opportunity cost expresses the basic relationship between scarcity and choice (Buchanan, 1991) and can be defined as the value of benefits foregone by not using resources in their next best alternative use (Palmer and Raftery, 1999). In this case, if a general practice chooses to implement or increase their use of role substitution, then it is the potential benefit forgone, which may manifest in patient dissatisfaction, if patients were more familiar with their GP and would prefer to see them. It could result in cancelled appointments or patients asking to see the GP regardless of the new structure, which could recreate the "bottle neck" system the practice was trying to address.

Figure 5: Illustration of the patient pathway when entering general practice before the use of role substitution



NB: for illustrative purposes only.

Figure 6: Illustration of the patient pathway when entering a general practice using role substitution



NB: for illustrative purposes only

The purpose of this budget impact analysis was to explore the financial implications of role substitution in general practices and to record whether there had been any shifts in health

service costs as a result of the increased use of non-medical health professionals and AHPs working to provide general medical services. The analysis explored outgoing costs of employing non-medical health professionals and AHPs; and what the foot-traffic of patients looked like i.e., how many patients were entering general practice and how many were seeing each of the health care staff employed in general practice? The analysis used two general practices in North Wales, UK as examples to demonstrate the impact of implementing role substitution in a real-world setting and the findings of the study were used to inform the subsequent qualitative component of this thesis (Chapter 6).

Aim and objectives:

The aim of this chapter was to prepare a BIA to explore the financial impact of implementing role substitution in two general practices in North Wales.

This chapter addressed the following research question:

4. What are the cost implications of increasing the use of role substitution within general practice?'

The specific objectives were as follows:

- To determine the volume of patients entering the general practices over a one-week time horizon before and after the increased use of role substitution.
- To assess the frequency of contacts made with each group of health care staff over a one-week time horizon before and after the increased use of role substitution i.e., how many patients are seeing each type of practitioner employed at the general practice?
- To determine the direct costs of consultations of the health care staff before and after the increased use of role substitution.

Methods

Study design

The study design was an observational design, conducted before and after the increased use of role substitution and involved the pre and post comparison of budgets as part of a BIA (i.e., before and after the increased use of role substitution).

A BIA is an economic assessment that predicts the potential financial impact of the adoption of a new health technology or intervention into a health care system with finite resources (Mauskopf et al., 2007). While economic analyses assess the additional health benefit gained from the adoption of a new health intervention, a BIA assesses the affordability of the intervention and reports costs only. A BIA can be used to predict how the adoption of a new health technology or intervention for a given condition will impact the overall expenditure for that condition and can be used to help make decisions about the allocation or reallocation of resources in health care systems (Health Information and Quality Authority, 2014). The BIA conformed to the guidelines outlined in the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) budget impact analysis good practice report (Sullivan et al., 2014).

Perspective

The BIA was conducted from a constrained NHS perspective (provider budget holder perspective) to determine the financial impact of role substitution in two general practices in North Wales. This study design provided a fairly narrow scope and was restricted to the consideration of the general practice budget only, with a specific focus on roles implicated in GP role substitution and did not cover the wider impact of resource allocation shifts on wider budgets in terms of the costs of diagnostic tests, referrals, prescriptions, consultation lengths, or impacts on GP workload such as increased supervision. As the scope of the study was restricted to the general practice budget it did not extend to in include resource allocation shifts to other health care services outside of the practice e.g., through referrals or natural shifts in resource use or diagnostics tests and prescriptions (see also discussion).

Context and population

The study was conducted in North Wales within a large geographical region, within one local health board (BCUHB). Within this region general practices vary, and include practices directly manged by the health board practice and those that follow a more traditional partnership model. The number of practices included within the study was pragmatically derived based on the resources available within the study and aimed to provide a picture of budget impact within two different practices (with variation both in terms of size and management structure) within North Wales.

In order to protect the anonymity of the practices, the practices were cited in this thesis as Practice A and Practice B. Practice A is situated in a large seaside town with a large

retirement population from England. Practice A has approximately 22,000 registered patients and is directly managed by the local Health Board (BCUHB). Practice B is situated in two seaside towns with a practice population of 7,600 and is a traditional practice partnership.

Identification and recruitment

Two general practices were identified to participate in the study, with one directly managed by the health board and one a traditional partnership model run practice. General practice identification was through discussion with a clinical advisor (candidate supervisor) to identify practices which met the following criteria, 1. that they were within the geographical region (BCUHB), 2. that there were indicators of increased role substitution being utilised and 3. that they were able and willing to take part in the study. Practices were contacted by the clinical advisor and recruited to participate in the BIA following ethical approval for the study. The eligibility criteria to participate was confirmed by the practices before commencement of the study.

Ethical approval

Ethical approval was received from the Healthcare and Medical Sciences Academic Ethics Committee, Bangor University. The clinical governance officer of the research and development department of the local health board confirmed that NHS ethics were not required for the BIA, as high-level anonymised data were used. However, a data sharing agreement was required, which was signed by all parties (Bangor University and members of the practice management team at Practice A and Practice B) before any data were collected. Bangor University's head of compliance approved this data sharing agreement prior to sharing and signing by the GP practices (Appendix 11). The data sharing agreement served two purposes: firstly, it protected the practices providing the data, ensuring that the data will not be misused; secondly, it prevented miscommunication between the provider of the data and the agency receiving the data, as all questions about the data retrieval, storage, management and use were discussed and agreed upon prior to data sharing.

Data collection

The identification of data to be collected was derived through discussions with the practice manager and included all roles which have been implicated in role substitution that were employed at the practices during the time horizon of the BIA (see chapter 1 for a full list of roles). High-level data (frequencies of consultations by categories of health care professionals) were obtained from the practice database in 2018, reported on retrospectively

by the practice manager. The data consisted of anonymised practice level data provided by the practice manager at Practice A and Practice B. Where data was not routinely collected, for example, on consultation duration the practice manager was asked to provide an estimated duration. Individual patient and staff level data were not accessed in the study, instead national sources of health and social care costs were used to calculate the total costs of consultations (Curtis and Burns, 2018).

The BIA included the following input data:

- Volume of patients entering the practices attending consultations with GPs, non-medical health professionals and AHPs performing role substitution at the practices.
- Frequency of contacts made with health care staff including GPs, nurse practitioners (NPs), advanced nurse practitioners (ANPs), pharmacists, and OTs.
- Average duration of consultations by health care professional.
- Direct costs of consultations with health care staff were costed using National Sources of Unit Costs (Curtis and Burns, 2018) reported in pounds sterling (£), and for the cost year 2017/18 where available, with local sources of cost estimates applied where national unit costs were missing.

The sample of data used in the BIA consisted of all patient consultations occurring within the study time period with GPs, non-medical health professionals and AHPs performing role substitution at the practices (see time horizon). High-level data (frequencies of consultations by categories of health care professionals) were used to determine the volume of patients entering the general practice, and the frequency of contacts with GPs, non-medical health professionals and AHPs over an identical period of one week before and after the increased use of role substitution at the practice.

Anonymised data was transferred securely from the GP practice manager to the candidate. Data checks were performed to identify any missing values and out of range values provided as part of the dataset, any clarifications required were resolved through direct communication with the practice manager before the database was finalised for analysis.

Time horizon

The time horizon of the study was between 2016 and 2018, with a one-week retrospective data collection period in both 2016 and 2018. As the data collected did not span more than 12 months discounting was not required. Data were obtained over an identical time horizon of one week in November 2016 (14.11.16-18.11.16) and one week in November 2018

(12.11.18-16.11.18) in both practices, when the use of role substitution increased within the practices. The time-horizon used within the study may have important implications on the results and generalisability of the findings (see discussion for further details). The timing of the data collection was selected to provide the most comparable two weeks, this was done in order to minimise the impact of seasonal changes in consultation rates such as those due to seasonal flu. The duration of the time horizon (i.e., one-week time horizon per year) was deemed to be practical in consultation with the practice managers who had limited resources to extract the required data and was thought to provide a reasonable period for comparison, enabling a sufficient number of consultations to be reported on to enable comparison within each of the practices. The one-week time horizon was considered to be proportionate to the resources available within the study and sufficient to meet the aims of the BIA to compare a high-level budget impact within a general practice using increased role substitution.

Valuation of resources

The financial impact of implementing role substitution was calculated using national sources of unit costs (Curtis and Burns, 2018) reported in pounds sterling (£) and for the cost year 2017/18 where available. Where unit costs were not available in the cost year database, costs were identified from previous year national unit costs PSSRU publications and inflated to 2017/2018 cost year using the inflation methodology (New Health Services Index using Consumer Prices Index) outlined in PSSRU (Curtis and Burns, 2018). Where unit costs were not available from sources of national unit costs, supplementary information was identified from published literature and local rates requested from the general practices participating in the study.

In addition to the consultation duration provided by the participating general practices it was necessary to make some assumptions about the wider resources required, for example, to estimate the cost of home visits, staff travel time was estimated to be an average of 15 minutes per home visit based on Kernick et al. (2002), in addition costs for carbon emissions were applied using the most recent benchmark (Curtis and Burns, 2018).

Unlike unit costs for primary care practitioners and GP consultations which are reported annually in national dataset, the average cost of consultations with locum GPs is not well reported. Unit costs for GP locum consultations were not available in the published PSSRU national unit costs (Curtis and Burns, 2018). While no nationally agreed unit cost per average GP locum appointment was identified, it was considered likely that there would be an

increased cost for a GP locum appointment, with slightly higher staff costs. The difference in salaries has been highlighted in national news reports with the highest paid locum doctor in Wales receiving 106% more than some salaried GPs in Wales (BBC News, 2018). Cost may vary depending on whether locum costs are recruited directly or through an agency. In addition, GP locum rates of pay are commonly negotiated at an individual level (BMA, 2021). Furthermore in 2017 changes to tax regulations in the UK has been implicated in a 6% increase in GP locum rates of pay (Rimmer, 2017). Looking wider at healthcare costs within the UK the cost of a locum consultant has been estimated to be 15% higher than a directly employed consultant (Hex, Collins and Webb, 2019). In 2017 the average rate of pay of locum doctors within the NHS was reported to be £70.41 per hour (Rimmer, 2017), rising to £74.74 per hour by September 2018 (Moberly, 2019).

As other resource costs associated with the GP appointment as estimated by PSSRU were considered likely to remain stable and in order to aid comparability between GP consultation appointment of different types a GP locum uplift was calculated and applied. This was achieved by first identifying an estimated rate of pay of a GP locum, before comparing this with the net renumeration of a GP. The average hourly rate costs of a GP locum was estimated from the local day rate from the GP practices involved in the study (£600 per day), with an hourly rate estimated based on an average 8.36 hour working day (see 10.3a PSSRU, 2018) and a cost per hour of £71.77. In comparison, based on PSSRU net renumeration rates of GPs in 2018 (£109,600 per year) and typical working weeks (42.8 weeks) and hours (41.8 hours) reported the rate of pay for a GP equated to a cost of £61.26 per hour (Curtis and Burns, 2018). Therefore, the increased salary cost of a GP locum resulted in an additional £0.18 per minute in costs compared with GPs, which was applied as an uplift to the GP consultation cost per minute rates as sourced from the PSSRU unit costs.

Data analysis

The results were reported as the net budget impact of the increased use role substitution (new scenario) versus the scenario before where role substitution was used to a lesser degree (previous scenario).

Descriptive statistics were calculated per practice consisting of:

- 1. the unit cost per consultation based on the average length of consultation in minutes multiplied by the unit cost per minute of consultation by health care professional.
- 2. the number of consultations by health care professional at each time point.

- 3. the total cost of consultations by health care professional at each timepoint. Costs of consultations were calculated by multiplying the average consultation length by the unit cost per minute (Tables 10 and 11).
- 4. the difference in the number of consultations between time points by health care professional and as a total of all included consultations.
- 5. the difference in costs between time points by health care professional and as a total of all included consultations.

Inferential statistical analysis was not conducted to compare results within practices or between practices due to sample size and amount of data collected. The statistical analysis was restricted to compare the data periods (reflecting the two scenarios of before role substitution and after role substitution) within practices and did not compare between the two included practices. A narrative comparison of the scenarios over time within the practices was conducted as the primary analysis. A high-level narrative comparison of differences between practices is included for wider discussion purposes only.

Sensitivity analysis

Areas of uncertainty in the data were explored using sensitivity analysis methods (York Health Economics Consortium, 2016), where potential variations in the data were explored to assess the impact on the study results. The unit cost of GP locum consultations were varied to explore two potential scenarios in addition to the base case analysis, 1. GP locum costs as one and a half times the unit cost of the base case GP locum consultation and 2. GP locum costs as twice the base case cost of GP locum consultations.

Results

Tables 10 and 11 report the average consultation length (including travel time for home visits) and its associated costs per health professional, and venue of the consultation (Table 10 only) e.g., clinic appointment, home visit etc. A member of the practice management team estimated average consultation lengths for each practitioner at Practice A (estimated average consultation lengths were identical for the one-week in 2016 and one-week in 2018), whereas average consultation lengths for each practitioner at Practice B were collected through routinely collected practice data and were calculated from the actual consultation lengths that were carried out within the time-period. Consequently, Table 11 reports on two time points as average consultation lengths were different for the one-week period in 2016 and one week period in 2018.

The longest appointments at Practice A were OT home visits lasting an average of 60 minutes per consultation plus 15 minutes of travel time (Table 10). The shortest appointments at Practice A were salaried GP, locum GP and NP telephone consultations, lasting an average of 5 minutes per consultation (Table 10). The consultation with the highest costs at Practice A were GP locum home visits costing £191 per home visit (Table 10). The least costly type of consultation at Practice A was the NP telephone consultation, costing £6 per consultation (Table 10).

The longest appointment at Practice B was pharmacist consultations lasting on average of 22 minutes per consultation (Table 11). The shortest appointment at Practice B were GP appointments lasting an average of 15 minutes per consultation (Table 11). The highest costing consultations at Practice B were GP consultations costing £60 in 2016 and £68 in 2018 (Table 11). The lowest costing consultations at Practice B were physiotherapist consultations, costing £11 per consultation (Table 11). Tables 12 and 13 are broken down into the total numbers of consultations for each health professional, with the associated estimated total costs of each type of health professional consultations, the findings of each health professional category are discussed in turn below. All costs reported refer to the estimated costs of consultations during an identical time period of one week in November 2016 and one week in November 2018.

Table 10: Unit costs of health service activity at Practice A

Type of service:	Average consultation length in 2016 and 2018 (minutes):	Travel time (minutes)	Unit cost per min:	Cost per consultation (with travel time for home visits):
ANP clinic	15	-	£1.55	£23
ANP home visit	30	15	£1.56	£70
ANP telephone consultation	10	-	£1.55	£16
GP home visit	30	15	£4.06	£183
GP surgery consultation	15	-	£4.01	£60
GP telephone call	5	-	£3.78	£19
Locum GP telephone call	5	-	£3.96	£20
Locum GP home visit	30	15	£4.24	£191
Locum GP surgery consultation	15	-	£4.19	£63
OT consultation	60	-	£0.62	£37
OT home visit	60	15	£0.63	£47
N/P consultation	15	-	£1.18	£18
N/P telephone call	5	-	£1.18	£6
Pharmacist clinic slot	20	-	£1.22	£24
Pharmacist telephone call	10	-	£1.22	£12
Physiotherapist consultation	20	-	£0.62	£12

 $\overline{\textit{NB. Cost per consultation was rounded to the nearest pound}\left(\pounds\right)}$



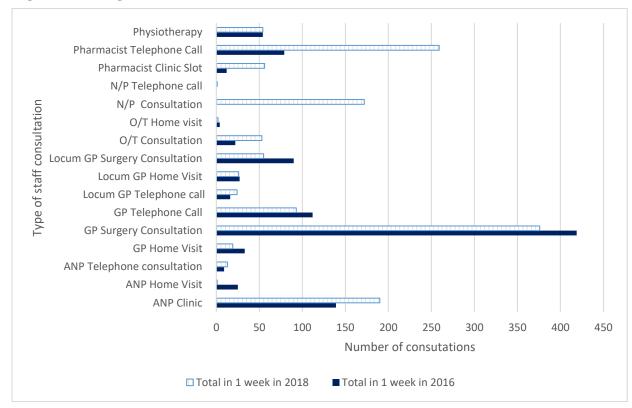
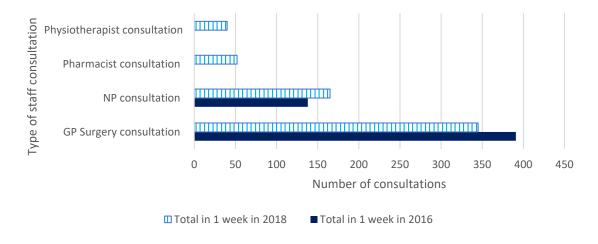


Table 11: Unit costs of health service activity at Practice B

Type of service:	Average consultation length in 2016 (minutes):	Average consultation length in 2018 (minutes):	Unit cost per min:	Cost per consultation in 2016:	Cost per consultation in 2018:
GP consultation	15	17	£4.01	£60	£68
NP consultation	19	19	£1.18	£22	£22
Pharmacist consultation	NA	22	£1.22	NA	£27
Physiotherapist consultation	NA	17	£0.62	NA	£11

^{*}NA: Not applicable - no consultations.

Figure 8: Changes in the number of consultations at Practice B between 2016 and 2018



Practice A

Between an identical time period of one week in November 2016 and one week in November 2018, the total number of consultations at Practice A increased by 33.9% (Table 12). Total estimated costs of consultations for the one-week period in 2016 and 2018 were £52,409 and £51,602 respectively (Table 12), resulting in a total estimated cost reduction of £807 following the increased use of role substitution in Practice A.

From 2016 to 2018, there was a decrease in the number of GP consultations (Figure 7). Firstly, GP surgery consultations decreased by 10.3% between 2016 and 2018, equating to an estimated cost saving of £2,580 in consultation costs between the one-week data collection period in 2016 and one-week period in 2018 (Table 12). GP home visits decreased by 42.4% and GP telephone consultations decreased by 17%, resulting in reduced estimated consultation costs of £2,562 and £361 for the one-week period between 2016 and 2018, respectively (Table 12). The number of GP locum surgery consultations and home visits over the one-week time period also decreased between 2016 and 2018, by 38.9% and 3.7%, respectively. This equated to an estimated cost saving of £2,200 in GP locum surgery consultations and £191 in GP locum home visits between the two one-week periods in 2016 and 2018 (Table 12). Nevertheless, the number of GP locum telephone consultations during the one-week time horizon increased by 50% between 2016 and 2018 resulting in an increased estimated cost of £158 to the practice.

Between the one-week data collection period in 2016 and one-week data collection period in 2018, there was an increase in the number of ANP clinic consultations and ANP telephone consultations. ANP clinic consultations increased by 36.7% with an estimated increase in consultation costs of £1,173. A 44.4% rise in ANP telephone consultations was reported between the one-week period in 2016 and the one-week period in 2018, with an estimated increase in consultation costs of £64. ANP home visits decreased by 96% between the two one-week periods in 2016 and 2018, resulting in decreased estimated costs of £1,680 during that period. During the one-week period in November 2016 the practice did not use NPs for surgery or telephone consultations (Table 12). During the one-week period in November 2018, NPs completed 172 surgery consultations and one telephone consultation resulting in an estimate cost of £3,096 and £6, respectively (Table 12).

There was a notable increase in the number of all pharmacist consultations between the one-week period in 2016 and one-week period in 2018; with an increase of 366.7% in pharmacist

clinical slots and an increase of 227.8% in pharmacists telephone consultations, with an estimated cost to the practice £1,056 and £2,160, respectively (Table 12). There was also a notable increase in OT surgery consultations (increase of 140.9%) with an estimated cost of £1,147 to the practice. Conversely, a 50% reduction in OT home visits was reported between 2016 and 2018, resulting in a cost saving of £94. The number of physiotherapy consultations remained constant during both weeks i.e., 54 consultations in 2016 and 54 consultations in 2018 (Table 12).

Practice B

Between an identical time period of one week in November 2016 and one week in November 2018, the total number of consultations at the Practice B practice increased by 13.8% (Table 13). Total estimated costs of consultations for the one-week period in 2016 and one-week period in 2018 were £26,496 and £28,926, respectively, resulting in a total estimated cost increase of £2,430 for consultations following the increased use of role substitution in Practice A (Table 13).

Between the one-week data collection period in 2016 and one-week data collection period in 2018, there was a decrease in the number of GP consultations (Figure 8). GP consultations decreased 11.8%; however, the estimated costs of GP consultations in 2016 and 2018 remained the same (Table 13) due to an increase in the average GP consultation length in 2018 (Table 11). Between the two one-week data collection periods in 2016 and 2018, NP consultations increased by 19.6% resulting in an estimated cost of consultations increase of £594 (Table 11). During the one-week period in November 2016 the Practice B practice did not employ pharmacists or physiotherapists to provide consultations to patients (Table 13). During the one-week period in 2018, the practice employed pharmacists to provide 52 consultations and physiotherapists to provide 40 consultations, resulting in an estimated cost of £1,396 and £440 for these consultations, respectively (Table 13).

Sensitivity analysis

The unit cost of GP locum costs at Practice A were varied to explore two potential scenarios in addition to the base case analysis 1.) GP locum costs as one and a half times the base case GP locum consultation, and 2.) GP locum costs as twice the cost of the base case GP locum consultation (Table 14). In scenario one, a unit cost of £30 per GP locum telephone consultation would result in an estimated cost of consultation increase of £240 between the one-week period in 2016 and the one-week period in 2018; a unit cost of £287 per GP locum

home visit would result in an estimated cost of consultation decrease of £287 between the one-week period in 2016 and one-week period in 2018; and a unit cost of £95 per GP locum surgery consultation would reduce estimated costs of consultations by £3,325 between the one-week period in 2016 and the one-week period in 2018 (Table 14).

In scenario 2, a unit cost of £40 per GP locum telephone consultation would result in an estimated cost of consultation increase of £320 between the one-week period in 2016 and the one-week period in 2018; a unit cost of £382 per GP locum home visit would result in an estimated cost of consultation decrease of £382 between the one-week period in 2016 and the one-week period in 2018; and a unit cost of £126 per GP locum surgery consultation would reduce estimated costs of consultations by £4,410 between the one-week period in 2016 and the one-week period in 2018 (Table 14).

Table 12: Differences in consultations and costs at Practice A between 2016 and 2018

Type of service	Total number of consultation in one week 2016	Total cost 2016	Total number of consultations in one week in 2018	Total cost 2018	Difference in consultations between 2016 and 2018 (%)	Cost difference between 2016 and 2018
ANP clinic	139	£3,197	190	£4,370	36.7%	£1,173
ANP home visit	25	£1,750	1	£70	-96.0%	-£1,680
ANP telephone consultation	9	£144	13	£208	44.4%	£64
GP home visit	33	£6,039	19	£3,477	-42.4%	-£2,562
GP surgery consultation	419	£25,140	376	£22,560	-10.3%	-£2,580
GP telephone call	112	£2,128	93	£1,767	-17.0%	-£361
Locum GP telephone call	16	£317	24	£475	50.0%	£158
Locum GP home visit	27	£5,152	26	£4,961	-3.7%	-£191
Locum GP surgery consultation	90	£5,657	55	£3,457	-38.9%	-£2,200
OT consultation	22	£814	53	£1,961	140.9%	£1,147
OT home visit	4	£188	2	£94	-50.0%	-£94
NP consultation	0	£0	172	£3,096	-	£3,096
NP telephone call	0	£0	1	£6	-	£6
Pharmacist clinic slot	12	£288	56	£1,344	366.7%	£1,056
Pharmacist telephone call	79	£948	259	£3,108	227.8%	£2,160
Physiotherapist consultation	54	£648	54	£648	0.0%	£0
Total:	1041	£52,409	1394	£51,602	33.9%	-£807

Table 13: Differences in consultations and costs at Practice B between 2016 and 2018

Type of service	Total number of consultation in one week 2016	Total cost 2016	Total number of consultations in one week in 2018	Total cost 2018	Difference in consultations between 2016 and 2018 (%)	Cost difference between 2016 and 2018
GP surgery consultation	391	£23,460	345	£23,460	-11.8%	£0
NP consultation	138	£3,036	165	£3,630	19.6%	£594
Pharmacist consultation	0	£0	52	£1,396	-	£1,396
Physiotherapist consultation	0	£0	40	£440	-	£440
Total:	529	£26,496	602	£28,926	13.8%	£2,430

Table 14: Sensitivity analysis to vary to unit cost of GP locum consultations at Practice A between 2016 and 2018

Type of service	Cost per consultation	Total number of consultation in one week 2016	Total cost 2016	Total number of consultations in one week in 2018	Total cost 2018	Cost difference between 2016 and 2018
GP locum cost base case – telephone consultation	£20	16	£320	24	£480	£160
GP locum cost base case – home visit	£191	27	£5,157	26	£4,966	-£191
GP locum cost base case – surgery consultation	£63	90	£5,670	55	£3,465	-£2205
GP locum cost x1.5 cost uplift scenario – telephone consultation	£30	16	£480	24	£720	£240
GP locum cost x1.5 cost uplift scenario – home visit	£287	27	£7,749	26	£7,462	-£287
GP locum cost x1.5 cost uplift scenario – surgery consultation	£95	90	£8,550	55	£5,225	-£3,325
GP locum cost scenario x2 cost uplift – telephone consultation	£40	16	£640	24	£960	£320
GP locum cost scenario x2 cost uplift – home visit	£382	27	£10,314	26	£9,932	-£382
GP locum cost scenario x2 cost uplift – surgery consultation	£126	90	£11,340	55	£6,930	-£4,410

Discussion

Summary of findings

Despite an increase in the total number of consultations between the one-week period in 2016 and the one-week period in 2018 at Practice A, estimated costs of consultations were £807 lower following the practice increasing the use of role substitution i.e., by reducing the number of GP consultations and increasing the use of non-medical and AHP roles within the practice. For the most part, the number of GP consultations at Practice A decreased between the one-week data collection period in 2016 and the one-week data collection period in 2018 and the number of non-medical and AHP consultations increased.

The total number of consultations at Practice B also increased between the one-week in 2016 and the one-week in 2018, which demonstrates the increased pressures placed on general practice in Wales. Overall, total estimated costs of consultations at Practice B rose by £2,430 between the one-week period in 2016 and the one-week period in 2018, but this was due to the practice employing pharmacists and physiotherapists to provide consultations in the one-week data collection period in 2018, and the increase in NP consultations between the one-week period in 2016 and the one-week period in 2018. Likewise to Practice A, the number of GP appointments at Practice B decreased between the two one-week periods in 2016 and 2018, while the number of non-medical health professional and AHP consultations increased.

Strengths and limitations

This novel study shows the financial impact of increasing the use of role substitution by using a real-world example with actual figures obtained from two general practices located in North Wales, UK. Moreover, this study demonstrates that work within this field can be accomplished by linking high-level data with published national reference costs as part of a case study to determine the budgetary impact of increasing role substitution in general practices. Exploring and assessing the financial impact of increasing the use of non-medical health professionals and AHPs working in general practice is important, as this will directly influence service delivery commissioning and models.

According to Kernick and Netten (2002), local unit costs should be derived from individual practices especially when local circumstances are relevant to the study (Kernick

and Netten, 2002). This study was limited by the trade-off between the accuracy of the cost data and the resources required to gain this information. This study predominately used published national cost estimates only as local unit costs were not available from the practice. Moreover, unit costs for GP locum consultations and costs for ANP, OT and GP locum home visits were not available in the published literature, therefore the most recent and appropriate benchmarks that were available were used to cost these consultations. More work to develop unit costs for practitioners such as GP locums is needed, and the methodology used by the PSSRU would be a useful framework to follow to achieve this in future work. There are no gold standards for cost estimates (Kernick and Netten, 2002); nevertheless, this study has been clear on how unit costs were derived when national unit costs were not available for some of the health service activity that took place at Practice A. Costs for GP locums were estimated and there may have been an underestimation of locum costs in the base case analysis, the sensitivity analysis considered scenarios of increased unit costs for GP locum consultations and indicated that due to the small number of visits to GP locums the difference in costs was likely to have a small budget impact. The change in costs for GP locum care was most noticeable in the case of clinic consultations which reduced by 39% between the oneweek data collection period in 2016 and the one-week data collection period in 2018. This can be compared with a 10% reduction in GP clinic consultations. The cost of GP locum care may be particularly important should there be a shift in employment patterns or sickness absenteeism which require more locum staff use. The rates paid to GP locums may vary from practice-to-practice and factors such as how many patient consultations take place per day must be considered. To benchmark our assumptions one local general practice reported a day rate of between £500 and £700 for GP locums, but without greater information on numbers of patient consultations per day and specific cost information for patient-related work, using these costs required a number of assumptions to be made. Limited sensitivity analysis was conducted to vary unit cost assumptions relating to the GP locum consultations to consider the impact of increasing the cost estimates however further methodological work is needed to increase the confidence in estimates of the cost of care by a GP locum.

This BIA provides an indicative snapshot of the cost implications of increasing role substitution in two general practices and therefore the findings may not necessarily by transferable to other settings. To obtain more accurate assessment of cost implications for other regions, future studies should consider the use of additional sensitivity analysis to vary

areas of uncertainty. For example, the number of patient consultations per day completed by practitioners could be varied to represent the patient flow at other practices in other regions.

The practice managers at both of the GP surgeries provided information relating to the length of consultations for each practitioner. One practice provided the accurate length of consultation times obtained from audits for each practitioner, whereas the other practice was only able to provide an estimate average consultation time per health professional. Ideally, we would have been provided with the same type of information from both practices (i.e., high-level information on the average across practices or accurate consultation lengths across both practices). We relied on busy practice managers for the provision of this information and therefore, were unable to obtain the same type of information on consultation length from both practices. These findings while based on a small sample of practices have important implications for the costing of resources in future health economic studies, with the length of consultations reported in this study as higher than the average length of consultation used in national sources of unit costs (Curtis and Burns, 2018). While the length of consultations estimated or reported from routinely collected clinic records was not validated as part of the research this study highlights that collecting local data that enables a local assessment of consultation costs may be important to embed within future studies. The approach to consultation costing will likely impact on the overall costs and conclusions of affordability may be different.

There are limitations of before and after design studies (Torgerson and Torgerson, 2008). This BIA did not have a control group to compare natural changes in costs over time (or costs changing due to other factors than role substitution), for example in general practices which did not report using role substitution. Consequently, the study design had little control of confounding variables that may impact on costs during the study time horizon. This study is therefore not able to make an assessment of causality with some changes in costs likely not attributable to the increased use of role substitution as reported by the practice. Further exploration of factors such as national resource use trends, staff employment rates, sickness absenteeism and other staff roles employed in general practice during this time may help explain changes in costs over time.

This study had a limited time horizon (over 2 years) and a short period of data collection (10 days of data collected in total, one-week at each practice) which may not accurately capture the annual costs to each practice. A longer period of data collection may

help iron out any factors that could impact on the total costs such as staff sickness, employment rates and full time equivalent (FTE) changes which may result in capacity issues, with a full year of data likely to provide a more comprehensive picture, this however would require increase resources to collect which was beyond the scope of this thesis research. Patient recall rates that show when patients have re-consulted at general practice for the same condition that they had initially presented with (implying that the issue was not resolved during their first appointment) was not captured in this study. A longer period of data collection could furthermore help provide better information on patient recall rates which have previously been implicated in role substitution and may not be captured within a one week period. A longer term follow up is needed to consider whether the indicators of shifts in resource use between roles are maintained over time. Previous BIA assessment have used a relatively short time horizon, on the basis of being most relevant to decision maker budget periods, and few studies have reported on cost implications beyond a few years (Garattini and van de Vooren, 2011). Future studies could consider the use of modelling techniques to assess the impact of variations in important variables and to consider the impact on budgets over a longer time horizon. Providing there is sufficient evidence on the patient journey, estimates of effectiveness and cost information patient level simulation modelling may be useful to project future budgets and to help explore affordability of role changes.

This BIA was narrow in its scope and focused on practices that self-reported the increased use of role substitution and focused on roles that were implicated in substitution from GP roles. Trueman and colleagues highlight the case for a narrow perspective in BIA that is relevant to the budget holder (Truman, Drummond and Hutton, 2001). Due to the 'silos effect' which restricts the transfer of funds from one budget to another in healthcare, the relevant perspective for BIA may not extend to cover wider healthcare services outside of their budget. Moreover, Trueman et al (2001) argue that "an effective primary-care treatment may reduce the need for secondary-care follow-up visits or emergency consultations due to exacerbations of a condition. Whilst improved management of such conditions is clearly beneficial to the patient it comes at a cost to the primary-care purchaser as any savings accrued in secondary care are rarely fully recouped. Therefore, the primary-care purchaser will be interested in the direct impact on their budget and not the holistic impact on health service cost" (Trueman et al., 2001, p.611). Considering the need to capture full information relevant to the budget holder in primary care future BIA work should consider capturing a wider range of costs and resources within a practice to be able to identify potential shifts in

resource use and associated costs that might spill over into other areas of the practice budget. There are likely to be resource implications due to role substitution that have not been measured in this analysis. Additional variables of interest that may have cost implications include employment rates of all staff roles, rates of staff turnover, full time equivalent (FTE) staffing figures, and rates of staff sickness. Furthermore, this BIA had a relatively limited scope and did not consider the wider implications on resources such as the possible impacts on prescriptions, diagnostic tests and the number of consultations. For example, role substitution may be associated with higher patient recall to general practice. This study failed to assess the patient journey in that some patients may have consulted with a non-medical health professional or AHP but then required an additional consultation with a GP in order to resolve their issue.

Previous literature

To our knowledge, this is the first study to assess the budgetary impact of increasing the use of role substitution within general practices in North Wales. We have not identified any other budget impact analyses to compare our current work with, where previous authors have explored the budgetary impact of making changes to their practice such as increasing the use of role substitution.

Decision making in two case studies in North Wales

Both practices have observed a rise in the use of different types of non-medical health professionals and AHPs to provide general medical services to patients, in order to both tackle the GP shortage crisis and to meet the demands of a changing patient population. Practice A is a large practice that is directly run by the local Health Board. In contrast, Practice B serves a smaller geographical location and is internally run by GP partners and the practice manager. Decision-making and subsequent implementation is therefore likely to differ between the two practices because of how they are managed. For example, GP Partnerships are independent, autonomous businesses therefore are likely to be able to implement changes at a much quicker rate compared to directly managed practices such as Practice A where their processes may be subject to external procedures requiring sign-off from senior health board members. Consequently, there may be a fall out in the time it takes to implement changes at Practice A, whereas if all partners are in agreement at Practice B they will have more freedom to adapt and trial their services before going into full

implementation. This in turn will have a knock-effect on population health and patient satisfaction.

Implications for practice and policy

Against a backdrop of increasing demands on limited resources within the NHS in Wales, there is a need to relate costs of increasing role substitution with their benefits. In both practices, role substitution appeared to work effectively as demonstrated by the reduction in GP workload and the increased use of other healthcare professionals within the practice. Nevertheless, we do not know if informed decisions were made relating to staffing and the configuration of the GP practices in order to enhance service delivery. Decisions relating to the skill mix of the general practice workforce should be dependent on the needs of the local population that the practice serves. In this exercise, both of the example practices were seaside towns with their local populations consisting of a large number of elderly patients; therefore, the increased use of non-medical health professionals and AHPs such as pharmacists employed for polypharmacy and OTs for their work in helping patients with mobility issues appears to be a good use of primary care resources. Despite this, we do not know exactly how decisions relating to the skills mix at the Practice A and Practice B practices were made, and whether or not these decisions were appropriate in terms of service commissioning and delivery. In order for the provision of role substitution to work well in practice, decisions relating to staffing and the best use of NHS resources need be made.

Future directions

After discussing these findings with a practice management team member, they stated that they wished that a formula existed to calculate the optimal staffing required to serve their patient population. Unfortunately, a set of standards on how to implement role substitution within practices do not currently exist. We propose a set of key elements to assist in the development of standardisation for role substitution (Box 1) discussed in the following paragraph.

General practices should assess the needs of their patients and determine what skill mix the practice needs in order to accurately meet the demands of their patient population. Shared decision-making involving both patients and clinicians is a vital step in achieving this

and is central to patient-centred primary care. Findings from MAGIC, a programme implemented within the NHS to help better understand the barriers to shared decision-making within routine practice revealed that clinicians can sometimes make assumptions that do not truly reflect the values, opinions and preferences of their patients (Joseph-Williams et al., 2017). A key strategy of the 'NHS long term plan' published in 2019 is to increase patient choice, which will allow patients to take more control of their health and to receive

Box 2: Key elements to assist in the development of guidelines or standardisation for role substitution

- 1. Assessing the needs of the patient population
- 2. Collaborative decision making and patient choice
- 3. Protected time sessions
- 4. Determine what resources are available to support points 1-3
- 5. Balancing resources to the needs and expectations of the patient population.

personalised care when they need it (NHS, 2019). Protected time sessions that give full representation of the whole primary care team, as well patient representatives are needed to ensure this. Practices need to consider what resources are available to increase the use of role substitution within their practice. Bringing in different types of non-medical health professionals and AHPs seems like a good method of giving patients more informed choice and will allow more personalised patient care, which are both aims of the NHS Long Term Plan (NHS, 2019). Nevertheless, the NHS is a taxed-based system where resources are finite; therefore, it is important that practices balance available resources to the needs and expectations of the patient population in which they serve.

Findings in relation to the conceptual framework of the thesis and theories of role substitution

The findings of this BIA chapter are concerned with the 'cost' dimension of quality of care proposed by Maxwell (Maxwell, 1992). Moreover, this BIA provides evidence of the different non-medical health professionals and AHPs roles that patients had access to during the two timepoints in 2016 and 2018. The findings raise questions in terms of the 'relevancy' of role substitution. It could be argued that the increased use of non-medical health professionals and AHPs along with the decreased number of GP consultations in order to handle patient demands demonstrates the relevancy of increasing role substitution within

general practices. This chapter does not provide any evidence on the acceptability, effectiveness or safety of increasing role substitution within general practice and therefore these findings must be handled with caution when considering the full implications of increasing role substitution in real world settings.

The findings presented in this BIA provided information on the changing dynamics of two general practice teams in terms of the types of non-medical health professionals and AHP roles that were being employed in general practice that can work to provide vertical substitution to GPs. However, it did not provide any further information on how the shifting of roles can be categorised or how changes in practice impact on professional boundaries and the subsequent impact on wider processes and outcomes.

Conclusion

In a case study using BIA in two general practices in North Wales, there was a reduction of GP appointments and a rise in non-medical health professional and AHP-led consultations. This demonstrated that role substitution could be used to address the bottleneck of insufficient GP appointments, as observed in these two differently managed practices. Role substitution is becoming increasingly common in the UK, with little guidance on how best to employ this method to achieve the best results for patients and practice staff configuration. When implementing role substitution within practices, informed decisions need to be made relating to the optimal skill mix of the primary care workforce to enhance service delivery. Shared decision making involving a full range of representatives is essential. Practices must balance available resources to the needs and expectations of the patient population they serve.

In addition to a lack of guidance on how best to allocate resources efficiently with respect to workforce configuration and skill mix, it is important to consider patient and provider experience, because healthcare serves as a market that requires some degree of consumerism (Cordina et al., 2018). This BIA chapter demonstrated a shift in resources through the increased use of non-medical health professionals and AHPs in two general practices, but what was then needed was to explore patient and staff views of role substitution.

CHAPTER 6: A QUALITATIVE EXPLORATION OF PATIENT AND PRACTICE TEAM MEMBERS VIEWS REGARDING ROLE SUBSTITUTION IN GENERAL PRACTICE

Introduction

Chapter 5 of this thesis demonstrated shifts in health service resources as a result of increasing role substitution in two general practices. What is not known is how these shifts in resources affect patients and providers. Consequently, with the view to help inform the commissioning of general medical services, the aim of this qualitative study was to explore the views of patients, non-medical health professionals, AHPs, GPs and receptionists on the substitution of non-medical health professionals providing general medical services instead of GPs. As highlighted in Chapter 3 of this thesis, there is a sparsity of qualitative research on the topic of role substitution in primary care with some roles more represented than others. Eleven studies were included in the review; four studies discussed pharmacists substituting for GPs (Gidman et al., 2012; Hatah et al., 2013; Lamberts et al., 2010; Stewart et al., 2009), six studies discussed physician associates substituting for GPs (Drennan et al., 2011: Drennan et al., 2017; Halter et al., 2017; Jackson et al., 2017; Taylor et al., 2013; van der Biezen et al., 2017), and one paper discussed physiotherapists within primary care teams (Dufour et al., 2014).

This chapter built on the systematic review of qualitative studies relating to role substitution in primary care (Chapter 3). In addition, this chapter begins with a brief synopsis of additional research relating to nurses, which was not included in Chapter 3. This chapter then goes on to describe a novel qualitative study conducted as part of this thesis, reports on key categories and themes identified across a broad range of roles in primary care including less well researched roles such as OTs, physiotherapists and care navigators (formally receptionists). This chapter concludes with a discussion on comparisons with previous literature, implications for practice and policy and directions for future research.

Qualitative evidence of role substitution relating to nurses: Cochrane review 2019

A Cochrane systematic review conducted in 2019 explored the qualitative evidence of role substitution of GPs by nurses (Karimi-Shahanjarini et al., 2019). The systematic review highlighted a lack of understanding regarding nurses' roles among patients and disagreement about the types of care that nurses should complete. The review indicated that patients

preferred physicians to complete more 'medical' types of care but acknowledged that nurses should perform follow-up consultations and preventative care (Karimi-Shahanjarini et al., 2019). These views were similar to the perspectives of physicians who also preferred nurses to complete 'non-medical' roles (Karimi-Shahanjarini). Moreover, the systematic review highlighted a number of factors that would support the successful implementation of doctornurse role substitution including better training and supervision, clearly defined roles, adequate referral systems, physicians' trust and acceptance of the expanded nurse role, better working conditions and financial incentives. Some nurses reported a struggle to communicate with physicians, while physicians appreciated collaborating with nurses when it reduced their own workload (Karimi-Shahanjarini et al., 2019).

Rationale for this study

In order to get a full picture of what is happening in practice, the perspectives of nurses will be explored in this qualitative chapter. It is also important to explore the views of other practice team members regarding all types of roles who may undertake role substitution or be involved in its implementation.

Aim

This chapter addressed the following research question:

5. How do patients and general practice team members feel about role substitution within their practice?

Objectives

- 1. To explore the barriers and facilitators to the acceptability, suitability and appropriateness of role substitution in general practice.
- 2. To assess the views of patients and general practice team members regarding the different types of non-medical health professionals and AHPs that now complete some roles that were previously completed by GPs in the past
- 3. To identify the views of patients and general practice team members regarding role substitution and treating complex cases in general practice.
- 4. To explore the views of patients and general practice team members regarding patient navigation to different health professionals
- 5. To explore how role substitution may affect or may be affected by external factors such as factors relating to the practice or healthcare system.

Methods

Qualitative research methodology was chosen as the most suitable methodology for this study as the purpose was to investigate the views and perspectives of role substitution in primary care and to uncover new insights that have not previously been explored in previous studies (Creswell and Poth, 2016). Qualitative research is particularly relevant for assessing and improving quality of care in the NHS (Chapman, Hadfield and Chapman, 2015). In addition, qualitative methods are useful for exploring the feasibility, acceptability and implementation of new interventions within clinical practice (Nelson et al., 2017). This study formed stage two of the mixed method, sequential explanatory design conducted in this thesis and the sampling approach and topic guides were informed by the BIA study presented in Chapter 5 of this thesis (further information is provided below).

Setting

Participants were recruited from two general medical practices in North Wales and were the same two practices that were recruited for the BIA study presented in Chapter 5 of this thesis. The practices were selected to provide examples of two very different models of primary care organisations. In order to protect the anonymity of the practices, the practices will be cited in this thesis as Practice A and Practice B. Practice A is situated in a large seaside town with a large retirement population from England. Practice A has approximately 22,000 registered patients and is directly managed by the local health board. Practice B is situated in two small seaside towns with a practice population of 7,600. Practice B is smaller than practice A and uses the more traditional partnership model. Interviews with the primary care team members were conducted in the general practice surgeries and patient interviews were conducted in the privacy of the patients' homes. Patients were also offered the option of conducting the interview at an alternative venue if they preferred.

Purposive sample

This study aimed to recruit a purposive sample of up to 20 patients and up to 10 health care team members (non-medical health professionals, AHPs, GPs and receptionists) from two general practices in North Wales (please see Table 15 for the planned patient sample matrix). The justification for interviewing more patients than health care team members was because

it was expected that patients would bring forward more differing views and perspectives regarding the topics outlined in the study objectives e.g., complex cases in terms of number of chronic conditions. Purposive sampling was used to obtain a diverse sample of 'information rich' cases that might have different views regarding role substitution in primary care (Patton, 2002). Purposive sampling is a form of non-random sampling whereby the researcher makes deliberate choices regarding potential participants due to the qualities or attributes the participant possesses (Etikan, Musa, and Alkassim, 2016). The purposive sampling technique is often used in qualitative research to ascertain specific types of participants who are able to elucidate a specific phenomenon of interest (Robinson, 2014)

As both the BIA and qualitative exploration used the same two practices as case studies, the findings from the BIA were used to inform the purposive sampling criteria. The BIA findings provided information on the different types of non-medical and AHPs roles that were being employed in the two general practices which were used to determine who could then be approached to participate in the qualitative interviews. The purposive sampling criteria for the patient sample were the frequency of visits to the surgery and the complexity of cases according to a frailty score generated by the practices' computerised records' databases (detailed description below). Complex cases were defined as patients who had multiple co-morbidities (Table 16). Multi-morbidity was defined as the "co-occurrence of three or more chronic conditions affecting three or more different body systems within one person without defining an index chronic condition" (Harrison et al., 2014, p.8). Patients with multiple chronic conditions experience poor quality of life, disability, psychological issues and an increased risk of mortality (Vogeli et al., 2007; Zulman et al., 2015). Patients with multi-morbidities have multiple needs and utilise a large number of resources within the healthcare system (Goodwin et al., 2013); therefore, it is expected that patients with multimorbidity will consult with a variety of different healthcare professionals within general practice. It is important to note that the definition of complex cases provided above and used as the criteria to obtain this sample, does not provide a full explanation of what may be considered as complexity in practice. Complex cases can also be used to describe patients who may also be experiencing social and emotional issues as well ill-health.

Frequent attenders can be defined as patients who attend general practice one or more times per month (Jiwa, 2000). Patients who are frequent attenders present at general practice with a variety of problems. There is some contention around the use of the term 'frequent attenders' with the suggestion that it may be perceived negatively (Morriss et al., 2012). For

consistency with other relevant literature (Dowrick et al., 2000; Jiwa, 2000), the term 'frequent attenders' is used in this study in order to indicate a higher number of visits rather than a misuse of services. Frequent attenders may fall into a group of patients who require a general need for medical care or may comprise a group who present with a variety of other issues such as psychosocial problems (Dowrick et al., 2000). Some frequent attenders at general practice have been described as 'problem patients' or 'difficult patients' defined as patients who frequently attend general practice and present a variety of different symptoms often lacking a physical pathological explanation (Jiwa, 2000). 'Normal attenders' can be defined as patients who attend general practice between 6 and 22 times in a 2-year period (Morriss et al., 2012). For the purpose of this study, occasional attenders were defined as patients who attend their general practice once or twice per year (Table 17). Frequency of attendance as a purposive sampling criteria was chosen as it was expected that patients who attend more often may have different experiences compared with those who attend less frequently, both of which are important for capturing a diverse range of views regarding role substitution.

The age and gender of the sample was monitored. Richie and Lewis advise that the banding of age ranges should be evenly distributed if it is not known how age might impact the perspectives of participants with respect to the subject matter e.g., 18-29, 30-44, 45-59, 60-79 and 80+ (Richie and Lewis, 2003). These age bands were used in this study in order to monitor whether there was an age-imbalance in the sample and to assist recruitment. Patients included in the sample must have attended general practice within one year of the study start date (01.02.19) to ensure that their experience was recent enough to accurately recall. Please see the sample matrix plan below.

Table 15: Planned patient sample matrix (sampling target number of cases and monitoring criteria)

Attendance at GP	Simple cases	Moderate cases	Complex cases	Age across attendance group:	
Occasional attenders	3-4	3-4	3-4		
Normal attenders	3-4	3-4	3-4		
Frequent attenders	3-4	3-4	3-4		
No. to achieve across all types of attenders (N=20):	6-7	6-7	6-7		
Sex across type of case:					
Male					
Female					

Note: greyed area indicates monitoring criteria while inner matrix cells were used as purposive sampling criteria.

Table 16: Categorisation of simple, moderate and complex cases based on number of chronic conditions

	Simple	Moderate cases	Complex cases
			(multi-morbidity)
Number of chronic	0	1-2	3 or more (affecting
conditions			3 or more different
			body systems)

Table 17: Categorisation of occasional, normal and frequent attenders based on the number of attendances at general practice per year

	Occasional attenders	Normal attenders	Frequent attenders
Number of GP	1-2 visits per year	3-11 visits per year	1 or more visits per
visits			month

Recruitment and recruitment materials

The purposive sampling criteria was given to the practice management teams who then identified patients matching the criteria from their patient records. In accordance with Welsh law, all recruitment materials were issued in both Welsh and English. BFA (PhD candidate) did not have access to any patient lists or patient information from the practice.

Patients

Patients were invited to take part in the study by a letter sent through the post from their general practice. The invitation letter (Appendix 12) contained a participant information sheet (Appendix 13) and reply slip (Appendix 14). Contact details (email and telephone number) were provided in the invitation letter so potential participants could contact the researcher if they wished to take part in the study, or if they wanted to discuss any aspects of the study before agreeing to take part. Alternatively, they could return a reply slip (Appendix 14) by handing it back to their general practice. Invitation letters were sent out in batches of 20 letters to monitor the sample and to prevent too many responses from patients wishing to take part that could not have been processed due to the time constraints of this study. BFA (PhD candidate) arranged an appointment with a member of the practice management team two weeks after the first batch of invitation letters had been sent out to review the level of uptake. This process was repeated after subsequent batches of invitation letters were sent out. BFA also regularly checked her email address and mobile phone device to monitor any responses sent via email or text message.

Primary care team members

Team members were invited to take part by a letter given to them by the practice manager at their place of work. The sample of healthcare professionals was selected from a list of the primary care team members provided on the practice webpages and a list of roles provided by the practice management team. The aim was to achieve a sample of different primary care team member roles. Invitation letters were then be passed on to the team member identified by the purposive sampling criteria by the practice manager. The invitation letter (Appendix 15) included a participant information sheet (Appendix 16) and reply slip (Appendix 14). Contact details (email and telephone number) were provided in the invitation letter so potential participants could contact the researcher if they wanted to take part in the study or required any further information. Alternatively, they were able to return the reply slip (Appendix 14) by handing it back to their place of work. Invitation letters to team members

were also sent out in batches to monitor the sample and to prevent too many responses from team members wishing to take part. Invitation letters were given out in batches of approximately ten letters until the sample of ten health care team members had been obtained.

Ethical considerations

In order to ensure that participants were fully informed, participants were given a participant information sheet (Appendix 13 and 16) and were given the opportunity to ask questions regarding the study. Written informed consent was taken from each participant (see Appendix 17 and 18 for consent forms). Each participant was given two copies of the informed consent form to sign, one was kept by the researcher (BFA) and the other was given to the participant. All patients who participated in the study consented for their GP to be notified of their participation (Appendix 19). Ethical approval was sought from the research ethics committee of the School of Healthcare Sciences in Bangor University and the NHS Research Ethics Committee (Wales REC 5). Please see Appendix 20 for the HTA and Health and Care Research Wales (HCRW) approval letter for this study.

Although it was not expected that contentious or upsetting subjects were likely to be discussed with participants, the PhD candidate (BFA) was aware that participants may raise them during interviews. For example, in the interview with participant PM3, the interview was stopped when he became upset when recalling an experience from his past and therefore, the recording device was stopped, and he was asked if he wanted to terminate the interview at that point or continue after having a break. In this instance, participant PM3 decided that he wanted to continue with the interview.

The PhD candidate (BFA) followed the Bangor University lone working policy to minimise risk when working out of hours and/or off campus when conducting interviews at the general practices and at patient homes (Appendix 21).

Confidentiality and data protection

All personal information was kept confidential and remained on the practice's computerised record database. BFA (PhD candidate) did not view or have access to the practice databases. In order to maintain confidentiality and anonymity, each participant was given an identification code from the outset and no personal or identifying information was used in any of the transcripts or in the write-up of the results of this chapter. Furthermore, particular

care was taken in the use of quotes taken from the interview transcripts and any quotes that were easily identifiable were not used. Before any audio recordings of the interviews were passed on for transcribing, the transcriber signed a confidentiality agreement (Appendix 22). The data was then transferred from the transcriber to BFA (PhD candidate) using a password protected Drop Box and stored on the encrypted M: Drive and U: Drive and was password protected, ensuring strict adherence to the Bangor University IT Systems and data protection policy.

Data collection

Interviews were selected as the chosen method of data collection as this method provides the opportunity to collect in-depth individual experiences from a diverse range of patients and team members on a one-to-one basis rather than other qualitative methods such as focus groups which may be affected by group dynamics. Focus groups were not considered as an appropriate fit for this study as participants may be reluctant to voice their views on the matter of role substitution in a public setting (Nyumba et al., 2018). Patients may bring up sensitive issues relating to their own health when discussing their views of role substitution and team members may want to discuss factors that they do not wish to divulge with colleagues, therefore one-to-one interviews were deemed the most appropriate method of data collection for this study. One-to-one interviews allow the researcher to ask open-ended questions and use probes to gain an in-depth understanding of patient and providers' experiences, opinions and knowledge of role substitution in practice (Rosenthal, 2016). Data was collected from individual face-to-face semi-structured qualitative interviews conducted at the general practices (for team members) or in the privacy of patients' homes, however the option of using an alternative venue if preferred by the patient was offered to all patient participants; however, none of the patients recruited in this study wanted an alternative venue. Interviews lengths varied between patients and team member groups with approximately 1.5 hours allocated for patients and 1 hour allocated for team members.

The topic guide for the interviews was informed by the systematic review of qualitative evidence on the topic of role substitution in primary care (Chapter 3). The information learnt from the BIA study (Chapter 5) regarding the types of health professionals employed in the practices was also used to inform the topic guide. The BIA builds a picture about the staffing at the practices which meant that the interview topics could then be framed around the different types of professions i.e., physiotherapists treating complex issues. Topic

areas were similar for both patients and team members; however, topics for patients focused on their perspectives regarding the receipt of role substitution (Appendix 23), whereas topics for team members focused on the delivery of care within the context of role substitution (Appendix 24). After the first few interviews, the topic guide was adapted in an iterative fashion (Barbour, 2013). Each interview was digitally recorded with permission, transcribed verbatim and analysed.

Analysis

Thematic analysis has been widely used in qualitative research (King, 2004). It offers a foundational method to support qualitative research analysis and provides a structure useful for novice researchers new to qualitative research (Braun and Clarke, 2006). The added value of thematic analysis allows the researcher to explore depth and richness, discuss themes, explore similarities and differences, and generate unanticipated and complex insights (Nowell et al., 2017) and therefore this method of analysis was deemed particularly relevant to the complex nature of role substitution.

Thematic analysis is particularly useful as it follows a well-structured approach and allows researchers to summarize key components of large data sets (King, 2004). There is no agreed method on how researchers can rigorously apply the method, with substantial variation in approaches taken in thematic analysis (Braun and Clarke, 2006). However, it is commonly regarded as a flexible approach that can be adapted in line with a study's context and research objectives. With this strength of flexibility comes the opportunity for researcher reflexivity and interpretation which are key factors to consider when conducting qualitative research. Researchers are not generally 'neutral' about their research area as their own experiences, beliefs and judgments will affect their interpretation of findings (Nelson et al., 2017). Reflexivity is the continuous process of self-examination in which the researcher 'turns the lens on themselves' to acknowledge their own 'situatedness' and 'positionality' within the research field, and who they are in relation to the research participants (Berger, 2015). In order to ensure rigour and minimise bias in qualitative research it is important that the researcher considers their position as an insider or outsider with respect to similarities or differences with the study participants and research context (Dodgson, 2019).

Reflexivity statement: I (PhD candidate) am a 31-year-old female with no previous experience of working in clinical or healthcare settings. I grew up in a relatively deprived area of North Wales (based on the Welsh Index of Multiple Deprivation) where factors such

as income, health, housing, community safety and access to healthcare services were issues. Although I have no serious health issues myself, I have had personal experience of ill-health as both of my parents had long term health issues that they suffered with since I was a child. The importance of good healthcare services and patient voice and experience is therefore very important to me. During each stage of this qualitative research, I acknowledged that my views and beliefs could possibly bare similarities to some of the patients, this was a conscious thought process that I reflected on but I did not make an audit trail of these reflexive practices during the course of this qualitative study. Although it is acknowledged that one's own personal beliefs, judgements and experiences may impact the interpretation of the results, I made conscious efforts to be mindful of this when conducting and analysing the qualitative interviews.

Framework analysis

The qualitative interviews were analysed using the Framework approach (Richie and Spencer, 1994), which is a widespread approach used for the thematic analysis of semi-structured interviews (Gale et al., 2013). The Framework method of qualitative analysis is a systematic, five-stage matrix that offers the option for both theme-based and case-based analysis (Dixon-Woods, 2011). It seeks to identify commonalities and differences in the interview transcripts and explores the possible relationships between different elements of the qualitative data, in order to derive descriptive or explanatory findings brought together around the themes (Gale et al., 2013). The Framework analysis was a good fit for this study, as it is a method that is widely used in healthcare research (Gale et al., 2013), and can be used to bring together a diverse range of patient and provider experiences within a primary care setting. Moreover, this method of analysis is noted for its transparency, clarity, and suitability for policy and applied research (Ward et al., 2013). It provides a clear visual matrix structure that facilitates the generation of themes by making comparisons within and between cases (Gale et al., 2003) and its systematic and rigorous approach offers flexibility and an audit trail (Ward et al., 2013).

The first stage of the analysis involved familiarisation of the data whereby each interview transcript was read carefully in order to become reacquainted with the data and alerted to early themes. The second stage involved identifying a thematic framework where key themes, categories and issues/discussion points from the transcripts, which were identified to form a coding structure (Richie and Lewis, 2003). The purpose of this stage was

to produce a detailed index of the data (Appendix 25) in order to categorise the data into manageable chunks of information which can later be retrieved and explored during the later stages of analysis (Pope, Zieband and Mays, 2000).

The index was developed both deductively from preconceived themes based on existing knowledge learnt from the systematic review of qualitative studies (Chapter 3) and inductively whereby additional themes emerged from the qualitative data (Gale et al., 2013). This combined approach allowed the researcher to firstly approach the data with preconceived themes based on the existing knowledge of the topic and then also explore the data to determine additional index categories (Smith and Firth, 2011).

The third stage consisted of applying the index to all the data by annotating (or tagging) the data from each of the transcripts with the numerical codes from the index. The fourth stage of analysis was charting, which involved synthesising the data and thematic framework to form charts. This stage involved summarising the data, whilst keeping its richness, context and the type of language used, and then inserting it into a thematic matrix (Ritchie and Lewis, 2003). Please see Appendix 26 for an example of a thematic matrix/chart that was used in analysis of this chapter. The final stage of the Framework analysis was the interpretation stage which involved deep exploration through the charts to "define concepts, map the range and nature of phenomena, create typologies and find associations between themes with a view to providing explanations for the findings" (Pope et al., 2000, p.116). The index was used to construct charts, with each main category and its related sub-categories plotted on a separate chart. Each of the sub-categories within each main category chart were allocated a column. Each participant was then allocated a row on the chart and the row location for each participant remained the same for each of the charts. Following the construction of the charts, the process of summarising the data into the relevant cells of the matrix was undertaken while preserving the context of the data and the language in which it was articulated by the participant. Please see Appendix 27 for an example of a major category interpretation exercise. The qualitative research presented in this chapter was informed by the COREQ checklist for the reporting of qualitative interviews (Tong, Sainsbury and Craig, 2007).

Results

Interviews were conducted between 21st June 2019 and 22nd November 2019. Eleven patients and ten primary care team members were interviewed across both practices. Eight patients

were recruited from Practice A and three from Practice B (Table 18 for details of patient characteristics). The purposive sampling was intended to be used until data saturation had occurred, with a sample of up to twenty patient participants. Due to difficulties in the recruitment process, including a low response rate to the batches of study invitation letters and difficulty engaging with the busy practice managers to arrange the distribution of the letters, we achieved a final sample of eleven patient participants. Nevertheless, despite achieving a lower target sample size than originally planned, data saturation was achieved as no new themes emerged after the first eight patient transcripts. Thematic data saturation can be defined as the point in which bringing in further participants will not obtain or identify new insights or themes from the data (Strauss and Corbin, 1994).

Table 18: Total final sample of patients achieved

	Practice A	Practice B	TOTAL
Men	1	3	4
Women	7	0	7
30-44	0	1	1
45-59	1	0	1
60-79	6	1	7
80+	1	1	2
Simple cases	0	1	1
Moderate cases	6	2	8
Complex cases	2	0	2
Occasional attenders	2	1	3
Normal attenders	4	1	5
Frequent attenders	2	1	3
TOTAL	8	3	11

Five primary care team members were interviewed in each of the practices (N=10). These included nurses, a pharmacist, non-clinical patient navigators (team coordinators), an OT and a practice manager. Please see Table 16 for details regarding the specific roles of the team members interviewed in this study.

Table 19: Total sample of primary care team members achieved across both practices

	Number of each practitioner
Practice nurse and clinical governance manager	1
Nurse practitioner	3
Team coordinator	2
Occupational therapist	1
Clinical pharmacist	1
General practitioner	1
Practice manager	1
TOTAL	10

Note: data is condensed across both practices both practices to ensure team member anonymity

Due to the small sample size of the participants interviewed in this study, details of the practices and specific roles of the team members have not been included in the results section below in order to maintain confidentiality and anonymity of the participants interviewed in this study. Consequently, views elicited from the interviews have been described in the results below as either 'patient views' or 'primary care team member' views.

Structure of the findings

This chapter has been structured in order to explicitly respond to each of the research questions to ensure that each question is adequately answered. The findings from the interviews have been structured under the following sub-headings:

- 1. **Role substitution in general** (relating to study objectives 1 and 3).
- 2. **Nurses** (relating to study objectives 2 and 3)
- 3. **Pharmacists** (relating to study objectives 2 and 3)
- 4. **Occupational therapists** (relating to study objectives 2 and 3)
- 5. **Physiotherapists** (relating to study objectives 2 and 3)

- 6. Factors relating to the team members, practice and wider healthcare system (relating to study objective 5)
- 7. **Factors relating to the patient** (relating to study objective 1)
- 8. Patient navigation by care navigators and team coordinators (relating to study objective 4)

Themes are discussed in detail in the following sections under each major sub-section heading. Some themes appear relevant under more than one sub-heading section, for example some themes that were relevant for nurses were also relevant for pharmacists. The results end with a synthesis of main themes across sections to highlight where repeated themes occur across professional groups and sub-sections, and where shared learning may have important implications.

General views of role substitution

The following section explores the general views of role substitution with respect to two of the study objectives: the barriers and facilitators to the acceptability, suitability and appropriateness of role substitution in primary care (**study objective number 1**), and the views and opinions relating to role substitution with respect to complex conditions (**study objective 3**). In order to answer the study objectives, results within each section highlights both major and sub-themes that were extracted from the data. Some of the themes discussed in this section are repeated in later sections and synthesised in full at the end of the results section of this chapter. It is important to note that views described under this 'general views of role substitution' section do not specifically relate to a certain type of practitioner in particular. Some of the views that were voiced were not related to a particular role, therefore this section provides general views relating to role substitution and different practitioners as a collective who may be working as substitutes for GPs in primary care. Views relating to specific roles are presented further down in this chapter under the 'breakdown of different healthcare practitioners' section.

Added value of alternative roles to GPs in primary care and opportunities for growth

When asked about their general views towards role substitution, patients and team members felt that bringing in more allied health professionals would provide added value to general practice as different practitioners bring forward their unique approaches, skills and expertise

to the practice. Moreover, some team members stated that some non-medical health professionals, AHPs and advanced practitioners may be more 'up-to-date' than GPs and may be better suited to complete some roles. In addition, some patients emphasised that GPs were *general* practitioners who have the ability to deal with all types of illnesses and conditions that come into general practice but may not have the expertise to know one area intimately.

"To be honest with you, I feel like when I go to the GP, I feel like they're a bit of a jack of all trades and a master of nothing"

(Patient, male, 30-44 years, occasional attender, simple case)

Patients and team members stated that using role substitution within their practice could potentially save time as patients would be able to see the most appropriate practitioner at their first point of contact.

Team members described how role substitution has given them the opportunity to develop and expand their roles, which in turn has led to a greater sense of autonomy and job satisfaction.

Most of the practice team members interviewed indicated positive views with respect to role substitution. Many team members felt positive and excited about role substitution and felt that role substitution was the way forward and a natural progression in primary care. This was reiterated by some of the patients interviewed who expressed that they were very happy with the changes that were happening within their practice and that they felt that general practice works better with new practitioners, as it opens up new services that were not previously available.

"I think it's opened up a whole world of different things, now, that you can do, especially in the practice. They're doing other things. It sounds like I'm trying to sell the place. You can also go and see a Citizens Advice person here. I don't know if you knew that"

(Patient, male, 60-79 years, frequent attender, moderate case).

Concerns about confusion for both staff and patients

A major concern amongst both patients and team members were that roles had become confusing to patients as a result of the increased number of different non-medical health professionals and AHPs that now work in general practice. Patients felt that there were too many practitioners and reported confusion about whom they had seen for consultations. Patients stated that they did not know what each practitioner was capable of doing. This was reiterated by team members, who also felt that the different job titles and roles of non-medical health professionals and AHPs were confusing for patients and suggested that this led to patient apprehension. This theme was strongly linked to a lack of information and patient education, which was highlighted as a sub-theme and as a potential facilitator for successful role substitution.

A lack of information as a barrier for successful role substitution: Both team members and patients felt that that patients do not have enough information about the different roles and scope of each role. However, some patients knew the roles because they had used the surgery often. Although it was mentioned by patients that the practitioner gives their name and job title to the patient at the beginning of the consultation, patients sometimes found it difficult to remember who they had seen. Many patients stated that they would like more information about what each practitioner can deal with and their level of training and qualification. Interestingly, a minority of team members were not aware of the full capability of some non-medical health professional and AHP roles.

"I think at the moment the roles are really confusing, they're confusing for everybody. You have such different roles with different names, you can't blame people for not really knowing what one role can do and another one can't."

(Primary care team member, female)

Despite this, patients and team members noted that information about the different roles of each practitioner within the practice was provided on the practice website and before the service changed (i.e. before the increased use of non-medical health professionals and AHPs within the practice). Patients noted that they had received an information pack/letter through the post. Team members' concerns about patients' confusion surrounding the different roles and capabilities of non-medical health professionals and AHPs was a strong theme.

Confusion surrounding job titles and opportunities for patient education: Team members felt that titles and similar uniforms led to confusion among patients. Enhancing patient education was mentioned by many of the team members interviewed. They highlighted the importance

of patient communication and education to empower patients to use the services efficiently. Some team members suggested the increased use of social media, and short video clips, to support patient knowledge surrounding the different roles and services that are now made available in primary care.

Confusion among the older generation of patients: Both patients and team members raised concerns about that the older generation of patients who may have found it difficult to deal with the changes occurring within their practices. This was confirmed by some of the older patients that were interviewed who stated that they did not like the confusion of not knowing what was happening when they visited the practice or who they were consulting with. This finding links with earlier points raised regarding confusion surrounding roles. Some of the younger patients stated that as younger patients they felt more comfortable and more able to adapt to the changes at their practices.

"So to begin with, it was confusing and I should imagine, to a lot of elderly people, that it is very, very confusing"

(Patient, female, 60-79 years, normal attender, moderate case)

Confusion on how best to use services: Team members were aware that many patients were still unsure of how best to use the services that was available to them and recognised that patient education was a major barrier to the acceptance and success of role substitution. They felt that patients still viewed the practice as a 'doctor's surgery' rather than a medical centre. This notion was supported by a couple of references made during the interviews about television advertisements often using slogans such as 'see your doctor' or 'visit your GP'.

"People are lost in the middle of it. We don't teach people how to use the NHS to its best. We don't teach people how the NHS functions. And so, what you're doing is, you're disempowering people all the time because they don't know. We assume people know because we know it, and they don't"

(Primary care team member, female)

Concerns about who is best placed in treating complex cases

There were some concerns from patients about non-medical health professionals and AHPs treating new symptoms and complex cases. Some patients stated that they would be very happy to see a non-medical health professional or AHP for complex cases, as long as the

practitioner was aware of their role boundaries and capabilities when treating the complexity. Team members also felt that it was acceptable for non-medical health professionals and AHPs to treat complex cases as long as they had the necessary skills and experience to deal with the issue, and that they had the opportunity to seek advice from a GP if needed. Some team members were concerned that some primary care practitioners could be exposed to situations that they were not capable of dealing with and may not be able to detect conditions that the GP would pick-up on. One of the practice team members interviewed stated that should they need to seek healthcare advice for mental health issues for themselves as a patient, they would prefer to see a non-medical health professional or AHP instead of a GP, as they often have more time with the patient and may offer a wider approach. Nurses, pharmacists and AHPs were considered by some team members as specialist practitioners, who tend to treat less complex cases in practice, but their contribution within primary care allows GPs more time to treat complex conditions. Time constraints as a barrier to treating complexity was highlighted by both patients and team members, who described the difficulties faced by GPs who normally were only afforded 10-minute consultations with their patients.

Patients and team members felt that different practitioners were suited for different purposes. Team members and patients felt that it was not always necessary for GPs, who are very qualified and knowledgeable, to deal with some of the work that they have been historically dealing with in general practice. In some instances, team members felt that non-medical health professionals and AHPs are better suited to complete certain roles over a GP and that they may in fact be more 'up-to-date' in some areas. On the most part, team members felt like they had clearly defined roles, and were aware of their limitations, but acknowledged that their roles were being rapidly extended.

Views relating to who is best placed to treat complex cases with respect to specific roles were discussed further below under the 'breakdown of different healthcare professionals' section.

Mixed views regarding the acceptability of role substitution: adapting to change

In the interviews, patients tended to take a neutral standpoint about the acceptability of role substitution. Some patients explained that they did not have a problem with seeing non-medical health professionals and AHPs instead of the GP. Other patients believed that they

just had to accept the changes that were happening in their practice. Some patients believed that role substitution was acceptable, so long as it was done correctly and that practitioners knew their limitations and received adequate training. Some of the team members interviewed admitted that there were mixed feelings about the acceptability of role substitution among patients but stated that some patients were slowly getting used to the new ways that primary care was being delivered.

"That is a change. That's a cultural change. But we'll always have that dilemma of the patient always wanting the GP." (Primary care team member, male)

Some patients were less positive with respect to increasing the number of non-medical health professional and AHPs within their practice and worried that it may lead to worse services, with some patients stating that the services had become impersonal and had lost individuality. Some team members and patients believed that role substitution was only being implemented within primary care in order to meet demand. Team members highlighted that patients need to be on board with the changes for role substitution to work successfully.

Difficulties forming sustained relationships with non-medical health professionals and AHPs: impacts on continuity of care

Patients felt it was difficult to develop relationships with their healthcare providers due to a lack of familiarity with the different team members within their practice. Patients stated that they would need to develop relationships over time by seeing the same practitioner, but sometimes this was not possible as some practitioners did not stay in their role long enough. Some patients did not feel that they have developed relationships with the practice team members as they did not attend the practice frequently enough. Patients and team members noted that confidence in healthcare providers was dependent upon individual characteristics rather than specific roles or job titles.

Difficulties forming relationships and a lack of familiarity with new professionals was also linked to concerns relating to continuity of care. Patients felt that trust and communication was hindered by seeing many different practitioners within the practice. Patients also stated that they were often unable to consult with the same practitioner and worried that they may not be aware of their full medical history. The issue of fragmented care

was also raised by some of the team members interviewed; however, they did feel that these issues would resolve over time if practitioners stayed within their roles. They also stated that patients' medical histories were accessible to each clinician and that they would not treat a patient before looking through their record.

Patients recounted when times were different at their practices where they were used to consulting with their family doctor who knew their medical history well. Team members believed that it may be the older generation of patients which had more issues with a lack of familiarity that they were used to in previous years with their family physician. This also links with issues raised previously in this chapter surrounding confusion of roles among the older generation of patients and a need for a culture shift among patients. Moreover, some team members stated that practitioners came to know the very complex patients who needed more attention and highlighted the importance of their MDT meetings to support continuity of care.

Breakdown of different health professionals

The following section of results explores the views and perceptions of patients and team members regarding the different types of non-medical health professionals and AHPs that now complete some roles that were previously completed by a GP in primary care (**study objective 2**). This section of findings has been categorised into the following subheadings: nurses, pharmacists, occupational therapists and physiotherapists. The views regarding whether it is acceptable for these practitioners to treat complex cases (**study objective 3**) is also discussed below in the following sections.

Nurses

Nursing roles are expanding

Team members felt that the implementation of role substitution within their practices has allowed nurses such as NPs and ANPs the opportunity to expand and develop their roles and skills and has enabled them to become autonomous practitioners.

Patients were aware that nurses' roles have expanded and that some nurses now complete a broader variety of tasks that were previously completed by GPs. Despite this, some patients stated that they would not specifically ask to see a nurse as they were unsure of

the full extent of what nurses could deal with. Moreover, team members reported that many patients were not aware that nurses work on different levels and that some nurses can diagnose, prescribe and refer.

"I think sometimes they're reluctant to see a nurse because they don't -. We've got nurse practitioners and they're reluctant to see the nurse because they don't realise that they can prescribe, they don't realise that they can refer."

(Primary care team member, female)

Many patients felt that nurses were better placed to complete some tasks that did not require a GP such as minor ailments, flu jabs, blood checks, lung and diabetes clinics. Some team members and patients referred to nurses as taking a holistic approach with their patients in terms of asking patients about their general wellness as a whole including any possible external factors, rather than just asking specific questions about their illness or condition alone. Some patients reported that nurses had prescribed medication to them previously, while others reported that the nurse had got the GP to come and prescribe treatment to them during their consultation. Team members felt that NPs and ANPs were very capable of prescribing medication as they were very knowledgeable with respect to their prescribing formulary and prescribing boundaries. They felt that nurse prescribers were equipped with enough knowledge to prescribe in primary care settings and could always seek advice from a GP if needed.

Confusion surrounding nurses' roles

In the previous major section under the 'general views of role substitution' category, a general lack of understanding of the different healthcare practitioner roles and capabilities was expressed by patients and team members. In addition to this, a specific lack of understanding of nurses' roles in particular was a strong theme identified from the interviews. Interestingly, some team members admitted to a lack of understanding regarding the full role capabilities of NPs and ANPs. According to both team members and patients, the different nurse titles and nurse uniforms added to the confusion surrounding nurse roles. It was reported by team members that both NPs and ANPs wore similar blue uniforms and that they could be confused with other practice team members that also wore blue uniforms such as phlebotomists and healthcare assistants. Additionally, team members mentioned that dropping the 'nurse' title might reduce some of the barriers that nurses experienced with

patients with respect to confusion surrounding nurses' roles. A possible alternative title to describe ANPs such as 'advanced clinical practitioners' was suggested.

"When you say "advanced nurse", most people don't even hear the word "advanced", they just hear "nurse". They don't know what that nurse is capable of doing".

(Patient, female, 60-79 years, normal attender, moderate case)

Increased role responsibility of nurses and working closely to guidelines

Team members recognised that expanding nurses' roles would consequently lead to more responsibility. However, team members and patients were confident that nurses would ask GPs for advice when needed. Team members felt that nurses would always ask for a second opinion from a GP if they were not certain of the correct path to take with patient care. Team members reported that nurses work closely to the Nurse and Midwifery Council (NMC) guidelines. Team members felt that GPs take many more risks as opposed to nurses who were described as 'risk averse'.

Nurses should only treat complex cases if they possess the necessary skills and expertise

Views about whether nurses should treat patients with complex conditions were generally positive. Most patients felt that it was appropriate for nurses to treat complex cases provided that they had the necessary training and expertise. This theme was also reported previously under the previous major category (general views of role substitution), where the importance of training and expertise was noted as an important factor when considering the acceptability of non-medical health professionals and AHPs treating complex cases. Some patients believed that some nurses have specific expertise in specific areas and therefore may be better placed than a GP to treat some conditions. It was mentioned that some of the nurses working within the practices specialised in diabetes and respiratory care. This view was echoed by the team members interviewed, who also felt that nurses know their patients well and were very capable of making decisions relating to complexity. Team members believed that nurses would always consult with a GP if they were unsure of what action to take with a patient, which links with separate sections of findings relating to team working. In parallel with patients views on this topic discussed above, nurses stated that they were happy to treat

patients with complex conditions as long as it was within their remit and they received adequate support. This supported the views of some patients discussed under the 'role substitution in general' section, who felt that dealing with complexity was acceptable, as long as the practitioner was aware of their role boundaries and capabilities. Only one patient felt that complex conditions should be reserved for the GP as they felt that the GP would have superior knowledge than a nurse. Some team members felt that the ability to treat complexity came with experience and knowledge.

Mixed views on nurses treating new and worrying symptoms: Some patients were not comfortable seeing nurses for new and worrying symptoms. They expected the GP to make diagnoses and felt that nurses would not be able to diagnose conditions that the GP could. Other patients felt that they would be happy seeing a nurse for new or worrying symptoms as long as the nurse had the appropriate knowledge and training and they could ask the GP for a second opinion, if needed. This finding related to the importance of training and teamwork, discussed previously in this chapter. Some team members were very positive about nurses treating new and worrying symptoms as they felt that nurses were able to communicate well with patients and felt that the GP was not needed in some cases as they might know more about certain conditions and bring forward new perspectives.

"So I think it's good to have fresh eyes on something" (Primary care team member, female)

One team member stated that they had previously been referred inappropriate cases that they were not comfortable dealing with such as chest pain and suspected appendicitis. Some members felt that the GP would be better placed to treat complex cases, if it was not an area that a particular nurse worked within. Two patients stated that they would rather see a nurse than a pharmacist for worrying symptoms.

Nurses develop good relationships with patients

Many of the patients interviewed reported positive past experiences with nurses. While some patients stated that they would prefer a GP consultation instead of a nurse appointment as GPs had superior knowledge, training and experience over nurses, others described how they would be happier speaking with a nurse compared with a GP in some instances. Patients

described feeling comfortable speaking with nurses about personal issues, and that it was easier to develop good relationships with nurses as they were good communicators who 'get to know' their patients at their level. This opinion was echoed by the team members interviewed, who described nurses as knowledgeable and approachable practitioners. This contrasts with the findings under the 'role substitution in general' section, where some patients voiced difficulties forming relationships and a lack of familiarity with new professionals.

Nurses were described as hard working and knowledgeable practitioners by patients and team members. Additional benefits of nurse consultations compared with GP consultations that were noted by patients and team members included longer and more available appointments.

Pharmacists

Pharmacists are considered as medication experts

Both patients and team members agreed that pharmacists were experts in medications, and some believed that pharmacists had superior knowledge of new medications compared with GPs. Many patients recounted helpful experiences of seeing a pharmacist for medication reviews. Medication reviews conducted by pharmacists were described as 'thorough' by team members. Other roles of the pharmacists cited by team members included hypertension clinics and helping patients with their medications, for example, showing them the correct method of using asthma inhalers. Some team members believed that pharmacists performing these roles in general practice relieves some of the demand on GPs. Moreover, some team members felt that pharmacists were well suited for polypharmacy due to their knowledge of medications and drug interactions. Pharmacists were described by both patients and team members as knowledgeable and competent practitioners; however, there was also a team member view that some practitioners working within their team were not fully aware of the capabilities of the pharmacist role.

"They've got the knowledge. That's their speciality, isn't it, which is what I've been saying. They're the specialist pill lady or pill person"

PF2, female, 60-79 years, normal attender, complex case

Some of the team members interviewed felt that role substitution has allowed pharmacists to expand and develop their roles. A minority of the patients interviewed stated that they were unsure of the pharmacist role within the practice. Moreover, some team members believed that patients were confused by the difference between community pharmacists and the role of the pharmacist working in the practice providing face-to-face consultations.

Confusion regarding pharmacists' prescribing authority

There was some confusion among patients regarding pharmacist prescribing. Some patients did not know whether pharmacists were qualified to prescribe and felt that the prescribing role should be reserved for the GP, while others felt that pharmacists were able to prescribe some medication that has already been prescribed by a GP. A few of the patients interviewed recounted experiences whereby the pharmacist had picked-up or discussed medication contraindications. In addition to this, some patients and team members highlighted the importance of communication between the pharmacist and GP when it comes to medication prescribing. Some team members and patients described pharmacists as cautious prescribers who work closely in-line within their scope of practice and the prescribing guidelines.

Concerns about the role of pharmacists when dealing with complex cases and new or worrying symptoms

Some patients and team members felt that it was appropriate for pharmacists to treat patients with complex cases as they are likely to be patients who are taking multiple medications. Furthermore, team members affirmed that complex cases were dealt through a MDT approach therefore the pharmacist would not be solely responsible for caring for patients with complex conditions. On the other hand, a couple of patients were unsure whether pharmacists had a role in treating complex cases and were unsure of their limitations.

With respect to worrying or new symptoms, some patients stated that they would want to see the GP. They felt happy to consult with pharmacists for minor problems but did not feel confident that the pharmacist could diagnose illnesses. Team members believed that the pharmacists' role does not include making new diagnoses as their role is to help patients with

their medication once a diagnosis has already been made. They felt that the pharmacist would consult with a GP if a patient presented with worrying symptoms.

"I don't feel like our pharmacist deals with new diagnoses. Once someone has been diagnosed with a blood pressure problem or diabetes problem, they're really good in helping with their medication because they're more aware of new medications" (Primary care team member, female)

Pharmacists are helpful additions to primary care teams and communicate well with their patients

Pharmacists were viewed as helpful additions to the practice by patients and team members. Benefits of the pharmacist consultation included in-depth medication reviews due to the fact that they have longer consultations which allows time for patients to talk about their medications with the pharmacist. According to team members, patients feel reassured when speaking with the pharmacists about their medication.

Patients and team members felt that pharmacists make conscious efforts to get to know their patients. Patients stated that they were happy speaking with a pharmacist and felt that they were able to develop good relationships with the pharmacists at their general practice. This contrasts with previous findings under the 'role substitution in general' section that reported difficulties forming relationships and a lack of familiarity with new professionals. Team members had good working relationships with pharmacists and would often go to the pharmacist for advice regarding medications.

Team members felt that some pharmacists are well placed to consult with patients directly, face-to-face as many pharmacists would be accustomed to dealing with patients when working as community pharmacists. It is worth noting that when asked about pharmacists working in their practices, some of the patients interviewed had not seen a pharmacist at their surgery and instead voiced experiences that they had with a community pharmacist. Those who spoke about community pharmacists said that they had good relationships with the community pharmacist and would use their services for minor ailments.

Patients stated that they were always able to access the pharmacist when they wanted to discuss their medications. They were happy that they could speak with the pharmacist over

the telephone and recalled past experiences of the pharmacist telephoning them back when they needed. Team members stated that it was quicker for patients to speak with the pharmacist over the phone instead of waiting for a telephone call from a GP, they felt that this also helped to unburden GP workload.

Occupational therapists

Previous sections of this chapter discussed nurses and pharmacists; this section now moves on to views relating to OTs working in primary care teams. It is worth noting that many of the patients interviewed had not seen an OT and were not aware of the role of the OT working within primary care. Consequently, most of the views elicited from the interviews regarding OTs were provided by the team members interviewed.

OTs are well suited for mental health consultations

Some of the patients interviews that elicited views relating to the OT role described the OT as a practitioner who can help with mobility issues. OTs were described by team members as having a large degree of experience in mental health and because of this, team members felt that patients were better placed seeing the OT instead of the GP if they were experiencing mental health issues. Moreover, the team members stated that patients can be booked in for an hour consultation with an OT which allowed them time to have in-depth discussions with their patients to help get to the source of the problem whether that may be bereavement, loneliness and social isolation or linking them up with support groups. If needed, OTs could refer their patients to the GP if a route of medication prescription if required and could refer serious mental health problems to the community mental health team. Further OT roles described by the team members interviewed included home visits, helping patients with activities of daily living (ADLs), supporting patients to manage stress, anxiety and their social and emotional wellbeing, as well as helping them manage their home-life. Team members viewed OTs as invaluable practitioners who could significantly benefit patients' lives by helping them manage and take responsibility of their own health. Moreover, team members felt that OTs helped reduce GP demand as mental health takes up a large proportion of the primary care workload.

OTs are well placed to treat patients with complex needs involving social and emotional issues

With respect to complex cases, team members felt that OTs were well placed to see some patients with complex cases as complexity could often include social and emotional issues rather than just the presence of multiple chronic conditions. On the other hand, when it comes to treating patients with new and worrying symptoms, OTs were not viewed by team members as practitioners who could deal with medical problems and were concerned about the possibility of missing red flag symptoms. Despite this view, one team members recalled a couple of past experiences where patients were given medical diagnoses (including a rare joint condition) following their consultation with an OT, as the OT had spent a good amount of time discussing their symptoms with them and was then able to discuss with a GP. They believed that their symptoms were missed by GPs who were only afforded ten-minute consultations with their patients.

OTs were welcome additions to primary care

OTs were regarded by team members as extremely valuable and important additions to primary care. Some team members did however feel that some patients were resistant to see an OT to begin with as they wanted to see a GP for issues around mental health.

Nevertheless, when reflecting on past experiences of receiving feedback from patients following an OT consultation, team members stated that many patients had valued the time they had received during in-depth, constructive conversations with the OT.

Although most of the patients interviewed had not consulted with an OT at their general practice, they did feel that having an OT available at their practice was a worthwhile addition. One patient valued the option of seeing an OT who could take the time to explore options rather than taking the medication route for depressive symptoms that he felt often happened during consultations with a GP.

Confusion regarding the OT role

In parallel with findings discussed previously in this chapter relating to confusion of roles, a strong emerging theme during the interviews was a lack of understanding of the OT role, because they were new additions to primary care. Most of the patients interviewed did not have knowledge of the OT role as they did not have any past experiences of consulting with one. This was also true for some of the team members interviewed who did not seem to have much knowledge of the OT role as some of the team members did not have an OT working within their practice. As discussed previously in this category, some of the team members felt that patients were not aware that OTs deal with mental health issues and mainly viewed them

as practitioners that help with mobility which demonstrated confusion surrounding the OT role.

"OTs are fine if you can't move and you can't do anything to come and assess you and see what you can do"

(Patient, female, 80+ years, occasional attender, moderate care)

"But people do think OT is, "Oh, it's just therapy, isn't it? Keep people occupied."
But no, they do massive amounts"

(Primary care team member, female)

Physiotherapists

Most of the patients interviewed had not seen a physiotherapist in the past and therefore were not fully aware of the role of the physiotherapist working within primary care. Only two of the patients interviewed had direct experiences of consulting with a physiotherapist in the past.

Physiotherapists are specialists in musculoskeletal problems

All of the primary care team members and patients who discussed physiotherapists during their interviews described physiotherapists as specialists in musculoskeletal (MSK) problems who had good knowledge of the human body. Some patients and team members stated that they would prefer to see the physiotherapist rather than the GP for joint problems.

The patients who had seen a physiotherapist in the past, recalled that the physiotherapist had prescribed certain exercises to help with their MSK problem. Some patients recounted positive experiences with the physiotherapist and stated that their pain had been significantly improved following a physiotherapist consultation. However, another patient did not feel that the exercises prescribed by the physiotherapist were useful for improving their joint condition and did not feel that they would have just been recommended exercise by the GP.

One of the patients interviewed felt that physiotherapists were able to deal with more than just MSK and recalled an experience whereby the physiotherapist had helped a family member with their breathing. Some of the team members interviewed noted that advanced

physiotherapist practitioners were independent practitioners who can diagnose, treat, prescribe, administer joint injection and refer patients for X-rays. Moreover, team members highlighted that the physiotherapists working within their practice were able to access patient records to see the whole picture of their patients.

Complex conditions and worrying symptoms were not deemed appropriate for physiotherapist consultations

With respect to complex conditions (also discussed in previous sections), some patients stated that they would not be happy seeing a physiotherapist for complex conditions or worrying symptoms. Concerns regarding this were also echoed by a team member who was not sure if physiotherapists should see patients with complex conditions, but did feel that the physiotherapist would be able link the patient up with the appropriate practitioner if they were to receive a patient with complex conditions for consultation.

Physiotherapists could reduce GP workload

Team members highlighted that a significant proportion of primary care workload is MSK; hence the addition of the physiotherapist to deliver primary care was deemed as very worthwhile. They felt strongly that the inclusion of physiotherapists within their practices would not only reduce GP workload, but would also reduce patient waiting times and help ease the backlog into secondary care.

"I reckon around 20 to 22 percent of consultations will be around pain, skeletal-type pains. If we can remove those away and pathway them straight into MSK then that works really well"

(Primary care team member, male)

Some of the patients interviewed stated that they had wanted to see a physiotherapist in the past but were not able to get an appointment. One patient felt that they would have been an ideal candidate to see the physiotherapist but were not given the option after consulting with their GP about their MSK pain.

Patients and team members felt that having the physiotherapist available as a first point of contact to patients was a significant benefit to primary care.

"Because normally I would have gone to a doctor and then he'd said, "Well I'll try and get you in to a physio." But it's changed, thankfully, and it's great. When you're in pain and you can't move, it's important that you see the right person, as soon as." (Patient, male, 60-79 years, occasional attender, moderate care)

Physiotherapists were welcome additions to primary care, but some patients lacked understanding of their role

Physiotherapists were regarded by patients and team members as very suitable and acceptable practitioners to work within primary care. Team members had very positive views of physiotherapists and suggested that more physiotherapists were needed in primary care. Most of the patients and team members that discussed physiotherapists during their interviews described physiotherapists as very knowledgeable and competent practitioners with a good level of education at university level. Although, some patient stated that they did not have any knowledge about physiotherapists' level of training. As discussed in previous categories, confusion surrounding the roles of nurses, pharmacists and OTs was reported in the interviews with both staff and team members. Confusion regarding the role of the physiotherapist was also reported. Some of the team members felt that some patients may want to see a GP instead of a physiotherapist as they are not fully aware of their role.

Factors relating to the team members, practice and wider healthcare system

This section of results considers views on how role substitution may affect or may be affected by external factors such as issues relating to the practice, practice team and wider healthcare system (study objective 5).

Increasing patient demand and limited resources

Concerns about team members shortages and increasing patient demands on primary care were voiced by many of the patients and team members interviewed. Patients noted that the practices were busy and were aware of GP recruitment and retention problems. Team members felt that role substitution was a necessity due to the increasing demands placed on general practice. They felt that more practitioners were needed to face increased pressures due to an aging population. Team members felt that having more practice team members would allow them to provide a better service to patients as they stated that they were not

currently working to the best of their abilities due to pressures on resources. One team member highlighted the importance of resource allocation decisions when hiring practice team members to ensure their skill mix fitted the demands of their patient population. Both patients and team members raised concerns about the number of GPs who were retiring early and felt concerned that the GP profession was not desirable to new medical graduates.

Moving away from hierarchies in general practice

Patient views regarding hierarchies in general practice were mixed. Some patients viewed all practitioners as being on an even level at their practice and felt that they should be respected equally as each practitioner is a professional in their own right. Conversely, some patients felt that there were bound to be hierarchies in general practice as different primary care team members have different roles and levels of experience and training. Some patients viewed the GP as being at the 'top of the list' of practitioners, with nurses and non-clinical patient facing team members being at 'lower levels'. Some patients believed that hierarchies in primary care should not be an issue, as long as the practice team members work well as a team and received the necessary training for their specific functions within the practice.

"Like in my work, you've got differently qualified people. I suppose at the end of the day, different people can bring different ideas and ways of bringing things to the table.

Like the doctor is at the top, then the pharmacist is next, nurses and blah blah blah, and then it just goes down. It's a way of life"

(Patient, female, 45-59 years, frequent attender, moderate case)

Some of the team members described hierarchies within general practice as damaging and a barrier towards the successful implementation of role substitution and its acceptance among patients. Many of the team members interviewed emphasised a change in culture regarding hierarchies within their practices. They described conscious changes that had been introduced to reduce barriers and hierarchical structures within their primary care teams. These included practice team members being told to address doctors by their first names, ensuring that communal areas were accessible to all team members (no separate break rooms or kitchens for just GPs to use) and social gatherings among practice team members to encourage social cohesion. With respect to GPs acceptance of role substitution and the restructuring of the practice team, some team members felt that some older GPs may be more resistant to changes

whereas younger GPs were viewed as more enthusiastic and adaptable to changes. Team members highlighted the importance of viewing each other as equals within the practice as it taught junior members that their opinion was valid and made it easier for team members to approach each other and ask for advice when needed.

Some team members felt that GP partners should be at the top of the list in terms of hierarchies as the 'buck stops at them' in terms of responsibility. Team members also respected GP partners for their professional positions as well as being their employers.

The importance of teamwork, training and support structures

All of the team members discussed the importance of teamwork and communication within their practices. Team members reported good working relationships within their practices and said that they were always able to approach colleagues for advice when needed. Some team members stated that they had a GP available within their practice who was actively involved in the training of NPs and ANPs. Team members felt that they were able to talk openly with their colleagues during their weekly MDT meetings.

Team members believed that role substitution could work well as long as there were sufficient support structures in place. Although team members stated that they were able to ask for advice from colleagues such as GPs when needed, some stated that there were not any opportunities to arrange set time periods for training and consequently felt that more formal structured support was needed.

"I can knock on a door. Wait, go in after a patient, and very often the doctor will either come through or give you secondary advice. Quite often, all I need is just another pair of ears."

(Primary care team member, female)

Expanded roles may be associated with increased workplace stress but could also increase job satisfaction

Concerns about the increasing pressure placed on primary care team members were raised by some of the patients interviewed. Some patients raised concerns about the job stresses associated with the expanded roles of nurses.

Some of the primary care team members reported increased stress levels at work with some team members describing their roles as 'very stressful'. On the other hand, some of the team members reported increased job satisfaction due to their expanded roles in primary care and the opportunity to develop their careers.

Increased role responsibility but salaries remain the same

Some patients were concerned that practitioners such as nurses and patient-facing nonclinical team members were given more roles and responsibilities, but that their salaries remained the same. This was also echoed by some of the team members interviewed. Some patients felt that it would be cheaper for practices to employ fewer GPs and more nonmedical health professionals and AHPs. Other issues relating to costs raised by the primary care team members and patients included the business models of GP practices and the importance of careful resource allocation decisions in order to make the best use of NHS funds.

Factors relating to the patient

This category of results presents views regarding the barriers and facilitators to the acceptability, suitability and appropriateness of role substitution in primary care with respect to patient factors (study objective 1).

The importance of patient choice when adapting to change

Although some team members felt that patient choice had been enhanced, due to the increased number of different practitioners available at their practices, this was not reiterated by the patients. They felt they were not given enough choice about whom they would like to consult with, some also felt that they had to accept the appointment given to them by the care navigator. Although some team members believed that some patients would always want to consult with the GP irrespective of the reason for their consultation, the patients recognised that GP appointments should be reserved for patients who were severely unwell. They went on to say that they would not expect to see a GP for minor illnesses or appointments for things like flu jabs or diabetes checks. A couple of the patients interviewed did feel that if they felt strongly enough about seeing a certain type of practitioner, they would make that known when arranging an appointment and felt that their requests would be dealt with

adequately. Team members highlighted the importance of patient choice and that if a patient felt adamant about seeing a GP, it was within their right to do so.

Concerns regarding access due to busy practices

Some patients stated that they did not have any trouble getting appointments at their practice, while others were not happy with the length of time it had taken for them to wait for an available appointment. Some patients were unhappy with the same-day service offered at their practice with some patients stating that they had travelled in on public transport only to be told to return at the end of the day when an appointment became available. A patient account recalled a distressing experience at their practice where they felt very poorly and needed to be seen:

"I kept going back to reception to say, "Look, I'm really not well." They could see I wasn't well. She said, "There's nothing I can do. You'll have to wait." After four hours – I'd got a friend with me and she said, "You can't sit here any longer." We just left"

(PF4, female, 60-79 years, frequent attender, moderate case)

Busy telephone lines when contacting the surgery were a major concern for patients, this included descriptions of having to resort to phoning the emergency services as they could not get through to their general practice over the phone.

Although the data for this study were collected before the Covid-19 pandemic, some patients were happy to contact the practice over email or video consultation, but some patients were concerned about the suitability and appropriateness of such services to the older generation of patients.

Patient navigation

Receptionists' roles had progressively changed into 'care navigators' who were responsible for sign-posting patients to see the correct primary care practitioner depending on their reason for consultation. One of the practices not only employed 'care navigators' who were situated at the reception desk, but also 'team coordinators' who performed a patient navigator role

within the practice but were situated in a separate office. This category of results presents the views of patients and team members regarding patient navigation (**study objective 4**) and is split into two separate sub-sections for views relating to care navigators and views relating to team coordinators. Comparisons between both roles are discussed at the end of the results section under the 'reflections on the major recurring themes across the data' heading and in the discussion section of this chapter.

Care navigators

Receptionists' roles were expanding

Patients were aware of the new role of the receptionists who now worked to sign-post and book patients in with the appropriate practitioner depending on the reason for their consultation. Patients were asked to give the care navigator (formally known as the receptionist) a brief description of why they required an appointment or were asked to fill-out a form at their practice and appointments were then put in order of priority. Patients felt that the care navigator role was important as it helped to reduce unnecessary appointments and avoided clogging up the appointments system at the practice. Team members described the care navigators as receptionists or administration team members who had decided to take on the role as care navigators. Care navigators were described by team members as crucial members of the practice team who serve as the first point of contact for patients and were responsible for taking information from and conveying information to patients, and helping them understand the services and options that were available. This links with findings discussed previously in this chapter about the importance of patient education as a facilitator to the acceptance and success of role substitution

"They give you a form and you fill in and you put down your symptoms. When you're at the desk, you have to tell somebody what your symptoms are and then they've got to decide where you go"

(Patient, female, 60-70 years, normal attender, moderate case)

Team members explained that they understood the pressures of the care navigator role as they were responsible for dealing with the forefront of patient needs and the effective communication of information to the patient population. Team members stated that care navigators were responsible for referring patients internally to the most appropriate

practitioner but were also responsible for encouraging patients to use community services such as common ailment schemes available in community pharmacies.

The importance of good communication between care navigators and patients

Some patients described care navigators as very helpful and welcomed by members of the practice team, while others felt that there were occasions were the care navigators could seem abrupt and dismissive. Nevertheless, patients also added that they felt that care navigators were often under significant pressures due to the large volume of patients that they deal with.

In light of the findings relating to confusion regarding non-medical health professional and AHPs roles and capabilities, discussed earlier, some team members felt that care navigators could do more in terms of promoting their services to members of the public. This would also help to enhance patient education about the changing nature of primary care delivery. However, some team members recounted experiences where they had heard their navigators advocating the roles and capabilities of the non-medical health professionals and AHPs to patients.

Team members highlighted that good communication skills among care navigators were essential in order to effectively convey information to patients. They felt that some navigators were better at communicating with patients than others but realised that this was down to personal character and day-to-day pressures in the practice. Team members felt that it was important that the care navigator role was respected as this would impact on how valued they felt within the team and consequently how well they communicated with patients.

"They are probably the least paid members of staff and least trained and yet they are the first point of contact. I think that first point of contact we have with people when -. And I don't just think this about here, I think this about any GP practice. That first point of contact is absolutely vital"

(Primary care team member, male)

A lack of privacy

Some patients felt strongly about disclosing personal information to the care navigator and a lack of privacy was a major concern. Some patients were worried about their personal information being heard by other patients at the practice when speaking with the care navigator about their problem. They preferred the method of filling-out the patient

consultation request form on paper; however, some of the patients voiced concern for people who may be illiterate, patients with disabilities and patients who experience impaired eyesight. Team members agreed that it was not appropriate for care navigators to ask patients to disclose personal information in busy waiting rooms but noted that there was a lack of office space for a room to have private discussions with patients. Some patients suggested the use of plastic screens on the reception desk to separate patients which would help them feel safer when speaking with the care navigator.

"Yeah, you do feel like you're basically getting a mini diagnosis there, with giving them a limited amount of information. Plus, what I don't like about that is, it could be something very personal and you're in a – everyone can hear" (Patient, male, 30-44 years, occasional attender, simple case)

Although patients accepted that the role of the care navigator was to ask them questions about their reason for consultation, trusting the navigator to keep information confidential was questioned by some of the patients interviewed. Team members accepted that some patients did not want to discuss medical issues with the navigators but affirmed that adhering to patient confidentiality was a strict regulation for all members of the practice team.

Concerns about care navigators' level of training

Concerns about whether care navigators could correctly refer patients to the appropriate practitioner due to a lack of medical training and knowledge were voiced by patients. Some patients and team members also raised concerns about care navigators missing red flag symptoms when speaking with patients over the telephone. Some patients felt that it was unacceptable for unqualified care navigators to make decisions regarding their health. On the other hand, some patients stated that they could rely on care navigators to make the correct decisions as they would have developed their knowledge and experience through dealing with the high volume of patients that contact the practices. Some team members did report some instances where they had been referred inappropriate cases by the navigator that were outside of their remit of expertise such as chest pain, women's health and paediatric cases. Some team members believed that navigators should receive more training about different nurse roles especially with respect to the differences between NP and ANP roles.

Many of the patients interviewed stated that they were unaware of the level of training that care navigators receive. Interestingly, many team members were also not sure of the types of training that care navigators receive to support their role or stated that they receive minimal training. However, a couple of team members described care navigator training as 'on the job' training with a focus on learning how to effectively communicate and deal with members of the public. One team member felt that care navigators should receive triage training as it would be safer for patients and less stressful for clinicians. Nevertheless, some team members stated that they could not recall any serious problems that had occurred since the care navigator role was introduced at their practices.

"I think one of the things with the whole thing about our role changes is that we've all been pushed into it without having the background training, and particularly some of the care navigators, they've had very minimal training"

(Primary care team member, female)

Despite concerns over training expressed by some patients and team members, some patients recalled very positive experiences where the care navigator had handled situations well, for example, phoning for a GP to come straight down to reception when a patient was experiencing chest pain.

Team Co-ordinators

It is worth noting that team co-ordinators were employed as practice team members in one of the practices included in this study; therefore, views relating to team coordinators described below are provided from patients and team members from that practice only.

Team coordinators: a new role

Similar to the care navigator role, the role of the team co-ordinators was to signpost patients to the most appropriate healthcare practitioner but were responsible for booking in planned clinic appointments for patients. It is worth noting that team co-ordinators did not sit at the front of reception but sat in separate offices and mainly consulted with patients over the phone or by email rather than face-to-face. Within the practice that employed team co-ordinators, the patient population was split into teams that each take on responsibility for caring for a specific group of patients and each team was assigned a team coordinator.

Patients described very positive experiences when dealing with their team coordinator. They stated that the team co-ordinator was able to help them understand which options and pathways they could take and would arrange for the clinicians to ring patients back when needed. Team co-ordinators were praised by patients for their prompt responses to emails and for reassuring patients in times of worry and distress.

Team co-ordinators were described by team members as very experienced members of team members who can offer reassurance to patients. Team members noted that the role of the team co-ordinators included handling referrals from district nurses and social workers and then referring patients on to the most appropriate clinician within the practice. Moreover, some team members explained that the role of the team co-ordinator was to plan some of the day-to-day work of clinicians. Similar to the care navigators, some team members reported instances where they had been given inappropriate referrals from the team co-ordinators.

Confusion regarding team co-ordinators' level of training and knowledge

Patients and some of the team members interviewed were not aware of the team co-ordinators level of training; however, some patients believed that team co-ordinators had more training and knowledge of health conditions compared with care navigators. Nevertheless, some of the team members interviewed stated that most of the training that team co-ordinators received in practice was 'on-the-job' training, but that they had brought over a great deal of knowledge from working for many years previously in general practices. Rather than completing mandatory training, team members noted that team co-ordinators have regular meetings with one another and the practice management team to discuss the vision and expectations of their roles within the practice.

Team co-ordinators were effective communicators and were accepted additions to primary care

Both patients and team members felt that team co-ordinators were able to develop good rapport with their patients and knew their patients well. Interestingly, despite patients agreeing that they were not aware of the background training of team co-ordinators, they felt more comfortable discussing their medical problems with the team co-ordinator compared with the care navigator. The issues of privacy when consulting with team co-ordinators was

not raised by patients or team members during the interviews. This was also noted by some of the team members interviewed, who felt that patients were more open and accepting of the team co-ordinators' role compared with the role of the care navigator. Team co-ordinators were praised by team members for their good communication skills and were viewed as an important links between patients and the clinical team members. Despite providing similar roles as care navigators in terms of patient navigation, some patients viewed team co-ordinators as being on a higher level than the care navigators within the practice. Some team members described a lack of team-working between care navigators (who sat on the front desk at the practice) and the team co-ordinators (who were located in separate rooms).

"I think you've still got that problem with reception but they [patients] don't seem to have a problem with the co-ordinators. They must see it as a different role and they seem quite okay about telling [team co-ordinators] things in confidence, letting them help them out"

(Primary care team member, female)

"They [team co-ordinators] don't want personal stuff because they [team co-ordinators] are professional people and they seem to have more knowledge, which is . And you feel comfortable with them because they are dealing with you on a personal basis. I think that's it. I think that's what it is. It's personal. They understand your medical problems"

(Patients, female, 60-79 years, normal attender, complex case)

Reflections on the major recurring themes across the data

Results are presented under key category areas: role substitution in general; nurses; pharmacists; occupational therapists; physiotherapists; factors relating to the team members, practice and wider healthcare system; factors relating to the patient; and patient navigation.

This qualitative study highlighted the complexity of role substitution. Role substitution was at various stages of implementation in the UK but was rapidly advancing. Patient views depended upon their experiences, which also depended upon the specific context of their GP practice. Role substitution involved many different team members with differing views. All of these complex components were set within the complex system of primary health care within the UK, which made for a broad research area. While the results

presented by section provide detail on the specific findings for each area, it is important to note that there are many parallels across roles and opportunities for shared learning.

There were many common themes, such as whether it was acceptable to staff and patients, and what the barrier and facilitators were to successfully implement role substitution changes. The recurring themes are reflected upon below.

Role substitution brought added value and expertise to primary care: A strong theme that was highlighted across the data was the notion that different non-medical health professionals and AHPs brought added value to primary care due to their unique approaches, skills and expertise. Pharmacists were experts in medication, physiotherapists were specialists in musculoskeletal health, while OTs were well suited to work in the area of mental health. There was a view that AHPs, nurses and pharmacists may be more up to date than GPs in some areas, and therefore may be better suited for certain roles. There was a strong sense of acknowledging the expertise and specialist skill of AHPs, pharmacists and different nurses. In contrast, there was a view that although GPs could deal with a wide range of illnesses and tasks, they may not necessarily know one area in depth. Rather than this being a criticism of GPs this could help highlight the added value of alternative roles working in primary care teams.

Roles of primary care team members were confusing to both patients and staff: Changes to practice brought the challenge of confusion about the roles and remit of different health professionals. Patients were unclear about whether or not pharmacists had the authority to prescribe, and some were not aware that OTs could deal with mental health problems and not just mobility issues. Some confusion was limited to patients rather than to professionals as team members highlighted mental health as a particular strength of OTs. There were specific factors that contributed to confusion such as busy practices, a high number of different roles, similarities in uniforms worn by practitioners and overly complicated job titles. Some population groups were more effected than others. For example, there was a concern that older people had prior experience of a traditional family doctor model of primary care and may not adapt as well to the changing roles within primary care. There was some evidence that it was not always clear after a consultation which professional the patient had seen. However, older people were more likely to have co-morbidities and complications that required complex treatment, often resulting in them seeing a greater range of clinicians and

having a greater experience of role substitution in practice. Frequency in attendance and experience of seeing newer roles may facilitate patients understanding of role substitution.

The importance of enhancing patient education was paramount and patients wanted to receive more information about roles, particularly around training and qualifications.

Understanding roles was important to patients to enable confidence in who they saw in primary care.

There were opportunities for roles with high patient contact such as receptionists to reduce confusion for patients about roles that were newer to primary care. Expanding roles, new roles and changing roles, often with no clear definition, resulted in confusion for health professionals as well as patients. There was wide variation in roles across practices, for example, the role of an advanced nurse practitioner in one practice may be very different in another practice. Interestingly, health professions appeared confident about the remits of their own roles; however, some had limited knowledge of other roles and the capabilities of different practitioners. Confusion about roles could have important implications, particularly when referring to different health professionals. There were many factors that linked to professional confusion around roles, such as limited 'on the job' training for care navigators and team co-ordinators. Role substitution is a complex issue and some confusion is inevitable, for health professionals to better support patients adapt to the rapid changes within primary care then first reducing confusion around roles amongst staff is important. The individuality of staff and contextual issues at different practices are important factors, a standardised approach to training and information may not be appropriate without adaptation to reflect variation.

Role substitution is happening anyway to meet demand, but a culture shift is needed for acceptance: There are high demands on primary care and role substitution has been highlighted as a potential solution or, if implemented unsuccessfully, be a cause of added pressure. Team members felt that role substitution was happening anyway and there was a sense of excitement by staff, supported by a welcoming of changes to practice by some patients. While the changes had happened rapidly, staff acknowledged that it may take time for patients to adapt to the change and that it required a culture shift. This culture shift has involved a process of moving away from seeing the family doctor for the majority of care, towards patients seeing a diverse range of skilled health professionals. However, it also requires patients to have greater ownership of their health, to be supported to make informed

choices, and encouraged to be proactive in protecting their own health. The importance of patient choice was also highlighted in the interviews among team members however, a clear barrier to patients accepting role substitution and make informed decisions about their healthcare was a lack of clear understanding about roles and capabilities of the practitioners that were available in primary care. Some team members stated that information had been provided to patients, but this was insufficient for patients to understand what services were available to them and how they could maximise benefit. Alternative forms of communication and novel ways of improving understanding of roles was needed. Some team members felt that it was the role of the care navigators to do more in terms of promoting the services to members of the public, which would also help to enhance patient education and a culture shift.

It is interesting to note that patients appeared to accept team co-ordinators, more than care navigators, despite not fully understanding what level of training or knowledge these groups have had. One factor which may influence this was the environment in which care was offered, and a perception of greater privacy that came with a separate working space away from the busy reception. Care navigators continued to be situated in reception, with competing demands on their attention, and in the view of the patient there was no visual change to the previous role of receptionist. By contrast, team co-ordinators might have been viewed as having a promotion to a new and private environment to offer care and advice to patients. Linked to this concept was the view of staff that hierarchies within practice could be damaging; however, a culture change was happening and a conscious effort to reduce hierarchal structures within primary care. Team coordinators were a new role that had been developed in one of the practices and this role may not be representative of other general practices. However, these difference in acceptability of the roles of team coordinators and care navigators may offer an opportunity for understanding acceptability of role substitution overall.

Continuity of care: Although good relationships between nurses, pharmacists and their patients were reported in the interviews there was concerns regarding continuity of care due to a large number of different professionals working in primary care. There was acceptance that improvement would likely occur over time. Key factors that could help mitigate against continuity of care concerns were practitioners remaining in their new roles to develop relationships with the patients, alongside having access to electronic patient medical histories. There were potential opportunities for care navigators to help with continuity of care by

linking patients with the same healthcare professional that they had seen previously. Patients and team members noted that confidence in healthcare providers was dependent on individual characteristics rather than specific roles or job titles.

Persistent concerns regarding access to healthcare: Role substitution has been proposed as a way to improve timely access to healthcare by allowing patients to see the most appropriate practitioner at their first points of contact. Team members reported that it might be quicker for patients to speak with a pharmacist over the phone instead of waiting for the telephone call from a GP. This was reported to help unburden GP workload. OTs were viewed as reducing demands on GPs as they performed mental health consultations, which take up a large proportion of primary care workload. Physiotherapists might also reduce GP workload by seeing patients with musculoskeletal problems, which make up a high proportion of primary care consultations. Patients felt that the role of the care navigator was important to help the system adequately manage demand. A number of different ways of accessing the practice was reported including telephone consultations, emails and e-consultations and video consultations. Nevertheless, some patients raised concerns about barriers to access for some populations particularly older people. Some patients reported difficulties getting through on busy telephone lines and some even resorted to phoning an ambulance when rapid access to primary care was not possible. Despite the potential advantages of roles substitution in relation to GP workload, concern remained regarding these barriers to access. Understanding the most common issues that present to primary care and being able to keep pace with rising demands is important to ensure that the right skill mix of staff is available.

Expanding roles mean greater responsibility for primary care team members: Patient and team members accepted roles were expanding in primary care teams and with this extra responsibility comes opportunities for career development, however stress was a concern. Patients felt unfairness with respect to greater responsibility for staff if there were no increase in salaries. Team members felt that GPs take many more risks compared with nurses and pharmacists, who worked closely to guidelines and were more risk averse.

Patients were also aware of the expanding roles of receptionists as care navigators and team members voiced concerns regarding pressures of the care navigator role. The importance of teamwork, training and support structures appeared to be important factors when considering increased role responsibility. It was evident that a great deal of team working was going on. Team members felt that they could always consult with a GP or other

team member if needed. Good communication between team members was an important factor mentioned by patients. It was important that care navigators communicated effectively with patients; they were at the forefront of primary care.

There were many risks to poorly implemented role substitution. If patients were not seen by the right professional, at the right time or by a professional without sufficient time or skills then patient care would suffer. Also, if role substitution were to result in increasing rates of frequent primary care attendance, then this may increase demand on services. The qualitative findings in this study did not point towards any harms to patients occurring in these local examples, particularly as skilled staff were aware of role boundaries and seeking support from team members – these remain important factor in reducing risks.

Discussion

General summary of findings in relation to the research objectives

1. To explore the barriers and facilitators to the acceptability, suitability and appropriateness of role substitution in general practice.

Our findings revealed a broad range of views regarding the barriers and facilitators to role substitution in primary care. The implementation of role substitution was believed by patients and team members to bring added value to practices, as different practitioners provided unique approaches, skills and expertise. Other benefits included access to new services, the potential to save time by allowing patients to see the most appropriate practitioner during their first visit at the practice, and increased opportunities for team members to expand and develop their roles within primary care. Barriers to role substitution included confusion among both patients and staff regarding roles, and difficulties forming sustained relationships with new practitioners working in general practice teams. Some concerns regarding access due to busy practices were reported. The importance of patient choice when implementing role substitution was also highlighted

Views regarding the acceptability of role substitution were mixed. Some patients expressed neutral feelings about role substitution and did not mind the changes that were happening in their practices so long as non-medical health professionals and AHPs know their boundaries and received the necessary support and training. Team members felt that

patients were slowly beginning to accept the changes and acknowledged the importance of patient acceptance for role substitution to work successfully.

2. To assess the views of patients and general practice team members regarding the different types of non-medical health professionals and AHPs that now complete some roles that were previously completed by GPs in the past

Concerns were raised about non-medical health professionals and AHPs being exposed to situations that they were not capable of dealing with. A major concern raised by both patients and staff was confusion regarding the different roles of non-medical health professionals and AHPs and their capabilities within primary care. In relation to this, a lack of information regarding the different roles and scope of practice of primary care practitioners was reported. Enhancing patient education was paramount to the success of role substitution. Patients found it difficult to develop relationships with their clinicians due to a lack of familiarity with the different team members at their practices.

Some of the reported themes relating to nurses included good communication between nurses and patients, increased role responsibility and nurses working closely to guidelines. Pharmacists' expertise and knowledge of medications was noted by patients and team members. Pharmacists were also described as helpful additions to primary care teams who communicated well with patients. OTs were considered important and valuable additions to the primary care team with considerable expertise in dealing with mental health issues, which accounts for a large proportion of primary care demands. Physiotherapists' expertise of musculoskeletal conditions was acknowledged by patients and team members and their contribution to easing GP pressures was noted.

3. To identify the views of patients and general practice team members regarding role substitution and treating complex cases in general practice.

Some concerns were raised about non-medical health professionals and AHPs treating complex cases; however, some patients and team members felt it was acceptable as long as they know their boundaries, had the necessary skills and experience, and were able to consult with a GP for advice. As discussed above (under study objective 2), the addition of different AHPs working in primary care might help to reduce GP workload and it was suggested that this could allow GPs more time to concentrate on complex cases. Nevertheless, it was noted that OTs have much longer appointments compared to GPs and may therefore be well suited to treat patients with complexity relating to social and emotional situation. Physiotherapists

were not deemed as appropriate practitioners to deal with complex cases; however, team members felt that physiotherapists would always consult with a GP when they came across complexity during their consultations. Team members voiced the views that complexity involved a multidisciplinary approach and therefore did not involve just one type of healthcare practitioner.

4. To explore the views of patients and general practice team members regarding patient navigation to different health professionals.

The expanding roles of non-clinical team members and the subsequent pressures placed on these types of staff members were reported. Concerns were raised regarding the lack of privacy in the waiting room setting. Patients felt that the care navigator role was important as it should help to reduce unnecessary appointments and should be used to promote patient understanding on how best to utilise services. Good communication and training were important factors to the success of the care navigator role. There was a lack of understanding regarding the level of training undertaken by care navigators and team co-ordinators. There appeared to be greater acceptance towards the team co-ordinator role compared with the role of the care navigator, which could be associated with issues relating to privacy.

5.To explore how role substitution may impact or may be impacted by external factors such as factors relating to the practice or healthcare system.

An inability to work to the best of their abilities due to increasing demand and limited resources were reported by some of the team members interviewed. There were mixed views among patients with respect to hierarchies; however, conscious efforts to move away from hierarchies in general practice teams were discussed by team members. The relationship between expanded roles and job stress or job satisfaction were described by some of the team members. Some patients also discussed increased responsibility of team members due to expanded roles and voiced concerns regarding salaries of healthcare providers.

Findings in relation to the conceptual framework of the thesis and theories of role substitution

This thesis used an evaluative framework with dimensions proposed by Maxwell for evaluating quality of care and is applied in this thesis to role substitution in primary care (Maxwell, 1992). The findings of this qualitative study can be linked to all six of the quality

dimensions, with some dimensions represented more than others (Maxwell, 1992). A detailed consideration of the thesis findings overall in relation to the acceptability, efficiency (including costs), access, equity, relevance and effectiveness (including safety) of role substitution are presented in the final discussion chapter of this thesis.

The findings of this qualitative exploration were also framed by an awareness of theories concerning role substitution and the potential conflict between groups of professions. The findings of this qualitative exploration can be explained and considered in relation to the following points and are discussed in detail in the final discussion chapter of this thesis (Chapter 7):

- Efforts to reduce hierarchies in the practice team.
- A lack of understanding of roles and boundaries among both patients and practice team members.
- The need for non-medical health professionals and AHPs to be aware of their professional boundaries and to work within their areas of clinical competence.
- The acceptance of expanding roles through vertical substitution and the importance of teamwork and communication.
- Role supplementation and specialisation.
- Diversification of 'receptionist' roles.
- Increased specialisation in nursing roles.
- Greater role responsibility for non-medical health professionals and AHPs consideration of salaries and status.
- Superiority in terms of expertise, training and professional autonomy.

Strengths and limitations

This chapter explores a diverse set of patient and professional views relating to role substitution. This study provides novel views from both patients and general practice team members regarding role substitution by a variety of different practitioners including nurses, pharmacists, physiotherapists and OTs. We also believe that this is the first qualitative study conducted in Wales to explore the views regarding primary care patient navigation by care navigators and team coordinators (who previously worked in a general practice receptionist or administration roles). Consequently, this study makes a valuable contribution to the

knowledge base of role substitution in the general practices in Wales especially in the areas of patient navigation and views regarding OTs and physiotherapists working in practices to provide face-to-face consultations. The diverse and complex nature of the topic, sample and context adds challenge to the synthesis of the research findings, the generalisability of the results and impact on practice. This study did not however explore the views of other types of AHPs such as advanced scope paramedics, practitioner psychologists, podiatrists, dieticians, social prescribers and approved mental health professionals that may be employed in Welsh general practices, as these types of practitioners were not employed at the two general practices we recruited from during the time this study was conducted.

This study was conducted ethically and transparently and ensured that participants were well informed regarding the study aims and procedures. This qualitative exploration included team members and patients from two different types of general practices in North Wales: a large practice directly run by the health board; and a smaller practice that uses the more traditional GP partnership model. Consequently, the insights provided in this qualitative study regarding the implementation of role substitution within these different types of practices were broad and diverse. The purposive sampling criteria was designed to be broad and inclusive to include a range of different primary care team members and a range of different types of patients from frequent attenders to occasional attenders, and patients with simple conditions through to complex cases. Although the recruitment of patients was lower than anticipated, insights from the patient interviews were still extremely broad and perceptive. We believe saturation of data was achieved after eight patient interviews and it was not expected that new themes would have emerged if more patients were interviewed.

This study was limited in respect to the findings relating to views on physiotherapists and OTs working in primary care as many of the patients interviewed had never consulted with these types of practitioners and were therefore unable to provide perspectives regarding these roles. Nevertheless, the primary care team members interviewed in this study were able to provide insightful and rich information about physiotherapists and OTs. Another limitation of the study was that in order to preserve anonymity and confidentiality of the study participants, we were unable to identify the team members' roles within the study findings. Consequently, all of the data provided in the write-up of the results were categorised as being 'team member' views.

It was intended that interviews were conducted with patients with a broad range of age ranges; however, the majority of the patients recruited in this study were older patients. This could suggest that older generations of patients may have stronger feelings regarding changes to their practice, which is why it was mainly older people who responded to the interview invitation. Nevertheless, this could also be down to more free time and fewer commitments elsewhere.

In this qualitative study, the researcher did not have access to any patient information during the sampling process and prospective participants were approached directly by the practice based on the purposive sampling criteria. It is important to note that due to the sampling approach undertaken in this study it was not possible to collect or compare information on the characteristics of the study participants versus the non-participants (those who were invited to take part in the study but declined or ignored the offer). "People who – by convention or cultural praxis – perceive themselves as relevant contributors to illuminating certain topics are easier to recruit than are those who perceive themselves as irrelevant. This leads, to a strong circular motion, wherein research in a particular field easily includes the most known voices but is less likely to include less known voices that could expand our scientific understanding of the field" (Kristensen and Rayn, 2015, p.129).

Moreover, people who are motivated to take part in interviews may have strong views on a topic which may explain their reason for choosing to take part in a study. It must be acknowledged that the views of the participants that were motivated to take part in the study may be vastly different to the views of individuals who declined or did not respond to the study invitation and will therefore limit the generalisability of the findings. Nevertheless, this is an issue that is commonly encountered when recruiting participants to take part in interviews.

The rigour of qualitative findings can be enhanced through 'double-coding'. More than one researcher independently assigned the pre-specified codes to the interview transcript data (Ranney et al., 2015). However, this study was part of an independent PhD project and all stages of analysis were completed by the PhD candidate (BFA). Nevertheless, BFA consulted with her PhD supervisory team in order to gain support and advice for each stage of the analysis. It must be acknowledged that the PhD candidate is a novice researcher in the field of qualitative study; however, BFA attended a qualitative interviewing one-day course before conducting the interviews. Moreover, the Framework method of analysis adopted in

this study was a well-suited method of analysis for less experienced researchers due to its highly structured systematic approach to qualitative analysis (Smith and Firth, 2011).

Comparison with previous literature

Chapter 4 of this thesis comprises a systematic review of qualitative studies on the topic of role substitution in primary care. The review identified six studies exploring the role of physician associates in primary care (Drennan et al., 2011; Drennan et al., 2017; Halter et al., 2017; Jackson et al., 2017; Taylor et al., 2013; van Der Biezen et al., 2017) and four studies exploring the contribution of pharmacists to general medical services (Gidman et al., 2012; Hatah et al., 2013; Lamberts et al., 2010; Stewart et al., 2009). There are important comparisons to be made between the previous literature identified in the systematic review and the results of this present chapter. Moreover, there are also notable comparisons between the findings of our qualitative study and the two qualitative review papers identified in the literature presented in the introduction chapter of this thesis (McInnes, 2015; Rashid, 2010).

Although the qualitative exploration presented in this chapter did not uncover views regarding PAs, the existing qualitative literature on PAs is comparable to many of the findings reported on in this chapter in relation to nurses, pharmacists, physiotherapists and OTs. Previous literature has reported on the uncertainty and unfamiliarity with the PA (Drennan et al., 2017; Halter et al., 2017; van Der Biezen et al., 2017; Drennan et al., 2011) and physiotherapist role (Gidman et al., 2012). Previous research reported in a review of reviews have also reported on a lack of understanding about the roles and scope of practice of nurses working in general practice teams (McInnes, 2015). Similarly, our study also reported on a lack of familiarity and understanding of the roles and responsibilities of nurses, pharmacists, physiotherapists and OTs among both patients and team members.

Previous PA studies (Jackson et al., 2017; Taylor et al., 2013; Drennan et al., 2011) and one of the pharmacist studies (Stewart et al., 2009) identified in the systematic review (Chapter 3) raised concerns regarding the increased requirement for supervision. Although our qualitative findings did not report on any concerns regarding the increased levels of supervision that may be needed due to increased role substitution, our findings did highlight the importance of effective team working and opportunities to seek advice from the GP when needed. The importance of teamwork, training and support structures appeared to be important factors when considering increased role responsibility for receptionists who are

taking on expanded care navigator roles. Findings from our qualitative exploration suggested good levels of teamwork, communication and support among team members, which contrasts to some of the findings identified in the systematic review regarding PAs and NPs who reported on difficulties building team support (Van der Biezen et al., 2017).

There was agreement between our findings and the finding identified in the systematic review chapter that pharmacists are considered as experts in medications (Hatah et al., 2013; Lamberts et al., 2010). Our findings indicated that patients were able to develop good relationships with the community pharmacist, which is divergent to findings identified in the systematic review that reported unfavourable views of community pharmacists among patients (Gidman et al., 2012). Territorialism in terms of protecting GP boundaries have been reported on in previous literature (Drennan et al., 2017; McInnes et al., 2015). Our findings expand on previous literature around GPs acceptance of role substitution and the restructuring of general practice teams. Some team members felt that some older GPs may be more resistant to changes whereas younger GPs were viewed as more enthusiastic and adaptable to changes.

The qualitative findings presented in this chapter revealed that patients are happy to consult with nurses for minor illnesses. Interestingly, this does not support some of the previous literature reported on in a review published in 2010, that cited patients' preference to consult with a GP instead of a nurse for minor illnesses (Rashid, 2010). Evidence from the qualitative exploration supports previous literature to some degree regarding the acceptability of non-medical health professionals dealing with complexity and serious issues. There were some concerns raised by patients in the interviews about nurses, pharmacists and AHPs treating complex cases. Likewise, previous research has also raised the issue of non-medical health professionals treating complex and severe conditions in the PA literature (Drennan et al., 2011; Drennan et al., 2017; Halter et al., 2017; Jackson et al., 2017; Taylor et al., 2013; van Der Biezen et al., 2017). Our qualitative findings expand on previous literature by providing some evidence to suggest that in some cases, patients and general practice staff felt that it is acceptable for non-medical health professionals and AHPs to treat patients with complexity. However, this was dependent on factors such as the opportunity to seek advice when needed, skill level and experience, and an awareness of boundaries. These findings further confirm the importance of adequate support structures, supervision and teamwork that has been discussed above. This links in with the differing views about the role of the GP as a 'specialist' versus a 'generalist' practitioner, which has been discussed previously in a study

by Drennan and colleagues (Drennan et al., 2017) and was also highlighted in our interview findings of this present chapter, with some patients viewing the GP as a 'jack of all trades, but a master of none' who may not have the expertise to know one clinical area intimately.

Our findings support previous literature on views that receptionists are crucial members of practice teams who serve as the first point of contact in general practice and are responsible for signposting patients to the correct healthcare professional based on their reason for consultation (Litchfield et al., 2022; Brant et al., 2018; Litchfield et al., 2017; Hammond et al., 2013). Previous studies have also acknowledged that despite the requirement to perform expanded duties, receptionists do not appear to receive adequate training or supervision (Burrows, 2020; Hammond et al., 2013). Moreover, an ethnographic study conducted in general practices in England and Scotland, found that receptionists are often required to use their own initiative, judgment and experience when booking in patient consultations, with one quote from a practice nurse stating that 'receptionists usually get it right' (Brant et al., 2018). Nevertheless, our findings disagree with this statement as some practitioners interviewed had recalled experiences when they had received inappropriate referrals from receptionists that fell outside of their area of competency and professional boundaries.

Previous research on patient views of the receptionist role mirror some of the findings presented in our qualitative findings presented in this chapter. For example, our findings found that some patients felt that there were occasions were the receptionist could seem abrupt and dismissive. Similarly, unfavourable interactions and perspectives have also been reported by patients previously (Ford et al., 2018; Jacobson et al., 2001). Moreover, issues relating to patient privacy and confidentiality when interacting with receptionists have also been discussed in previous studies (Patient Association, 2019; Lecky, Hawking and McNulty, 2014; McInstry et al., 2009; Jacobson et al., 2001).

Implications for research and practice

Future studies are needed to explore the views of both patients and primary care team members about the acceptability of employing a full range of different types of practitioners to provide face-to-face consultations in primary care. Further qualitative research exploring substitution by roles not included within this study is needed, such as mental health practitioners and paramedics. Confusion among patients surrounding new and extended roles of primary care practitioners was an important finding in this study. Policy makers and

practice managers may wish to establish better methods of communication with patients regarding the changes that are occurring within their practice. Enhancing patient education is likely to support the acceptance of role substitution in primary care among patients.

Conclusion

This qualitative study provides insights regarding the barriers and facilitators to role substitution and its acceptability among patients and primary care team members. This study offers novel findings in relation to patient navigation and offers both patient and provider views relating to some of the new additions to general practice teams including OTs and physiotherapists. The study findings should help to inform practice and policy with respect to resource allocation decisions when employing non-medical health professionals and AHPs to meet the demands of certain patient populations. Policy makers and practice managers should consider methods of enhancing and supporting patient education regarding these role substitution changes.

CHAPTER 7: DISCUSSION

This discussion chapter begins with a summary of the findings of Chapters 2 to 6 in relation to the research questions presented in the introduction chapter of this thesis (Chapter 1). To answer the broad scope of the thesis, two systematic reviews (Chapter 2 and Chapter 3), an online survey (Chapter 4), and a sequential explanatory mixed-methods study comprising of a budget impact analysis (BIA) (Chapter 5), and a qualitative study (Chapter 6) were conducted. This thesis incorporated an explanatory mixed-methods design with the intention of combining components of both the quantitative and qualitative research phases to provide a better understanding of role substitution in practice. The areas of integration across the quantitative (Chapter 5) and qualitative (Chapter 6) phases are discussed and reflected upon in this chapter.

This discussion chapter then goes on to describe the strengths and limitations of this thesis and the implications for practice and policy (including some key recommendations for practices). This chapter presents the findings of updated literature searches since 2017 and reflects on how this this new evidence impacts the findings of the review chapters of this thesis. A discussion of how the updated literature also compares and contrasts with the findings of the qualitative study (Chapter 6) are considered and recommendations for future research are provided.

This thesis used an overarching conceptual framework first described by Avedis Donabedian (1980) and elaborated by Robert Maxwell (1984; 1992) to judge quality in healthcare. Moreover, the thesis findings are also considered in relation to theories of role substitution and dynamic systems of health professions. The conceptual framework and theories of role substitution are revisited at the end of this discussion chapter.

Scope and approach of the thesis restated

With some roles traditionally performed by the GP now being carried out by non-medical health professionals and AHPs, evaluation of this change in service design was needed. These different roles and variations to skill-mix provide an opportunity to bring additional specialist skills into general practice. In broad terms, this thesis aimed to explore the advantages, disadvantages and consequences of role substitution. Early indicators suggested that the substitution of skills could potentially reduce GP workload and allow GPs more time to

manage more complex cases. Nevertheless, we did not know if this model of primary care delivery described as role substitution in this thesis was deemed as appropriate and acceptable to both the patients and the general practice workforce, or if it served as a cost-effective use of limited NHS resources.

Summary of findings in relation to the research questions

The answers to the five research questions have been summarised below:

Chapter 2 addressed Research question 1:

What existing literature is there on the cost-effectiveness of role substitution in primary care?

The systematic review of the literature presented in Chapter 2 of this thesis (also published as Anthony et al., 2019), uncovered six full economic evaluations assessing role substitution in primary care settings. The review identified economic evaluations of specific interventions comparing nurse or pharmacist-led care compared with GP-led care with respect to specific areas of illness or patient populations. There was limited evidence that nurse-led care for common minor health problems was cost-effective compared with GP care. However, nurse-led interventions for chronic fatigue syndrome and pharmacy-led services for the medicines management of coronary heart disease and chronic pain were not deemed to be cost-effective when compared with GP-led care. It is not known whether nurses and pharmacists can provide cost-effective care for other roles and health conditions that GPs treat in primary care. There was variability in the quality of the studies identified through a critical appraisal with four of the included reviews ranked as good quality economic evaluations and two considered as moderate quality. This systematic review highlighted gaps in the literature where more research was needed. For example, the review did not identify full economic evaluations comparing both costs and outcomes for AHPs.

Chapter 3 addressed Research question 2:

What existing literature is there on the barriers and facilitators to role substitution in primary care?

The systematic review presented in Chapter 3 of this thesis highlighted several studies for pharmacists and PAs providing general medical services in primary care. Only one

qualitative study focusing on physiotherapists in primary care was identified. The qualitative evidence highlighted a number of role substitution barriers and facilitators in relation to a wide range of issues such as staff relationships, definitions and understanding of roles, factors relating to the patient, general practice team and healthcare system. Facilitators relating to the pharmacist role included their expertise in medications, GPs acceptance of pharmacist prescribing, opportunities for pharmacists to fulfil information needs that were not met by GPs and the potential for pharmacists to reduce GP workload. Barriers to the increased use of pharmacists reported in the systematic review were concerns about increased requirements for supervision, pharmacists' level of knowledge of patients' medical history and their lack of training in treatment and diagnosis. Barriers regarding community pharmacists included a lack of trust and familiarity of the community pharmacist role.

Facilitators relating to the PA role included their ability to provide vertical substitution to GPs, working within the medical model and their capacity to deal with uncertainty. Further facilitators to the PA role included their potential to help meet patient demand, improve access to services and reduce GP workload. The evidence also suggested that, compared to nurses, PAs may require less supervision and could deal with a greater volume of work. An identified barrier was that there were uncertainty and unfamiliarity with the PA role and some resistance towards the PA role from GPs and NPs reported.

For physiotherapists, the main facilitators identified were that physiotherapists have a major role to play in musculoskeletal health and were considered an integral part of the general practice team. Moreover, further facilitators noted were physiotherapists potential to deal with a large proportion of the general practice workload and their integration within teams may result in better use of other practitioners. The systematic review concluded that that there was a shortage of qualitative evidence for other roles such as OTs, practitioner psychologists, podiatrists, dieticians, social prescribers and approved mental health professionals.

Chapter 4 addressed Research question 3:

To what extent is role substitution being implemented locally in general practices across Wales?

Chapter 4 of this thesis presented the findings of an online survey of primary care cluster leads, which aimed to assess the extent to which non-medical health professionals and AHPs were providing general medical services in the NHS in Wales. Cluster lead respondents voiced their concern regarding a primary care workforce crisis in Wales. Cluster lead respondents also provided additional comments regarding possible strategies to increased role substitution within their clusters. As reported at cluster level, the results of this survey provided an indication of a wide range of different healthcare professionals being employed in general practices in Wales to provide face-to-face consultations with patients. Cluster leads provided information on a variety of strategies to increase the uptake of role substitution including the ongoing support to employ and train AHPs and increase the uptake of independent prescribing by nurses and pharmacists. It was indicated from the survey that mental health and social issues appear to take up a large portion of general practice demands, demonstrated by the increased employment of mental health practitioners and the development of social prescribing in Wales as reported by the cluster lead respondents.

At the time of the survey, data in relation to primary care workforce planning in Wales was already routinely collected through the NWSSP; however, no data was available for the year 2019. Data collection for our survey presented in this chapter took place between November 2018 and 2019 and provided some information for a very small window in 2019 where statistics on general practice teams staff was not available from national sources. Moreover, routinely collected data in Wales did not provide a breakdown of the different types of direct patient care staff until 2020. Although this survey did not directly measure employment rates of staff at practice level, the findings provided some indication of the types of practitioners that are being utilised in Wales, as reported by cluster leads who play an important role in supporting local health needs in terms of allocating appropriate resources within their clusters (Auditor General for Wales, 2018).

Chapter 5 addressed Research question 4:

What are the cost implications of increasing the use of role substitution within general practice?

The financial implications of increasing the use of role substitution within general practice is important within the context of a GP workforce crisis and limited healthcare resources. Chapter 5 of the thesis presented a BIA to demonstrate whether there had been any shifts in health service provider costs as a result of the increased use of non-medical health

professionals and AHPs working to provide general medical services in two general practices in North Wales.

Despite an increase in the total number of consultations between the one-week data collection period in 2016 and the one-week data collection period in 2018 at Practice A, estimated costs of consultations were £807 lower following the practice increasing the use of role substitution i.e., by reducing the number of GP consultations and increasing the use of non-medical and AHP roles within the practice. For the most part, the number of GP consultations at Practice A decreased between the one-week period in 2016 and the one-week period in 2018 and the number of non-medical and AHP consultations increased. The total number of consultations at Practice B also increased between the one-week period in 2016 and the one-week period in 2018, which demonstrates the increased pressures placed on general practice in Wales. Overall, total estimated costs of consultations at Practice B rose by £2,430 between the one-week data collection period in 2016 and the one-week data collection period in 2018, but this was due to the practice employing pharmacists and physiotherapists to provide consultations in the one-week period in 2018, and the increase in NP consultations between the one-week period in 2016 and the one-week period in 2018. Likewise to Practice A, the number of GP appointments at Practice B decreased between the one-week period in 2016 and the one-week period in 2018, while the number of non-medical and AHP consultations increased.

The BIA presented in Chapter 5 of this thesis provided some evidence on the cost implications of role substitution in practice. Non-medical health professionals and AHPs may cost less to train and employ compared with GPs. However, this does not mean lower costs overall, as factors such as resource use including consultation length, number of appointments and the potential for repeated consultations must also be considered. The BIA was narrow in its scope and only provided estimated costs of consultations over a short time horizon. BIAs cannot assess whether role substitution is good value for money as they are not full economic evaluations that consider a full range of costs and outcomes. Moreover, the BIA only considered the general practice budget and did not extend to consider resource allocation shifts such as prescriptions, referrals or diagnostic tests. Future research would need to make use of consultation and patient clinical record data to obtain information on process outcomes in order to gain a greater understanding of the financial implications of role substitution. This chapter did not provide any evidence on the acceptability, effectiveness or safety of increasing role substitution within general practice and therefore these findings must

be handled with caution when considering the full implications of increasing role substitution in real world settings. Resource allocation decisions about whether to invest in role substitution should not be solely based on partial economic assessments such as BIAs that presents findings on cost information alone. Instead, a full range of evidence is required to compare both costs and benefits, as well as the potentially harmful consequences of role substitution (National Institute for Health and Care Excellence, 2014). The full range of limitations of the BIA presented in Chapter 5 of this thesis are presented later on in this chapter under the 'strengths and limitations' section.

There is no gold standard or overarching guidance on how best to implement role substitution and practices appear to be using their own strategies that are not currently translated into policy. If role substitution is implemented incorrectly, it may have detrimental impacts on patient safety. The longer-term budget impact of role substitution and the interplay between costs and effects warrants further attention. Future research that considers resource use in primary care and the cost-effectiveness of role substitution is needed. The budget impact analysis identified a shift in resources through the increased use of role substitution within two practices, but from a societal perspective it is important to assess how these changes in care are valued by patients and healthcare providers. Shared decision making involving a full range of representatives is needed. Practices must balance available resources to the needs and expectations of the patient population they are serving; therefore, the views of stakeholders on changes in practice are crucial for successful implementation.

Chapter 6 addressed Research question 5:

How do patients and general practice team members feel about role substitution within their practice?

The final stage was to explore how patients and general practice team members feel about the increased use of role substitution within their practice. The interview topic guide was informed by the evidence gaps identified in the systematic review of qualitative studies. The BIA also identified the different groups of practitioners that were employed at the two case study practices and these roles were then included as topics for discussion in the qualitative interviews. Chapter 6 of this thesis presents a range of patient and provider views surrounding role substitution general practices. There is strong evidence of confusion and a lack of information about the roles and responsibilities of non-medical health professionals

and AHPs. Many patients are supportive of seeing alternative professionals and appear to place trust in the healthcare system; however, having suitable skills and qualifications was important to patients. Concerns were raised regarding privacy and the acceptance of care navigators among patients. Patients appear to be gradually accepting the changes to general practice, particularly those patients who are in regular attendance and high users of services. There was some concern around the acceptability of role substitution, which may be overcome by better patient education.

If role substitution is going to be accepted, addressing concerns about the care navigator role, loss of family doctors, continuity of care, and unclear information about roles and capabilities of practitioners is needed. Patients and staff felt that having new roles brought added value to primary care, with non-medical health professional and AHP roles bringing a unique set of skills and expertise which can enhance services. Recognising the boundaries of healthcare professions, appropriate support structures and effective team working are important factors for the safe implementation of role substitution. Efficiency for patients was highlighted as a potential positive outcome of role substitution, with waiting times reduced in some cases and a more precise navigation of patients to the staff member with the appropriate skills. However, these findings were not supported across all practices or within practices. High demand for services and patient navigation challenges meant that at times patients sought care outside of general practice from emergency services, which would incur a higher cost of resource use from secondary care services.

Sequential explanatory mixed methods – integration across the health economics and qualitative workstreams

Mixed method designs serve as particularly effective tools for assessing complex processes and systems in healthcare (Fetters, Curry and Creswell, 2013). Ivankova and colleagues define mixed methods as a study design that can be used for collecting, analysing and integrating both quantitative data and qualitative data at some stage of the study process in order to increase understanding of a particular research problem (Ivankova, Creswell and Stick, 2006). As described in Chapter 1 of this thesis, there are many difference study designs within the field of mixed methods research. However, there are three core designs that are often used within social and health sciences research: convergent designs, sequential exploratory designs and sequential explanatory designs (Creswell and Planko Clark, 2017). "In sequential designs, the intent is to have one phase of the mixed methods study build on

the other, whereas in the convergent designs the intent is to merge the phases in order that the quantitative and qualitative results can be compared" (Fetters et al., 2013, p.2136).

As part of this thesis a sequential explanatory mixed methods study was conducted and involved a two-stage process: collecting and analysing the quantitative data first (see chapter) and then the qualitative data (see chapter 6) (Creswell and Creswell, 2017; Ivankova, Creswell and Stick, 2006; Tashakkori and Teddlie, 1998). The integration of quantitative and qualitative procedures and data can occur at the design, methods, or interpretation and reporting stages of a study (Draucker et al., 2020; Fetters et al., 2013). Integration in the sequential explanatory design conducted as part of this thesis occurred at two points, during the methods, and the interpretation and reporting stages of the study. The points of integration are presented below, and the mixed methods approach utilised in this thesis is also reflected upon further below in this discussion chapter.

In mixed methods studies, integration or 'mixing' at the methods stage involves linking the methods of data collection or analysis procedures of the quantitative element to the data collection procedures or analysis of the qualitative element, and this linking can be carried out through four approaches: connecting, building, merging and embedding (Creswell and Planko Clark, 2017). Integration at the methods level of the sequential explanatory design of this thesis occurred through 'connecting' and 'building' (Figure 9). 'Connecting' is when the data from one element informs the sampling frame for the other element (Fetters et al., 2013). This form linking is particularly useful when the purpose is to gain knowledge about participant characteristics to inform purposive sampling in the qualitative phase (Creswell and Planko Clark, 2017; Morgan, 2014; Tashakkori and Teddlie, 1998).

In the mixed method study of this thesis, the data from the BIA was used to inform the sampling frame for the qualitative interviews (Figure 9). As both the BIA and qualitative exploration used the same two practices as case studies, the findings from the BIA provided information on the different types of non-medical health professional and AHPs roles that were being employed in the two general practices who could then be approached to participate in the qualitative interviews. Similarly, this information allowed for integration through 'building' at the methods stage, which occurs when results from one data collection procedure informs the data collection approach of the other procedure (Fetters et al., 2013). The information generated by the BIA study (Chapter 5) regarding the types of health professionals employed in the practices was used to inform the topic guide. The BIA provided a picture about the staffing at the practices which meant that the interview topics could then be framed around the different types of professions e.g., as we knew that

physiotherapists were currently being employed at the practice, it was then possible to tailor the topic guide to include questions framed towards obtaining views and experiences regarding physiotherapists.

Figure 9: Integration through methods

Approach	Description
Connecting	Data from the quantitative phase informs the qualitative sampling frame.
	The findings from the BIA identified the different non-medical health professional and AHP roles being employed in the practices. This information then informed our sampling strategy e.g., physiotherapists and OTs could be included, PAs could not be included.
Building	One data collection procedure informs the data collection approach of the other. Items for inclusion on the topic guide were informed from the BIA e.g., topics for interviews regarding the PA role were not included as PAs were not employed at either practice.

There are three approaches to the integration of quantitative and qualitative data at the interpretation and reporting stage of mixed-methods studies: integrating through narrative, integration through data transformation, and integration through joint displays (Fetters et al., 2013). This thesis used a narrative 'staged' approach where the results of each step are reported in stages as the data was analysed and reported on in separate chapters (Chapters 5 and 6). However, a high-level integration of some of the data has also been presented in this discussion chapter at the interpretation stage through a 'joint display' which involved bringing the data together visually (using a table, figure, matrix or graph) to bring forward new insights beyond the scope of the findings obtained from the separate quantitative and qualitative stages (Gutterman, Fetters and Creswell, 2015). Figure 10 presents a matrix that links the BIA data with the some of the emerging themes from the qualitative exploration. Where appropriate, the matrix also maps the findings to the six dimensions of quality in healthcare proposed by Maxwell (Maxwell, 1992). Full consideration of the thesis findings in relation to the six dimensions are presented further below in this discussion chapter. Due to heterogeneity of the data across the two workstreams, complete integration was not possible, and this is reflected upon in the next section of this discussion chapter.

The findings of the BIA indicated a decrease in GP consultations and an increase in non-medical health professional and AHP consultations at two practices between 2016 and 2018. This demonstrated a shift in resources and indicated the increased use of role substitution at the two practices used as case studies in this thesis. The qualitative findings provided insight into how patients and team members are impacted by this in practice and how these findings link to some of the quality dimensions proposed by Maxwell (1992). As shown in the visual matrix (Figure 10), some of the domains of quality of care are represented more than others. Moreover, some of the integrated findings are considered in relation to the domains of quality but have not been directly assessed or measured in this thesis (domains illustrated in red upper care font in Figure 10) and requires further investigation in future studies. For example, the quantitative findings indicated a decrease in GP consultations between 2016 and 2018. The potential threat to continuity of care due reduced GP consultations was an emerging theme discussed by patients and general practice staff in the qualitative findings. Lack of continuity of care in general practice may have detrimental impacts on patient care and safety (Murphy and Salisbury, 2020); however, measing patient safety was beyond the scope of this thesis. The two domains of quality that have been directly assessed in this thesis were acceptability and costs. However, this framework has also helped identify underrepresented areas that will require further investigation in order to provide a more comprehensive assessment of quality when implementing role substitution in practice. In addition to this, although some of the domains of quality that have been considered in this study, they have not been directly measured. Rather, issues relating to domains such as effectiveness, safety, equity, access and efficiency were discussed in the interviews by the patient and staff participants (see conceptual framework section further below), however, going forward, each of the red domains will require the utilisation of different methods to make objective assessments in order to gain a full judgment of role substitution quality (Maxwell, 1992).

Figure 10: Integration at the interpretation and reporting level

BIA findings (assessment of the cost dimension, Maxwell, 1992).	Findings from the qualitative interviews – what does this mean to patients and team members?	Dimension of quality (Maxwell, 1992)
Reduction in GP consultations	 Patients not given a choice about which healthcare professional they can consult with but acknowledged that GP appointments should be reserved for patients with the greatest need. The importance of patient choice was recognised and team members felt that patients should have the option to consult with a GP. Threat to continuity of care due to loss of the patient-doctor relationship 	EQUITYSAFETY
Increase in nurse consultations (NPs and ANPs)	 Nurses reported to have good relationships with their patients Mixed views about nurses treating complex cases or worrying symptoms – some acceptance as long as nurses know their boundaries and possess the necessary expertise and skills. 	AcceptabilitySAFETY
Increase in pharmacist consultations	 Pharmacists' lack of training in treatment and diagnosis Pharmacists' expertise in medications and their role could improve access to services Pharmacists communicate well with patients 	SAFETYACCESSAcceptability
Increase in physiotherapist consultations	 Physiotherapists valued members of the team Not deemed as appropriate practitioners to deal with complexity Physiotherapist role in MSK may potentially free up GP time 	AcceptabilitySAFETYEFFICIENCY
Increase in OT consultations	 OTs valued members of the team OTs have longer appointment and may be suited to deal with complexity relating to social and emotional situation. OTs role in consulting with patients with mental health issues may potentially free up GP time 	 Acceptability SAFETY and EFFECTIVENESS EFFICIENCY

Critical reflection of the mixed methods process

The sequential explanatory mixed methods design undertaken as part of this thesis involved collecting and analysing both quantitative and qualitative data during separate phases, where both types of data were collected at the same two practices used as case studies. The first phase involved collecting and analysing quantitative data in a BIA to explore the financial implications of increasing role substitution. This stage informed the sampling and topic guide for the next stage of the sequential explanatory design. The second stage involved collecting qualitative data through semi-structured interviews to explore how patients and staff felt about the increased use of role substitution in their practices (demonstrated by the findings of the BIA i.e., a reduction in GP consultations and an increase in non-medical health professional and AHP consultations at the practices). The first stage revealed the increased use of the role substitution and the financial implications in term of the costs of consultations, what was needed was to build upon this evidence to explore what this meant in practice to both care recipients and providers.

The primary purpose of conducting a mixed methods study as part of this thesis was to inform and build, in order to provide a complimentary understanding of role substitution. In mixed methods research, 'mixing' or 'integrating' is not always achieved during every stage of the research process (Fetters et al., 2013). On reflection of the study process, the mixed methods study was successful at integrating at the methods stage of the study process, as described above through 'connecting' and 'building' (Clark and Planko Clark, 2011). On reflection, both approaches to integration at the methods stage were particularly helpful as both the BIA and qualitative interviews used the same two practices to obtain data. The findings from the BIA informed the selection of the staff interview participants as well as the development of the interview topic guides for the qualitative phase. The approaches of linking through 'connecting' and 'building' would not have been feasible if interviews were not conducted at the same practices recruited as case studies for the BIA. Moreover, cases study research occurs within bounded structures of time and place and can simplify the phenomena being investigated by uncovering the direct experiences of individuals, small groups and organisations (Creswell, 2013; Yin, 2003).

One of the challenges often encountered by researchers conducting mixed methods is the successful integration of quantitative and qualitative data during analysis and interpretation (Tariq and Woodman, 2013) and has often been described as 'not achieved' or 'difficult to do' (Bryman, 2007). In consequence, some mixed-methods studies may present

the findings of the quantitative and qualitative elements separately and will involve linkages across each of the included chapters (Halcomb, 2019). This is particularly appropriate where the aim is to use one method to inform the development of the next stage (Halcomb, 2019), as intended in this thesis. In many instances, mixed methods researchers do not start out with the intention of integrating their findings as their purpose was to answer two distinct research questions and therefore handling their quantitative and qualitative findings as two separate domains is appropriate (Bryman, 2007). On the other hand, exploring connections between quantitative and qualitative findings have the potential to bring forward added value even if the research was not designed for that purpose (Hammond, 2005).

This thesis presented a high-level integration of the findings at the reporting stage of the study process and made use of a joint display to show the points at which the data from both phases connected. While the BIA findings suggested the increased use of role substitution at the practices, qualitative interviews allowed us to understand what this meant to those directly impacted by these changes to practice. Thus, the findings from the qualitative interviews were used to contextualise the results of the budget impact analysis (Bowen, Rose and Pilkinton, 2017). It is acknowledged that this 'mixing' presented in the joint display was a high-level attempt at integration at the final reporting stage of the mixed methods process. In hindsight, the thesis would have benefitted from the use of a joint display earlier on in the mixed methods process to help inform decisions about data collection and analysis (Fetters et al., 2013).

It was not until later on in the study process that the difficulties of integrating the quantitative data with the qualitative data became evident, and from reflecting on the mixed methods process, it is acknowledged that there were a number of practical barriers that hindered successful integration. Firstly, the nature of the data may cause significant difficulty when researchers are attempting to fuse together vastly different types of information especially when one type of data appears to be more intrinsically interesting or compelling that the other data set (Bryman, 2007). This was especially true during the PhD studentship, where greater priority in terms of the interpretation and write-up was given to the qualitative phase of the sequential design as this information provided interesting insights into the complex nature of role substitution in practice.

The heterogeneity of data across the two phases also made full integration of the data unfeasible. Nevertheless, the purpose of this thesis was not to integrate all data sources and analyse it to answer one singular research question, but rather to integrate the different types of data in order to generate insights into a broad range of research questions, resulting in

enriched understanding of the complex nature of role substitution (Tariq and Woodman, 2013). Moreover, an additional barrier to the integration of findings across the workstreams was the lack of an exemplar study or guidance on how best to combine qualitative and cost data. There is a significant lack of published mixed-methods studies that combine qualitative and economic evidence, "unfortunately, to date, virtually no research has combined quantitative and qualitative approaches in the economic evaluation of health services" (Dopp et al., 2019, p.3).

Although the sequential explanatory design is advantageous for 'beginner' researchers as it follows a straightforward two-stage process, a significant challenge of conducting mixed methods in general as a novice researcher was a lack of formal training in mixed methods (O'Cathain, Murphy and Nicholl, 2010). Future mixed methods studies that intend on integrating qualitative and health economics data would benefit from research teams that can bring together specialists in both fields (Bryman, 2007).

The studies conducted in the sequential design of this thesis built on each other, complemented one another and aided the interpretation of the sequential work. In 1989, Greene, Caracelli and Graham set out a conceptual framework, which identified 'complementarity' as a key purpose for conducting mixed-methods (Greene, Caracelli and Graham, 1989). They also highlighted that mixed-methods studies may be conducted with a purpose for expansion intent, which aims for scope and breadth by employing multiple components (Greene et al., 1989). The multiple methods undertaken in this thesis, provided an opportunity to address the complex nature of role substitution and pointed to areas of future research that offer further insight on the topic. Mixed methods allow researchers to build on evidence in a real-world context and can be used to provide a broad view of issues relating to implementation and service evaluation, rather than traditional methods of evaluation such as RCT designs that often require a number of years to achieve results. Meaningful results within short timeframes that are relevant to ongoing practice and management of current budget cycles are needed. There are opportunities for research to inform practice, through carefully designed pragmatic clinical trials of more novel roles that are being substituted into primary care. However, it is important to consider that as organisations make changes in practice that they must evaluate the services in real-time with service evaluation and natural experiments. A combination of evidence-based practice and practice-based research is needed to evaluate role substitution both before and after implementation.

Strengths and limitations of this thesis

The work undertaken in this thesis makes a valuable contribution to the evidence-base of role substitution and has implications for policy, practice, and future research in this area. This thesis provides some recommendations for practices to consider when employing non-medical health professionals and AHPs to perform some roles that were traditionally performed by GPs. Recommendations are presented in the BIA chapter of this thesis (Chapter 5) and in the implications for policy and practice section below.

To the author's knowledge, the systematic review of economic evaluations presented in Chapter 2 of this thesis and published as Anthony et al. (2019) was the first systematic review of its kind to identify full economic evaluations of role substitution by non-medical health professionals and AHPs in primary care. The systematic review undertook comprehensive searches using robust methodology and followed PRISMA guidelines (Moher et al., 2009). The Drummond checklist was utilised to assess the quality of the economic evaluations included in the systematic review. It is acknowledged that this appraisal tool does not provide a full of assessment of the quality of the study design in which the economic evaluation is embedded. Other tools may be helpful to consider wider issues which can contribute to areas of uncertainty in the data that may impact of the quality of the economic evaluation. Using a tool to assess the risk of bias in randomised trials (e.g., Higgins et al., 2011) would be useful to assess the quality of the study design in which the clinical effectiveness evidence used in the economic evaluation was based upon.

Chapter 3 of this thesis presented a separate systematic review exploring the barriers and facilitators of role substitution in primary care and presents a wide range of perspectives from patients, doctors, nurses, CCG leaders, managers and PA educators. This systematic review was limited by the small number of qualitative studies for each type of health care professional performing role substitution. The largest number of studies uncovered related to PAs (six paper), but there were less studies for pharmacists (four papers) and physiotherapists (one paper). The systematic review failed to identify qualitative evidence on views and perspectives relating to other groups of AHPs. Nevertheless, updated searches presented further below in this chapter has uncovered more evidence in these areas and demonstrates the rapid growth of evidence on views and perspectives of role substitution.

Chapter 4 presented the findings of an online survey which aimed to explore the extent to which role substitution was being implemented at a national level. To the author's knowledge, this was the first survey of its kind to ask cluster leads to self-report on the use of

role substitution within their clusters in Wales and presents useful findings regarding the strategies that clusters are using to increase role substitution in clusters. It is acknowledged that there were many limitations to the survey methodology and subsequently, the interpretation of the survey findings must be handled with caution. In summary, the study was limited as it was a self-report survey with a small sample size. All of the cluster lead respondents reported the use of role substitution within their cluster; however, this may be due to the fact that cluster leads who responded did so because role substitution was already being implemented within their cluster. It may be likely that the non-responder cluster leads would have provided very different answers to the survey questions; this is known as nonresponse bias and is a common problem in surveys. Relating to this limitation was the issue of self-selection bias which is a common issue in surveys (Bethlehem, 2010). Another limitation of the survey was the inability to determine whether or not the response rate by clusters were impacted by the sample characteristics of the clusters as we did not collect information on the total number of practices within each cluster or any information on the approximate size of the patient populations that the clusters serve. The failure to capture this information in order to compare the characteristics of respondents versus non respondents is a major limitation of this study that significantly impacts the generalisability of the survey results. An additional shortcoming of the survey was the inconsistency of the terminology and weaknesses in the framing of some of the survey questions, which has been discussed in detail in Chapter 4 of this thesis.

Chapter 5 of this thesis presented a BIA and provided novel findings of the financial implications of increasing the use of role substitution by using a real-world example with actual figures obtained from two general practices located in North Wales, UK. This study was successful in linking high level data with published national reference costs as part of case study to assess the affordability of increasing role substitution in real-world scenarios. This study only provided an indication of the affordability of implementing role substitution based on cost estimates of increased non-medical and AHP consultations. The BIA was narrow in its scope in that it could not provide any evidence on the effectiveness, cost-effectiveness or safety of role substitution. In addition, the BIA presented in this thesis only considered the general practice budget and did not capture information how role substitution may implicate the wider healthcare system. This study did not include any evidence on the impact of role substitution on process outcomes such as re-consultation rates, prescriptions, referrals and clinical investigations which will inevitably have significant consequences on the NHS budget. Future research in this area must therefore make use of consultation and

patient clinical record data to gain a wider understanding of whether role substitution is safe and effective in practice, and whether it is a good use of scarce NHS resources. Previous costing analyses have already been successful in exploring the wider clinical and wider service impacts of role substitution in the UK (Drennan et al., 2015; Venning et al., 2000).

The BIA predominately used published national cost estimates only as local unit costs were not available from the practices. Unfortunately, unit costs for GP locum consultations and costs for ANP, OT and GP locum home visits were not available in the published literature, therefore the most recent and appropriate benchmarks that were available were used to cost these consultations. Future work to develop unit costs for healthcare practitioners such as GP locums is required, and the methodology used by the PSSRU would be a useful framework to follow to achieve this in future. Unit costs for GP locum consultations were estimated; consequently, there may have been an underestimation of locum costs in the base case analysis. The cost of GP locum care may be particularly important should there be a shift in employment patterns or sickness absenteeism which require more locum staff use. Without greater information on numbers of patient consultations per day and specific cost information for patient-related work, using these costs required several assumptions to be made. The author conducted limited sensitivity analysis to consider scenarios of increased unit costs for GP locum consultations to explore these uncertainties within the costings; nevertheless, further work is needed to develop methodologically sound unit cost estimates for GP locums to increase the confidence in future cost analyses.

A major limitation acknowledged in this study is the inability of BIAs to consider the clinical effectiveness or safety of role substitution in relation to costs. A significant limitation of this before and after design study was that it did not have a control group to compare natural changes in costs over time (or costs changing due to other factors than role substitution), for example in general practices which did not report using role substitution. The study design had little control of confounding variables that may impact on costs during the study time horizon. This study design is significantly limited by the inability to make an assessment of causality with some changes in costs likely not attributable to the increased use of role substitution. In order to help explain cost changes over time, assessing factors such as resource use trends, staff employment rates, sickness absenteeism and other staff roles employed in general practice is needed. Moreover, considering the need to capture full information relevant to the budget holder in primary care, future BIA work should consider capturing a wider range of costs and resources within a practice to be able to identify

potential shifts in resource use and associated costs that might spill over into other areas of the practice budget.

The length of consultations estimated or reported from routinely collected clinic records used in the BIA was not validated and consequently the approach to consultation costing will have likely impacted on the overall costs and conclusions drawn from the BIA study regarding the affordability of role substitution. The short time horizon and period of data collection is a further limitation acknowledged in the BIA. A longer period of data collection would inform factors that could potentially impact on the total costs such as staff sickness, employment rates and FTE changes which may result in capacity issues. Moreover, a longer data collection period would also be needed to capture information on patient recall rates, as patients may require additional consultations to resolve a problem or condition that was not resolved during their initial consultation with a non-medical health professional or AHP. A full year of data would have provided a more comprehensive picture; however, this would have required increased practice resources to capture the data which was beyond the scope of this thesis research. The finding presented in this chapter alone cannot sufficiently inform decisions about whether to invest or disinvest resources into increasing the use of role substitution. This BIA presented in Chapter 5, only provided a restricted picture relating to the affordability of increasing the use of non-medical health professional and AHPs based on estimated consultation costs over a short data collection period. To gain a greater understanding of role substitution in practice, a full range of evidence is required to compare both costs and benefits, as well as consideration of the potentially harmful consequences of role substitution (National Institute for Health and Care Excellence, 2014). In consequence, due to the narrow scope of the BIA, there are likely to be resource implications that have not been measured in this analysis. Future cost analyses in this area should endeavour to capture the full range of wider costs and resource use that may spill over into other areas of the practice budget.

In Chapter 6 of this thesis, interviews were conducted with ten primary care team members. This study explored the real-world application of role substitution using two different general practices as case studies which provided real-world situations and tested views directly in relation to role substitution and how it is implemented and transpires in practice (Flyvbjerg, 2006; Krusenvik et al., 2016). Purposive sampling was used to identify staff members with differing roles within the practice. It was not possible to report the specific roles of the team members interviewed in this thesis because the sample was taken from two practices and the anonymity and confidentiality of the participants had to be

protected. In-depth qualitative research delving deeper into the experience of each specific role may provide further information on how role substitution varies across practices and specific roles. This study provided novel views from both patients and general practice team members regarding role substitution by a variety of different practitioners including nurses, pharmacists, physiotherapists and OTs. To the PhD candidate's knowledge, this was the first qualitative study conducted in Wales to explore the views regarding patient navigation by care navigators and team coordinators (who previously worked in a general practice receptionist or administration roles). This study makes a valuable contribution to the evidence base on the acceptability of role substitution in general practice in NHS Wales.

While through this thesis many roles were included, it is acknowledged that it has not identified all roles where substitution occurs, and further research is needed. The roles that were included in this were constrained by the available literature presented in the systematic reviews and the available roles that employed in the two practices that were used as case studies in the thesis. Evidence points towards increasing the use of PAs in primary care (Drennan et al., 2011; Drennan et al., 2012; Drennan et al., 2015; Drennan et al., 2017). Unfortunately, PAs were not included in the BIA or the qualitative exploration of this thesis and future work to explore this new profession in Wales is needed. Moreover, the survey presented in Chapter 5 of this thesis, indicated that a wide range of non-medical health professionals and AHPs were being utilised in some general practices in Wales; consequently, further research is needed to address whether additional considerations on costs, benefits and patient and provider perspectives may be observed for these roles.

This thesis benefited from using a conceptual framework first described by Avedis Donabedian (1980) and elaborated by Robert Maxwell (1984; 1992) to judge quality in healthcare and was used to consider the findings presented in each chapter of the thesis. Consideration of the thesis findings in relation to the conceptual framework and theories of role substitution are discussed in detail below in a separate section of this discussion chapter.

Implications for practice and policy

The work completed in this thesis has identified many practice and policy implications. It is important to recognise that changes to practice are complicated and take place within complex systems, which has been recognised through the survey (Chapter 4) and qualitative research (Chapter 6). When considering if there is a consensus on what GP roles can be successfully substituted by non-medical health professionals and AHPs, there remains

uncertainty around many roles and may require consideration of individual skills and expertise. Looking across the breadth of the methods utilised within this thesis, the findings suggest that nurses can successfully complete roles such as treating minor illnesses and the management of some chronic conditions such as diabetes, asthma clinics and the management of coronary heart disease. Evidence from the qualitative interviews suggested that some specialist nurses such as ANPs may have expertise in certain areas, but their ability to complete particular roles will depend on individual skill level and expertise. Practice managers and GP partners must therefore establish the skill set and experience when employing individual ANPs to determine their scope of practice to ensure that they are working within their remit and being utilised to the best of their ability. Findings from this thesis revealed that pharmacists are being employed in primary care to conduct medication reviews and are often considered as 'experts' with respect to their knowledge of medications, and consequently appear to be well suited for this role.

Physiotherapists and OTs are being employed in primary care to complete consultations for MSK and mental health, respectively. However, there remains a lack of evidence to demonstrate the cost-effectiveness of these practitioners to provide these roles in general practices. Future studies that could provide evidence on both the effectiveness and cost-effectiveness of less well evidenced types of practitioners may also help to increase the acceptability of these roles within practice. For example, if future studies report cost-effective results for OTs providing consultations for patients with mental health issues, practice managers and GPs may be more confidence to make decisions about whether they should employ OTs at their practices.

This thesis also demonstrated that role substitution may be less beneficial in some instances, for example in cases that require the expertise of the GP, such as when treating patients with particularly complex conditions, when making new diagnoses and the detection of red-flag symptoms. Although general practice teams are expanding to include a wideranging skill-base, GPs will always remain an integral part of primary care, they serve as the focal point of the MDT team and are needed to offer their skilled opinion and make final decisions in areas that remain uncertain for non-medical health professionals and AHPs. As highlighted in the introduction chapter of this thesis (Chapter 1) different nursing roles are difficult to define and may vary from practice to practice and across the devolved nations, this role ambiguity was further confirmed by the qualitative findings of the thesis (Chapter 6). Clearly defined nursing roles that can be understood by both patients and practice teams are needed to ensure patient and primary care team confidence in these different nursing roles.

This thesis acknowledges that specific role duties will vary between different practitioners and practices; however, efforts are needed to ensure that there is some consistency in the terminology and remit used. Ideally, there needs to be some sort of agreed definitions at a higher national level. However, it is also essential that individual practices take responsibility of not only ensuring that roles are clearly defined, but also that both patients and all members of the primary care team are aware of each practitioners' capabilities. Only then can patients make informed decisions regarding their healthcare, which will hopefully transpire into a shift in culture for enhanced public responsibility about their own health.

As outlined in Chapter 1 and Chapter 6 of this thesis, patient choice and understanding are fundamental for role substitution to be successfully implemented. Practices need to come to an agreement, through shared decision making, about how best to communicate with the public to get this vital information across. Alongside national efforts to define roles, consistent education campaigns to improve health literacy relating to roles that may increasingly be substituted are needed. At a public policy level, caution is needed in public health campaigns with clearer messages about roles and avoiding adverts that emphasise the 'see your GP message'.

Findings from the qualitative interviews (Chapter 6) indicated that practices were already starting to use alternative methods to provide healthcare and communicate with patients, such as the increased use of email and telephone consultations. Since the Covid-19 pandemic, the use of these methods and newer methods such as e-consultations are currently the predominant method of accessing primary care. Data gathered for this thesis were collected before the pandemic and it is acknowledged that processes have now needed to change rapidly. Care navigators face new decisions such as who to prioritise for face-to-face consultations. Decisions relating to the most appropriate practitioner based on reasons for seeking healthcare remain; however, it is not known how well all of these services work through remote methods and which groups of patients may face barriers to access. Greater attention on research that seeks to comprehend these real work situations to address these issues is warranted. Understanding the impact of the Covid-19 pandemic on primary care both in the short and long-term is necessary to inform practice and policy guidelines.

This thesis acknowledges that role substitution may be happening due to contingency rather than forward planning and that there is no 'one size fits all' solution to its successful implementation. In order to make best use of limited healthcare resources, practices (through shared decision making involving the whole primary care team and patient representatives) need to assess the needs of the patient populations that they serve and determine the optimal

skill mix that can be achieved by using limited resources to their best use. It is important that planning reflects rapidly changing population needs, with an ageing population and future generations who may have more experience of technology and remote healthcare following the Covid-19 pandemic. Practices should consider using health economics tools such as BIA (Sullivan et al., 2014) or PBMA (Brambleby and Fordham, 2003) to explore cost implications and weigh-up costs and benefits of changing skill-mix within their individual practices. If healthcare expenditure increases due to the increased use of role substitution, practice management teams need to consider whether benefits such as enhanced care and satisfaction are worth the rise in costs. Conversely, practices may experience cost savings by employing less costly alternatives to GPs, but there is also the potential for inefficiencies such as fragmented care and unnecessary appointments.

The role of the care navigator in general practice is evolving, but there is no clear guidance on how best to develop this new role. Practices need to consider different methods and training to support this role in order to avoid inappropriate signposting of patients, which could result in increased costs and wasted resources due to repeated unnecessary appointments with different practitioners. Moreover, practices should help to support skills such as how to reflect on work practices and experiences, how to improve the quality of their patient communication, how to handle adverse events. It is vital that practices provide sufficient support structures and opportunities for care navigators to seek advice from more experienced members of the practice team when needed.

This thesis has covered implications for role substitution within primary care, but it is important to recognise that primary care exists within a wider system of healthcare. There needs to be attention on potential spill over effects of role substitution with resource use evaluated from a wider, whole NHS perspective or societal perspective. This thesis did not assess the effectiveness or safety of role substitution which have important implications of implementing role substitution in practice. It is fundamental that practice managers and GPs consider the evidence gaps in these areas when employing non-medical health professional and AHP roles in general practices.

Comparisons with existing literature and recommendations for future research - Updated literature searches since systematic review searches in 2017

The two systematic reviews in this thesis (Chapter 2 and 3) included literature searches up to 31st July 2017 and a large body of evidence has since been published on this topic since the searches were conducted.

Updates searches for the qualitative evidence: Updated searches were performed in Ovid MEDLINE, CINAHL, Cochrane Library, National Institute for Health and Care Excellence (NICE), and the Centre for Reviews and Dissemination database. Searches were carried out on 6th October 2022 to retrieve studies published since 2017 (when the last searches ran to in Chapter 3). The search strategy performed in Ovid MEDLINE can be viewed in Appendix 4. In order to recover a comprehensive set of relevant literature and to increase sensitivity, the searches were purposely broad. The search strategy included the terms 'role substitution', 'task shifting', 'general practice', and 'primary care'.

The updated literature searches since the last searches were carried out identified ten qualitative studies on the views and perspectives of role substitution in primary care. The majority of the identified studies were conducted in general practice settings; however, one study also included some views on community pharmacist settings in comparison to general practice-based settings (Savickas et al., 2020). Another study, conducted in the US, described the setting as primary care and the findings related to experiences working within primary care teams with primary care physicians (Rouch et al., 2022). In the US, "primary care physicians include the specialties of family practice, general practice, general internal medicine, and general paediatrics and, for women patients, obstetricians and gynaecologists provide primary care" (Bindman and Majeed, 2003, p.631).

Of the ten qualitative studies identified, six studies explored views and perspectives of pharmacists working in general practice (Mann et al., 2022; Bartlett, Bullock and Spittle, 2021; Karampatakis et al., 2021; Savickas et al., 2020; Ryan et al., 2018). Findings from qualitative focus groups in England found that patients' acceptability of pharmacists working in general practice was high, they were viewed to add value through their expertise in medications, however, some patients had a low level of knowledge regarding their role (Mann et al., 2022). Pharmacist views of a 1-year transition programme to support pharmacists to enter general practice in Wales found that interaction with the wider general practice team was a critical factor to the successful integration within teams. Moreover, pharmacists' lack of clarity of their role was a barrier to their successful integration within general practice (Barlett et al., 2021). In a separate study, advantages of pharmacists working

in general practice in England voiced by patients included the potential to increase access and quality of care (Karampatakis et al., 2021).

Savickas and colleagues, reported positive views to support the introduction of a novel pharmacist-led atrial fibrillation screening intervention in general practice in England. Pharmacists were viewed as an under-utilised professional group with the potential of reducing GP workload. In addition, patients preferred the general practice setting to consult with a pharmacist in comparison to community pharmacy settings due to factors such as privacy and commercialisation (Savickas et al., 2020). Finally, a study by Ryan and colleagues revealed that pharmacists were viewed to provide a complimentary role within general practice teams with the potential to decrease other clinician workloads; however, the importance of adequate training and clear knowledge of pharmacist competencies were deemed important (Ryan et al., 2018). A separate study explored stakeholders' views of non-medical roles including PAs, pharmacists and ANPs working in general practices in England (Nelson et al., 2019). Some of the main themes discussed included ambiguity of new roles, reduced GP demand and practitioners knowing their limitations (Nelson et al., 2019).

The updated evidence base on the views and perspectives of pharmacists working in general practice support and expand on the findings presented in the systematic review (Chapter 3). The evidence in the systematic review reported on a lack of knowledge regarding the pharmacist role among patients (Gidman et al., 2012), which was also a finding that was reported in our qualitative exploration (Chapter 6). Interestingly, the updated literature on this topic also indicates an uncertainty among pharmacists' themselves with regards to their role in general practice which was viewed as a barrier to their successful integration within general practice teams and subsequently highlights the need for clearly defined roles (Barlett et al., 2021). Increased quality of care, improved access and the potential to reduce GP workloads were facilitators of pharmacists' involvement in general practice identified in the updated literature searches (Karampatakis et al., 2021; Savickas et al., 2020; Ryan et al., 2018). Improved patient services, quicker access to consultations and reduced workloads were also noted in our systematic review (Stewart et al., 2009) and were reported as findings in the qualitative interview findings (Chapter 6). Issues relating to the community pharmacy setting in terms of threats to confidentiality and privacy noted by Savickas and colleagues (Savickas et al., 2020), was also an emerging theme in our qualitative exploration and all of the pharmacist studies identified in the systematic review (Gidman et al., 2012; Hatah et al., 2013; Lamberts et al., 2010; Stewart et al., 2009). The

evidence obtained from the updated searches have also expanded upon what was previously known about pharmacists from the systematic review evidence and the qualitative evidence presented in Chapter 6 and provides some evidence on the views of how their roles are expanding to provide innovative services in general practice (Savickas et al., 2020).

Apart from the one study exploring the roles of pharmacists, PAs and ANPs reported earlier (Nelson et al., 2019), the updated searches identified only one other study reporting on views relating to PAs working in general practice in England (Argal and Hoskin, 2021). A qualitative online questionnaire reported on findings relating to the frequency and nature of clinical supervision received by PAs during their first year of practice. The results indicated that PAs were on the most part satisfied with the degree of supervision they received; however, some barriers to their satisfaction were insufficient induction, a lack of structured supervision/support and insufficient communication with their GP supervisors (Agarwal and Hoskin, 2021). Findings from the systematic review (Chapter 3) also raised concerns regarding the levels of supervision required to support PAs (Drennan et al., 2011; Jackson et al., 2017; Taylor et al., 2013). Evidence from Argwal and Hoskin, build on the systematic review evidence by exploring this topic in greater detail to provide further evidence on how best to clinically supervise the PA role (Argwal and Hoskin, 2021).

One qualitative study conducted in England aimed to explore patient acceptability of physiotherapists working in general practice based on the views of patients and different members of the general practice team (Morris et al., 2021). The physiotherapists were described as first contact practitioners that patients could consult with directly without an initial GP referral. The authors concluded that overall patients were generally accepting of the physiotherapist role; however, there were a number of factors that were viewed to impact their acceptability. Patients expressed the importance of having a choice to see a GP or physiotherapist for anything they deemed 'serious'. In addition, patients expressed the preference for physiotherapist to consult with the GP for prescriptions to treat serious or complex conditions. Interestingly, the role of receptionists to influence patients' acceptability of physiotherapists was an emerging theme in terms of reassuring patients that physiotherapists could provide diagnoses. However, this was hindered by patients views of receptionists being a low status role and their lack of qualifications to signpost to the most appropriate practitioner. The importance of receptionists promoting the role of the physiotherapist was viewed as an important factor influencing their acceptability. Moreover, information regarding their role, qualifications and training were important to patients.

Reduced waiting times to consult with a physiotherapist compared with a GP was a facilitator voiced by patients (Morris et al., 2021).

The systematic review only identified one qualitative study exploring the views of GPs and NPs regarding the role of physiotherapists in primary care (Dufour et al., 2014). The evidence from Morris and colleagues, builds on the evidence-base on this topic by providing a patient perspective on physiotherapists (Morris et al., 2021). Evidence from the systematic review did not report on the issue of physiotherapists treating patients with complex or 'serious' conditions, although this was a topic that was discussed in our qualitative interview findings (Chapter 6); therefore, this updated evidence presented by Morris and colleagues contributes to this gap in knowledge in terms of published evidence regarding physiotherapists dealing with complexity in primary care.

The updated literature searches found one study exploring perspectives about the integration of paramedics in general practice (Muldoon and Seenan, 2021). Findings from interviews with GPs in Northern Ireland reported that delegating tasks to paramedics improved GP happiness, job satisfaction and feelings of support in the workplace. Paramedics were well accepted among GPs who highlighted the potential that paramedics can make to alleviate pressure through better workload planning, collaboration and improved work-life balance. Nevertheless, although GPs recognised the need to change the delivery of services there were concerns about how paramedics would complement existing services and whether they would be accepted among patients (Muldoon and Seenan, 2021). This study fills a clear evidence gap that was identified following the systematic review conducted in 2017 (Chapter 3) as we did not identify any paramedic studies at the time of the searches. Moreover, we did not uncover views regarding paramedics working in general practice during the qualitative interviews.

One US study reported on OTs experiences of working in primary care (Rouch et al., 2022). Results found that OTs' motives to work within primary care teams were driven by participants' perceived value of the field of occupation therapy within primary care including the ability of OTs to work holistically. Moreover, participants felt that OTs could provide a complimentary role to primary care teams through consultation with patients with unmet chronic care needs that currently fall through the gaps in the current service provision in primary care teams (Rouch et al., 2022). OTs described their contribution to patient-centred care by promoting self-management and also described treating patients with complexity including patients with anxiety and depression, chronic pain and multiple chronic conditions (Rouch et al., 2022). This study contributes to the qualitative evidence-base on OTs working

in primary care. The systematic review presented in Chapter 3 of this thesis did not identify any OT studies; however, views and perspectives of the OT role were identified during the qualitative interview findings presented in Chapter 6 of this thesis. Similar to the findings of Rouch and colleagues, the role complimentary role of the OT, their contribution to patients with complexity, and their ability to work holistically were also findings reported on in our qualitative exploration.

The overwhelming majority of the qualitative literature identified from the updated searches were from the UK, which signifies the continued development of role substitution in response to increasing pressures placed on the NHS. The searches identified peer-reviewed evidence on the views and perspectives relating to OTs and paramedics working in general practice which were previously not identified during our previous literature searches. There remains a lack of evidence on the acceptability of other groups of healthcare professionals working in general practice teams such as practitioner psychologists, podiatrists, dieticians, social prescribers and approved mental health professionals.

Updated searches to identify economic evaluations since 2017: Updated searches were performed in Ovid MEDLINE, CINAHL, Cochrane Library, National Institute for Health and Care Excellence (NICE), and the Centre for Reviews and Dissemination database. Searches were carried out on 6th October 2022 to retrieve new evidence since 2017 (when the last searches ran to in Chapter 2). The search strategy performed in Ovid MEDLINE can be viewed in Appendix 1. In order to recover a comprehensive set of relevant literature and to increase sensitivity, the searches were purposely broad. The search strategy included the terms 'role substitution', 'task shifting', 'general practice', and 'primary care'.

Updated searches since the searches conducted in the systematic review of economic evaluations (Chapter 2) identified four full economic evaluations of role substitution in primary care. Two economic evaluations assessed role substitution by physiotherapists (Ho-Henriksson et al., 2022; Bornhöft et al., 2019), one by nurses (Doherty et al., 2018), and one by OTs (Cockayne et al., 2021). One cost-utility analysis compared physiotherapist care with GP care when assessing patients presenting with suspected knee osteoarthritis in general practice in Sweden (Ho-Henriksson et al., 2022). Findings indicated no statistically significant differences in QALYs or total costs between physiotherapist and GP-led care. Both the physiotherapist and GP-led care groups observed improvements in their health-related quality of life one year after baseline; however, physiotherapist-led care achieved slightly lower QALYs but at lower cost compared with GP-led care (Ho-Henriksson et al.,

2022). Another cost-effectiveness analysis also conducted in Sweden compared initial assessment of MSK presentations by the physiotherapist compared with initial assessment by the GP (Bornhöft et al., 2019). Physiotherapist-led care was deemed more cost-effective with slightly greater QALYs and lower total costs compared with GP-led care. From a societal perspective (considering productivity losses), the probability of the intervention being cost-effective was 85% at a willingness to pay threshold of 20,000 Euros (Bornhöft et al., 2019).

An economic evaluation conducted in England, UK compared the cost-effectiveness of nurse-led care compared with GP-led care for the treatment of gout (Doherty et al., 2018). The nurse-led care intervention was cost-effective compared with usual care provided by the GP, with a cost per QALY gain of £5066 at two years for nurse-led care (Doherty et al., 2018). The final economic evaluation was funded by the NIHR Health Technology Assessment programme and assessed the cost-effectiveness of an OT delivered home assessment for reducing falls in older adults compared with usual care which consisted of care delivered by the GP, other health professionals and a falls prevention leaflet (Cockayne et al., 2018). This England-based study found that the OT intervention was £19 higher and produced 0.004 less QALYs per patient compared to usual care. Consequently, the authors concluded that the OT home assessment intervention was not cost-effective compared with usual care (Cockayne et al., 2022).

Findings from the systematic review of economic evaluations presented in Chapter 2 of this thesis revealed a lack of evidence on the cost-effectiveness of AHPs working in general practice. The updated literature searches have demonstrated that research has progressed in this area with regards to the cost-effectiveness of physiotherapist and OT-led care. An OT home assessment intervention was not deemed as a cost-effective alternative to GP-led care for preventing falls in older patients (Cockayne et al., 2022). The qualitative findings presented in this thesis have highlighted OTs contribution to mental health consultations in general practice therefore future research would benefit from assessing the cost-effectiveness of OTs performing this role in comparison to GP consultations. The updated literature searches identified both positive (Bornhöft et al., 2019) and neutral (Ho-Henriksson et al., 2022) findings in relation to the cost-effectiveness of physiotherapists working in general practice for some roles (knee osteoarthritis and MSK presentations. In order to further the evidence-base in this area, future research may wish to explore the costeffectiveness of more roles carried out by physiotherapists in general practice such as helping patients manage their conditions, providing education and disease prevention. There remains a lack of evidence comparing the cost-effectiveness between GPs and other healthcare

professionals such as practitioner psychologists, podiatrists, dieticians, social prescribers and approved mental health professionals.

Looking at partial economic evaluations may help provide further information on the potential economic impacts of role substitution and warrants further evaluation. For example, Drennan et al (2015) points to the potential cost impacts of PAs. Drennan et al (2015) identified that PA appointment may be longer in time when compared with GP appointments; however, costs were lower overall. There was no evidence of PA appointments resulting in higher incidences of re-consultation compared with GPs, and findings showed patients had a high-level of satisfaction with PA consultations. This thesis did not include an assessment of the cost implications of employing PAs in general practice, as PAs were not employed in either of the case study practices.

Following the publication of Chapter 2, further discussion on this topic (Vrijhoef, 2020) has highlighted the importance of careful interpretation of findings and the transferability of role substitution research taking into account the complex nature and contextual factors that can influence costs and benefits. Previous studies identified in my economic evaluation systematic review only included direct costs. There was no information on length of consultation and patient recall (i.e., re-consulting for the same condition, as the issue was not resolved during a patient's first appointment). The largest cost driver in previous studies was staff salaries. This chapter advocates for caution and further development in economic evaluations of role substitution. There is little in the field to draw on, and a lack of transparency in describing included costs and this could result in misleading conclusions. Previous studies state that role substitution was either cost-effective or not costeffective, but only a narrow set of costs were taken into consideration. The concluding points are that there is a lack of evidence and the need for further economic evaluations with clear methods, particularly what costs are included and why. This is required to develop the evidence base and produce robust research that furthers the exploration of role substitution, particularly as implementation has been widespread, and there are indicators of success such as it has provided a practical solution to GP shortages. A wider societal perspective which is able to capture a broader set of costs and benefits, for example, inclusion of possible patient productivity losses warrants further consideration. Future clinical trials evaluating role substitution should consider conducting full economic evaluations concurrently.

As described in chapter 1, this thesis used a conceptual framework that was first described by Avedis Donabedian (1980) and elaborated by Robert Maxwell (1984; 1992) to judge quality in healthcare. This thesis is concerned with the introduction of workforce innovation therefore it is appropriate to consider conceptual models used to judge quality in health care and whether any health care innovation should be adopted. Quality in healthcare is multidimensional and subjective in nature, therefore making it difficult to define and measure (Quentin et al., 2019; McLaughlin and Kaluzny, 2004). The following section of this discussion chapter considers the findings from the systematic review and empirical chapters in relation to the six dimensions proposed by Maxwell for judging the quality of healthcare. The overall findings across the thesis chapters are synthesised below in relation to the following six dimensions: effectiveness (including safety), acceptability, efficiency (including costs), access, equity, and relevance (Maxwell, 1992).

Effectiveness (including safety)

The empirical studies of this thesis did not assess the effectiveness or safety of role substitution which have important implications of implementing role substitution in practice and is highlighted as significant limitation of this thesis. Nevertheless, the systematic review of economic evaluations (Chapter 2) presented findings of the concurrent clinicaleffectiveness papers to provide contextual information that was relevant alongside the interpretation of the economic evaluations. Chapter 2 presented findings of five RCTs that assessed the clinical effectiveness of role substitution in primary care. Nurse-led care was found to demonstrate favourable findings for disease management in terms of diagnosis and appropriate treatments for patients with heart conditions (Khunti et al., 2017). Moreover, a separate RCT found no differences in health status or disease burden between nurse-led and GP-led care when treating minor common minor health problems (Dierick-van Daele et al., 2010). The third RCT assessed differences between nurse-led care and treatment as usual provided by the GP on fatigue and physical functioning in patients with chronic fatigue syndrome (Wearden et al., 2010). Results from the clinical effectiveness study found that nurse-led PR care led to a statistically significant improvement in patient fatigue compared with TAU, however there was no statistically significant difference in physical functioning (Wearden et al., 2010). In terms of the effectiveness of pharmacists substituting for GPs, the fourth RCT reported on in Chapter 2, did not find any significant differences between GP led care and pharmacist led care on primary clinical outcomes including aspirin related management and lifestyle measures (Community Pharmacy Medicines Management Project Evaluation Team, 2007). Finally, a RCT conducted by Neilson and colleagues, reported on significant benefits for pharmacist-led care on anxiety and depression scores compared with treatment as usual provided by the GP (Neislon et al., 2015).

Although not a direct assessment on effectiveness, the findings presented in the systematic review of qualitative studies (Chapter 3) and the qualitative study of this thesis (Chapter 6) presented some findings in relation to perceived safety. Issues relating to the safety dimension highlighted in the systematic review included pharmacists' lack of training in treatment and diagnosis which could potentially threaten patient safety. Issues reported on in Chapter 6 of perceived safety issues included continuity of care, triage training for care navigators, and whether non-medical roles and AHPs should treat complex issues or patients presenting with new or worrying symptoms. Positive findings relating to the safety dimension also included some patients' recounts of positive experiences with the care navigator role, including when a care navigator called for a GP to come down to reception when a patient was experiencing chest pain. This study presented only a small amount of qualitative evidence relating to the perceived effectiveness of role substitution, which was presented by a patient who recounted a past experience of consulting with a physiotherapist who had helped to significantly reduce the patient's pain.

In order to judge the quality of role substitution, evidence on the effectiveness and safety of employing non-medical health professionals and AHPs to perform roles traditionally completed by the GP is essential. The survey presented in this thesis did not present any findings that can be discussed in relation to the effectiveness and safety of role substitution. A major flaw of the BIA presented in this thesis was the inadequacy of the study design to consider effectiveness as well as costs. Evidence on the effectiveness and safety of role substitution is lacking especially for less well researched AHP roles.

Acceptability

The qualitative evidence presented in the systematic review (Chapter 3) and unearthed in the qualitative study (Chapter 6) provides insightful evidence on the acceptability of role substitution to both patients and practice team members. Firstly, evidence from the systematic review (Chapter 3) indicated that PAs are a well-accepted contribution to primary care teams.

Patients' acceptance of the PA was built on trust which was said to be gained through familiarity of the PA role. Attractive features of the PA role included their ability to provide vertical substitution to GPs, working within the medical model and their capacity to deal with uncertainty. The systematic review evidence also suggested that, compared to nurses, PAs may require less supervision and could deal with a greater volume of work. The pharmacist role as a prescriber was acceptable to GPs as long as they followed protocol and worked under close supervision. Moreover, GPs were more likely to accept community pharmacist services if they trusted the pharmacist and if they knew them well or had already developed good working relationships with the pharmacist. Physiotherapists were an acceptable group of AHPs and were welcomed as an integral part of the practice team by nurses and GPs.

Findings on views and perspectives of role substitution unearthed in the qualitative exploration (Chapter 6) suggested that pharmacists, OTs and physiotherapists were well accepted members of the general practice team. Pharmacists were noted for their expertise in medications, OTs for their involvement in the area of mental health, and physiotherapists for their contribution to MSK health. Nurses were found to have good relationships with their patients; however, the importance of nurses training and expertise were important factors when considering the acceptability of nurses treating complex cases. There appeared to be greater acceptance towards the team coordinator role compared with the role of the care navigator, which may be linked to issues relating to privacy.

During the qualitative interviews, patients tended to take a neutral standpoint about the acceptability of role substitution. Some patients explained that they did not have a problem with seeing non-medical health professionals and AHPs instead of the GP. Other patients believed that they just had to accept the changes that were happening in their practice. Some patients believed that role substitution was acceptable, so long as it was done correctly and that practitioners knew their limitations and received adequate training. Some of the team members interviewed admitted that there were mixed feelings about the acceptability of role substitution among patients but stated that some patients were slowly adapting to the new ways that services were being delivered.

The BIA presented in chapter 5, did not assess the acceptability of role substitution. Although the survey presented in chapter 4 of this thesis did not directly ask whether role substitution was acceptable to respondents, it did provide information on cluster leads' strategies to increase role substitution within their cluster which could possibly be interpreted as their acceptability of using role substitution within their cluster. Nevertheless, this

inference is only based on the responses of the clusters leads that were represented in this survey therefore the findings are not representative of the whole cluster lead population. Consequently, non-respondent views may have been vastly different and may have been opposed to strategies to increase role substitution within their cluster.

Efficiency (including costs)

The systematic review of economic evaluations (chapter 2) and the BIA (chapter 5) presented findings relating to the costs of role substitution. In summary, the findings of the systematic review (Chapter 2) found that nurse-led care for common, minor health conditions was less costly than GP care. Nurse-led care for treating chronic fatigue syndrome and for the secondary prevention of heart disease was more costly than usual GP care, as was pharmacist-led care for medicines management and chronic pain.

The analysis of costs presented in the BIA chapter demonstrated the financial implications of increasing role substitution in two general practices in North Wales used as case studies. Between 2016 and 2018, the total number of consultations increased at both case study practices. Moreover, the number of GP consultations reduced and the number of non-medical and AHP consultations increased at both practices. In one practice, costs of consultations were £807 lower in 2018 compared with 2016, whereas costs increased in the other practice by £2,430 over the same period. Although the BIA presented findings in relation to the affordability of increasing the use of non-medical and AHP roles to provide general medical services, they did not offer any evidence on the efficiency of role substitution.

It is also worth noting, that the issue of costs was highlighted by one of the cluster lead survey respondents who reported on the increased use of alternative clinicians into the practices to ease the issues of being unable to recruit GPs and the inability to afford the rising costs of GP locum cover (Chapter 4). Although not directly assessed, some findings relating to the perceived costs of role substitution were reported on in the qualitative evidence (Chapters 3 and 6). Some issues relating to costs reported on in Chapter 3 were concerns about whether community pharmacists placed financial incentives above patient care. Views relating to the cost-effectiveness of PAs were mixed (Chapter 3). PAs may be less costly alternatives to GPs but it was also acknowledged that they may prove to be more costly overall due to lower levels of productivity and their need for a greater amount of supervision (Chapter 2). Moreover, PAs lack of prescribing authority was linked to a lower level of

efficiency and they were therefore viewed by some as being a more costly practitioner compared to NPs with prescribing authority (Chapter 3). Conversely, physiotherapists were viewed as an efficient type of practitioner with the potential to reduce the number of unwanted diagnostic tests and inappropriate referrals (Chapter 3). Issues relating to costs raised by patients and primary care team members in the qualitative interviews (Chapter 6) included the business models of GP practices and the importance of careful resource allocation decisions to ensure the best use of NHS funds. Interestingly, some patients felt that it would be less costly to employ fewer GPs and more non-medical health professionals and AHPs.

Although non-medical roles and AHPs may be less costly to train and employ than GPs, we do not know if they are a good investment of NHS budgets. There are likely to be resource implications of role substitution that were not measured in the BIA. Additional variables of interest that may have cost implications include employment rates of all staff roles, rates of staff turnover, FTE staffing figures, and rates of staff sickness. This BIA had a relatively limited scope and did not consider the wider implications on resources such as the possible impacts on prescriptions, diagnostic tests and the number of consultations. For example, the qualitative findings indicated the potential for physiotherapists and OTs to free GP time by contributing to MSK and mental health consultations, but we do not know if this is an efficient use of resources. Role substitution may be associated with higher patient recall to general practice. Patient recall rates that show when patients have re-consulted at general practice for the same condition that they had initially presented with, implying that the issue was not resolved during their first appointment. For example, a patient may initially consult with a non-medical health professional or AHP about a condition but then may return to general practice and request a GP appointment as their condition/issue has not been resolved during their first visit. This thesis provides some cost information for non-medical health professionals involved in role substitution, but information is lacking for AHPs. The principle of efficiency in health economics is concerned with maximising the benefits from available resources or ensuring that the benefits gained exceed the benefits forgone (Kernick, 2002). "The concept of economic evaluation underpins efficiency choices in health care" (Kernick, 2002, p.147). In order to ensure efficiency within general practice teams going forward, full economic evaluations that can assess a full range of costs and outcomes are needed.

Access

Despite not being directly measured or assessed as part of this thesis, consideration of the access domain is reported on in some of the thesis chapters. The systematic review of qualitative studies (Chapter 3), the impact of PAs and pharmacists employed to meet high patient demands and improve access to services was noted. The potential impact of role substitution on access was also discussed in the qualitative interviews (chapter 6). Team members voiced that it was quicker for patients to speak with pharmacists rather than waiting for a telephone call from a GP which in turn helped to reduce GP workload. Team members felt strongly that physiotherapists could not only help to reduce GP workload by managing MSK consultations but could also reduce patient waiting time and ease the backlog in hospitals. The importance of the care navigator role in helping to reduce unnecessary appointment was voiced by some patients. At the healthcare system level, issues relating to staff recruitment and retention were acknowledged among participants. Role substitution was viewed as being a necessity to help improve access to services by allowing patients to be seen by the most appropriate healthcare professional based on their reason for consultation. Despite this, access issues were still a problem at the practices, with busy telephone lines cited as a major issue.

Although the impact of role substitution was not directly considered in the health economics chapters of this thesis, the link between health economics evidence and access can be discussed more generally. Economic evaluations (reported on in Chapter 2) aim to assess the relative value of interventions or policy compared to an alternative, to ensure that patients have access to evidence-based health care when they need it. The findings of the survey (Chapter 4) can also be interpreted in relation to the access dimension as the study provided some information on the types of practitioners that are available to patients in the clusters that were represented in the survey. Similarly, the BIA also provided evidence of the different non-medical health professional and AHP roles that were available to patients to during the two timepoints in 2016 and 2018.

Equity

Equity was not a direct consideration with respect to the overall thesis aims; nevertheless, this was an important issue that was presented in the qualitative findings of the thesis (chapters 3 and 6). Results of the systematic review (chapter 3) reported that some patients felt that they did not have a choice about whether they could consult with a GP or a PA, which was the only issue relating to equity that emerged from the systematic review. The issue of choice is also raised in the qualitative interview findings (chapter 6) and is relevant to the BIA data

(chapter 5). The findings of the BIA reported a reduction in GP consultations at the two practices used as case studies. The qualitative findings provided some insight into how patients and staff members may feel or be impacted about this in practice. Patients reported that they are not given a choice about which healthcare professional they can consult with; however, it was also acknowledged that GP appointments should be reserved for patients with the greatest need. Moreover, some team members recognised the importance of patient choice and felt that patients should be able to consult with a GP, should they wish to. Although some team members felt that patient choice had been enhanced, due to the increased number of different practitioners available at their practices, this was not reiterated by the patients. They felt they were not given enough choice about whom they would like to consult with, some also felt that they had to accept the appointment given to them by the care navigator. Although some team members believed that some patients would always want to consult with the GP irrespective of the reason for their consultation, the patients recognised that GP appointments should be reserved for patients who were severely unwell.

The systematic review of economic evaluations (chapter 2) and the BIA (chapter 5) did not explicitly present findings in relation to equity; however, this domain is relevant to the field of health economics more generally. Health economics considers the fair distribution of health care resources by assessing the cost-effectiveness of interventions. The NHS within the UK is founded on equity principles, health care can be equitably distributed and in addition health interventions can impact on equity that is derived from health. Access to health care in the UK is based on clinical need and is free at the point of access to patients. There are however only limited resources and as such decisions about how resources should be allocated, in order to maximise societal welfare are required. This thesis did not directly assess the impact of role substitution on equity; however, through the use of the conceptual framework the equity domain has been identified as an area that requires further consideration in order to judge the quality of role substitution. Additional factors must be explored in order to establish the links between increased role substitution and equity considerations for example, how rural towns and areas of increased deprivation may be impacted by potentially reduced opportunities to see the GP and the role of alternative clinician consultations on fragmentation of care.

Relevance

Some of the thesis findings can be discussed in relation to the 'relevance' domain proposed by Maxwell (Maxwell, 1992). The findings of the BIA (chapter 5) demonstrated the

increased use of non-medical health professionals and AHPs along with the decreased number of GP consultations. This could be interpreted as findings to support the relevancy of practices using role substitution to compensate for in increasing patient demands at the practices. There is evidently a primary care workforce crisis in Wales and this was reported by cluster leads who responded to the survey presented in chapter 4 of this thesis. As reported at cluster level, the results of the survey provided an indication of a wide range of different healthcare professionals being employed in general practices in Wales to provide face-to-face consultations with patients. Cluster leads provided information on a variety of strategies to increase the uptake of role substitution including the ongoing support to employ and train AHPs and increase the uptake of independent prescribing by nurses and pharmacists. Mental health and social issues appear to take up a large portion of general practice demands, demonstrated by the increased employment of mental health practitioners and the development of social prescribing in Wales as reported by the cluster lead respondents. This was also supported by the findings presented in chapter 6 which related to the appropriateness and relevance of role substitution in terms of the extent to which services are matched to the particular needs of the patient population. According to the team members interviewed, OTs and physiotherapists are particularly relevant members of general practice teams as mental health and MSK consultations take up a significant proportion of primary care demands (also reported on in the survey findings).

Consideration of the thesis findings in relation to theories of role substitution and the dynamic system of professions

Role substitution was defined in this thesis as some roles and tasks that were previously completed by a GP and are now completed by non-doctors. Nevertheless, the vertical shifting of roles and tasks between GPs and non-medical health professionals and AHPs, as well as the horizontal shifting that inevitably occurs across non-medical health professional and AHP professions is not straightforward and may occur through several different means. Due to the complex nature of substituting tasks between professions working in general practice, and the different approaches by which this is achieved, concepts such as role substitution, skill mix and task shifting are difficult to define and measure (Jenkins-Clarke et al., 1997). As discussed in chapter 1 of this thesis, role substitution also has significant implications on professional boundaries and jurisdictions. The following section discusses the findings of each of the thesis chapters in turn, in relation to theories of role substitution and the dynamic

system of professions. The findings of some of the chapters can be applied to a greater extent in relation to theories of roles substitution, this is due to the availability of detailed information about the format and extent of role substitution and the nature of the data collected. In consequence, Chapter 3 and Chapter 6 offer the most insightful findings and discussion in relation to the ways in which roles shift and the subsequent impact on professional boundaries.

Chapter 2: Role substitution is a complex system change; however, the economic evaluations to date have focused on a narrow range of professional groups and types of substitution. The findings presented in this systematic review of economic evaluations were interventions of vertical substitution between GPs and the following non-medical health professionals: nurses, pharmacists, and community health practitioners. This systematic review did not focus on the wider factors important to role substitution which have been discussed in more detail in other chapters of this thesis, for example, theories of professional boundaries and jurisdiction which by their nature were more likely to be included within other types of study design e.g., qualitative methods. This highlights the need for consideration of the value of different study fields and methods to explore the full range of role substitution theories.

Chapter 3: The findings of this systematic review were framed by an awareness of theories concerning role substitution and the potential conflict between groups of professions. As discussed in Chapter 1 of this thesis, when considering role substitution, the notion of boundaries as barriers and indicators of difference between and within professions is an important factor to consider as different groups of occupations will often strive to maintain, defend, expand and change their professional boundaries (Abbott, 1988). Findings from this systematic review highlighted GPs' concerns that community pharmacist prescribing may contest with GP prescribing and potentially harm the GP-patient relationship; however, some GPs did not deem this to be an important concern in light of the GP shortage crisis which indicates that GPs may be open to the expanding boundaries of community pharmacists. In addition, pharmacists were enthusiastic regarding their independent prescribing role and felt supported by GPs. Nevertheless, there were apprehensions among both community pharmacists and pharmacists employed in general practices about prescribing outside of their areas of competence. As discussed in Chapter 1, although the expanded roles of pharmacists to prescribe medication allows them to provide vertical substitution to GPs, it does not mean that they hold the same status as GPs. This was demonstrated by the qualitative findings as some patients viewed GPs to be at the top of the hierarchy of status who have the power to

control the actions of pharmacists. The findings of this systematic review indicated that GPs do not fulfil all information needs relating to medications, which suggests that pharmacists have the potential to provide a supplementary role as their work can complement GP activities (Laurant, 2007).

As proposed by Sibbald and colleagues, skill mix can occur through innovation which is the concept of creating a new job/occupation through the introduction of a new type of worker (Sibbald et al., 2004). PAs were an innovation that were employed to provide vertical substitution to GPs. Professions often have domains which overlap whereby equivalent or comparable activities are carried out (Feyereisen and Goodrick, 2019; Abbott, 1988). This was evident from some of the findings of the systematic review which demonstrated that PAs can provide horizontal substitution to nurses and that some nurses already complete the same work that the PA can offer to general practice teams. There was also evidence to suggest possible role conflict as the inclusion of PAs within general practice teams brought forward resistance and hostility from other health professionals, particularly from nurses. Moreover, nurses defended their role and considered themselves the best group of healthcare professional to work as GP substitutes and the best use of NHS spending as opposed to PAs who they felt were an untried and untested new occupational group. These findings support the notion that professions are constantly in conflict with one another, where they compete with each other for recognition of their cognitive claims and their rights to manage specific tasks (Abbott, 1988). The potential for contest between PAs and GPs was also highlighted with some concerns raised about the possibility that the role of the PA could threaten GP jobs and undermine the GP role.

In contrast, physiotherapists were a welcomes addition to practice teams and their contribution to the area of musculoskeletal health was noted. There was no evidence of role conflict with regards to the physiotherapist role. Moreover, physiotherapists were considered to be well placed in chronic disease management and self-management compared with other professionals who were already providing these services, which demonstrates the potential for role enhancement within the physiotherapist profession (Sibbald et al, 2004).

Chapter 4: The findings presented in this survey indicated that clusters were employing non-medical health professionals and AHPs to provide vertical substitution to GPs. Nevertheless, it did not provide any further information on how these innovations may impact on professional boundaries or whether the increased use of different practitioners had resulted in disputes between or across professions.

Chapter 5: The findings presented in this BIA provided information on the changing dynamics of two general practice teams in terms of the types of non-medical health professional and AHP roles that were being employed in general practice that can work to provide vertical substitution to GPs. Nevertheless, it did not provide any further information on how these changes in practice impact on professional boundaries and the subsequent impact on wider processes and outcomes.

Chapter 6: The findings of this qualitative study presented in this chapter were framed by an awareness of theories concerning role substitution and the system of professions. Interdisciplinary interactions within the two practices were evident from the qualitative findings. Vertical substitution can be defined as the transfer of tasks across professional boundaries from one healthcare professional to another, where one profession is superior in terms of their expertise, training and professional autonomy (King et al., 2015). The jurisdiction of nurses to provide vertical substitution to GPs was a strong theme and through this subordination, it was recognised that the roles of nurses are expanding, which has consequently meant greater responsibility but also enabled them to become autonomous practitioners where they can complete a broad range of tasks previously completed by GPs (Contandriopoulos et al., 2018). Nevertheless, participants acknowledged the importance of nurses being aware of their professional boundaries and that they should only perform certain tasks if they fell under their areas of expertise and if they had undergone the necessary training. Some team members were open to disciplinary change as they felt that nurses could potentially bring forward new insights when treating patients with new symptoms. During the interviews it was mentioned that some nurses has become specialised in diabetes and respiratory care. Nurses who become specialised within an area will have undergone specialised training that will subsequently lead to an increased level of professional autonomy (Nancarrow and Borthwick, 2005). Nevertheless, specialisation within some professions may not lead to financial rewards or higher status, as it often does within the medical profession (Nanarrow and Borthwick, 2005). This was acknowledged during the interviews as participants raised an awareness of the expanding roles and responsibilities of nurses and non-clinical roles despite an absence of increased salaries.

Vertical substitution between GPs and other professions was also highlighted in the interviews. Firstly, pharmacists' contributions to medication reviews and their superior knowledge of medications and their potential to relieve some of the demands placed on GPs were noted. In order to avoid conflicting information about medications, participants

highlighted the importance of good communication between pharmacists and GPs. Despite this indication of overlapping roles, this qualitative exploration did not uncover any evidence to suggest contest between GPs, pharmacists or any of other professional groups and therefore indicates the consensual delegation of tasks. Team members described good working relationships with the pharmacist and stated that they were able to consult with the pharmacist for advice regarding medications.

Moreover, vertical substitution between GPs and OTs in the area of mental health, and between GPs and physiotherapists in the area of MSK were reported to be accepted and valued by team members. Nevertheless, an awareness of jurisdictional boundaries within their roles was acknowledged. Participants voiced an awareness regarding the lack of authority for the OTs working within their practice to prescribe medications; however, they stated that OTs were able to consult with GPs when they felt that patients may require a prescription. It appeared that OTs were able to provide a supplementary role to the work already completed by GPs in the area of mental health. Patients were able to be booked in for an hour consultation with an OT which allowed them time to have in-depth discussions with their patients about issues such as bereavement, loneliness and social isolation or linking them up with support groups. This type of supplementation may not result in encroachment of GP roles, as the GP works within the medical model whereas the OT can offer a more holistic and integrated biopsychosocial approach within their one-hour consultation. Moreover, due to their longer consultations, there was also the suggestion that OTs could also potentially pick up on symptoms which could otherwise be missed by GPs. Nevertheless, the work of OTs in the area of mental health could result in role encroachment of other professions, such as mental health practitioners who may work in general practice teams; however, our qualitative findings does not support this notion as this topic was not discussed during interviews nor were any mental health practitioners included in our participant sample. According to Andrew Abbott, different groups of occupations will often strive to maintain, defend, expand and change their professional boundaries (Abbott, 1988). There was some evidence to suggest an acceptance by team members for OTs to expand their roles to treat complex issues, when the complexity involves social and emotional issues rather than just the presence of multiple chronic conditions.

Although the physiotherapist role was accepted and valued by team members, there was some resistance from patients who were not satisfied with their consultation with the physiotherapists and felt that the GP would not just simply 'prescribe exercises'. In contrast,

physiotherapists were deemed as integral members of the general practice by team members who valued their contribution to MSK health, a role that appears not to overlap with the professional boundaries of the other professions working in the general practices.

This qualitative study presented some findings in relation to intra-boundary influences within the general practice teams, where boundaries expand within particular profession and can therefore result in the generation of hierarchies within the profession (Abbott, 1988). This was evident through the diversification of some of the patient facing non-clinical roles working within the practices. In the concept of diversification, roles expand within a profession through the detection of new and novel ways of working that other disciplines have not yet gained 'ownership' of (Nancarrow and Borthwick, 2005). The roles of receptionists have diversified to perform care navigation by sign-posting patients to see the correct primary care practitioner depending on their reason for consultation. Despite both the care navigators and team coordinators having similar professional backgrounds (receptionists and administration), the roles and tasks performed by the team coordinators had expanded beyond the care navigator role who sits at the front desk of the practice. Similar to the care navigator role, the role of the team co-ordinators was to signpost patients to the most appropriate healthcare practitioner, but they also had expanded roles in terms of booking in planned clinic appointments for patients. The formation of hierarchies within this new type of care navigation role was evident, team coordinators appeared to have higher status; they were situated in an upstairs office and patients accepted and valued their role more than they did the care navigator role. The jurisdictional boundaries of the work of care navigators and team coordinators was not clear from the findings of the interviews, but they did not appear to be based on any formal training or expertise.

Confusion around roles and boundaries was a key finding in Chapter 6. General practice team members were confident about the remits of their own roles; however, some had limited knowledge of other roles and the capabilities of different practitioners. Confusion about roles could have important implications, particularly when referring to different health professionals. There were many factors that linked to professional confusion around roles, such as limited 'on the job' training for care navigators and team co-ordinators. If roles and boundaries are not fully understood, this will have implications on how roles can be substituted, shifted and supplemented in practice.

The theory of negotiated order suggests that social interactions between professions represent a negotiated social order or structure which means that hierarchies between professions are not certain, instead they are subject to continuous negotiation in the social order of professions (Faberman, 1979; Strauss, 1978). The issue of hierarchies within general practice teams was a major theme that emerged from the interviews with many team members emphasising a culture change regarding hierarchies within their practice teams. They described conscious changes that had been introduced to reduce barriers and hierarchical structures within their practice teams. Team members highlighted the importance of viewing each other as equals within the practice as it taught junior members that their opinion was valid and made it easier for team members to approach each other and ask for advice when needed. Some team members felt that GP partners should be at the top of the list in terms of hierarchies as the 'buck stops at them' in terms of responsibility. Moreover, the role of the GP as a specialist who's time should be spent dealing with the most complex cases was acknowledged by the interview participants. Team members also respected GP partners for their professional positions as well as being their employers.

The findings presented mixed patient views of hierarchies in general practice. Some patients viewed all practitioners as being on an even level at their practice and felt that they should be respected equally as each practitioner is a professional in their own right.

Conversely, some patients felt that there were bound to be hierarchies in general practice as different health care professionals have different roles and levels of experience and training. Some patients viewed the GP as being at the 'top of the list' of practitioners, with nurses and non-clinical patient facing team members being at 'lower levels'. Some patients believed that hierarchies in general practice should not be an issue, as long as the practice team members work well as a team and received the necessary training for their specific functions within the practice.

Inter-professional change in general practice requires a teamworking approach which is reliant on the extent to which occupational groups are willing to delegate tasks and accept changes to traditional professional boundaries and the consequence of blurring roles (Masterson et al., 2002). The qualitative evidence presented in Chapter 6 demonstrated good working relationships and teamworking in the two general practices used as case studies in this thesis. Non-medical health professionals and AHPs were confident to approach the GP or other practice staff for advice when needed. approach colleagues for advice when needed. Practice staff indicated that expanding roles could work well in practice as long as there were

sufficient support structures in place. Although team members stated that they were able to ask for advice from colleagues, some stated that there were not any opportunities to arrange set time periods for training and consequently felt that more formal structured support was needed.

The findings mainly indicated accommodation of non-medical health professional and AHP roles rather than occupational resistance. Nurses, pharmacists, physiotherapists and OTs were praised for their interpersonal skills, competence in their areas of expertise. It was evident that OTs and physiotherapists were paving the way to establish themselves as novel practitioners in general practice with the ability to provide expertise in the areas of mental health and MSK, respectively. There was some evidence to suggest that older GPs may be more resistant to changes whereas younger GPs were viewed as more enthusiastic and adaptable to changes. According to the theoretical literature, professions are constantly in conflict with one another, where they compete with each other for recognition of their cognitive claims and their rights to manage specific tasks (Abbott, 1988). This results in professional boundary disputes in an effort to gain control, status and power, where more senior professionals such as GPs may endeavour to defend their boundaries, whereas less senior groups of health care professionals attempt to challenge these boundaries (Battilana, 2011). This qualitative study (Chapter 6) did not present any explicit evidence of conflicts or boundary disputes at the general practices. In contrast, effective inter-professional teamworking was reported where it appeared, on the most part, that the occupational groups interviewed were willing to delegate tasks and accept changes to their traditional professional boundaries (Materson et al., 2002). Nevertheless, due to the small sample size of the team members included in this qualitative study, it was difficult to interpret any explicit desires of the individual professions to maintain, defend, expand or change their professional boundaries as we were unable to identify the team members' professions within the study findings, in order to preserve their anonymity.

Critical reflection of the overarching framework of the thesis and theories of role substitution

The application of the conceptual framework has helped to integrate findings from this thesis to explore a range of questions relevant to the changing use of role substitution in Wales.

This has helped consider the relevance to practice and consider areas where further inquiry is

required. Further research built on a foundation of relevant theory and conceptual frameworks relevant to role substitution can continue to address unanswered questions.

Better quality of care is associated with higher satisfaction among patients, healthcare providers and suppliers and better organisational performance (Peckham and Wallace, 2018; Mosadeghrad, 2012; Sollecito and Johnson, 2012). The NHS is a complex health system made up of several component parts (Burton et al., 2018). Quality in healthcare is multidimensional and subjective in nature, therefore making it difficult to define and measure (Quentin et al., 2019; McLaughlin and Kaluzny, 2004). Moreover, the complexity, intangibility and heterogeneity within general practices further adds to this complication (Mosadeghrad, 2012). This conceptual framework provided a helpful structure to consider all of the thesis findings in relation to the dimensions proposed by Maxwell to judge quality of healthcare. When considering the findings overall from this thesis, there is a clear lack of attention on the effectiveness and safety of role substitution especially for less well researched AHP roles. This thesis used the conceptual framework retrospectively and was a helpful model to consider the overall findings and to identify the dimensions of quality that were less represented in this thesis. It may be helpful for future studies to use this model or a similar model to help judge quality during the set-up or design stage of a study, with a clear aim of measuring the full range of quality domains proposed by Maxwell to judge the quality of role substitution (Maxwell, 1992).

In addition, this discussion has also considered the findings from this thesis against relevant theories of role substitution as outlined above, acknowledging that there is a taxonomy of role substitution forms. Defining different forms of role substitution and considering the impacts of shifts in resources at a micro level is important and has been previously utilised by Drennan is relation to PAs (Drennan et al., 2014). Drennan and colleagues has also successfully applied the same conceptual framework adopted in this thesis and considered theories of role substitution in relation to the integration of PAs in primary care (Drennan et al., 2017; Drennan et al., 2014). More recently, Francetic and colleagues have used a similar framework that builds upon Donabedian's model to assess skill-mix change and outcomes in primary care in England (Fancetic et al., 2022).

As with conceptual frameworks relating to quality of care, frameworks for role substitution in health care are also important and van Schalkwyk and colleagues consider a framework of task shifting in healthcare that takes a systems perspective to consider the

impact of changes to practice (van Schalkwyk et al., 2020). Looking at task shifting independently of wider role substitution allows them to look in detail at the different ways in which task shifting occurs. In addition, this approach allows them to consider where tasks may shift outside of the health service, for example to patients in the form of self-management (van Schalkwyk et al., 2020).

As discussed above, consideration of the findings in relation to the overarching conceptual model of the thesis was implemented retrospectively and future research would benefit from applying a conceptual framework at the design stage of the study. Similarly, the findings of this thesis were also considered retrospectively in relation to theories of role substitution. In hindsight, the thesis would have benefitted from the application and consideration of such theories at the design stage of the studies. It is acknowledged that thesis explored role substitution through a high-level lens when considering the ambiguity between the ways in which role substitution has been considered and assessed in this thesis, versus the different ways role substitution actually takes place in practice and its subsequent implications on professional jurisdictions. As part of the work undertaken in this thesis, I explored how role substitution was already being implemented within the health service and through the course of this PhD I developed an understanding of the theoretical concepts of how role substitution can be characterised. Role substitution is already widespread in general practices in Wales without practices' theoretical understanding of these taxonomies of role substitution. Areas of uncertainty in the definition of role substitution are of critical importance to this thesis and have significant implications on the measurement of role substitution and its potential value in practice.

Moreover, potential shifts in resource use following role substitution should also be assessed, for example, whether there is higher recall to general practice, or an increased number of unnecessary investigations ordered by non-medical health professionals and AHPs. Moreover, findings from this thesis have suggested that role substitution may have the potential to reduce GP workload, for example, through the use of physiotherapists and OTs helping to ease the pressures of MSK and mental health consultations, respectively. Further investigation to objectively assess whether roles substitution can reduce GP workload and improve efficiency is required. GPs remain an integral part of primary care and it is clear that not all GP roles can be substituted as discussed earlier in the implications for policy and practice.

Ideally evaluation required measurement before, during and after intervention. However, role substitution is rapidly being applied in practice. Understanding what has changed in practice (e.g., changes to processes and roles) is important to consider how it has impacted on outcomes. Future studies should consider embedding process measures that apply a full taxonomy of role substitution theories to consider at a micro-level what has changed and explore how this might impact on a full range of outcomes, considering the full spectrum of the quality of healthcare (conceptual framework). Approaching role substitution evaluation at a high level with ambiguity in the definition of types of substitution that have been employed is likely to lead to uncertainty in findings, with limited details available of attribution of effect and confidence in the appropriate selection of outcomes to be measured. Brocklehurst and colleagues (Brocklehurst et al., 2016), when considering role substitution in dental services distinguish between different types of role substitution taxonomy, noting that "unlike role supplementation, role substitution has the potential to improve efficiency and the capacity to care and lower costs. In addition, it has the potential to reduce inequalities in service delivery as resources can be diverted to the population with the greatest need." (Brocklehurst et al., 2016, p.1). In this thesis BIA considered raw staffing levels at two timepoints with a high-level self-assessment of role substitution occurring by the general practices. This study did not collect detailed process outcomes to provide details of how roles changed during this period and did not define different types of role substitution. This can lead to difficulties in the interpretation of resource use data and has implications for the measurement of effectiveness in future studies.

Original contribution of the thesis restated

The empirical studies of this thesis explored role substitution specifically in Wales. Previous research has tended to focus on the role substitution context in other parts of the UK, this PhD study fills important evidence gaps for the Welsh context. For example, evidence on the cost implications and acceptability of role substitution in Welsh general practice was lacking. Novel findings across a wide range of roles were presented through the consideration of whole-practice team dynamics to explore the costs and acceptability of role substitution in real-world settings. This thesis provides a novel contribution to the field of health economics of role substitution, including a published systematic review of economic evaluations synthesising the evidence on the cost-effectiveness of role substitution of in

primary care. This thesis presented the first budget impact analysis of its kind to explore the financial implications of increasing role substitution in Wales, using two different general practices as case studies.

The lessons learnt from this thesis provide a stronger foundation for future research into role substitution looking at the whole general practice team, in order to better understand the ways in which staffing shifts and roles change in Wales. This thesis highlights the importance of clearly defined roles both in terms of practice and future research to understand role substitution. By using two general practices as real-world case studies, this thesis has been able to consider theory relating to role substitution including factors such as team dynamics, hierarchies, and professional boundaries. In addition, considering the entire general practice team within these case studies has allowed for the inclusion of less well researched roles such as OTs and physiotherapists who are establishing themselves within key areas of general practice such as mental health and MSK, respectively. This thesis contributes novel findings regarding views about the role of patient navigators in Wales, who play an important role in the process of role substitution.

This thesis sets the foundations alongside a growing evidence base to further role substitution research in Wales. By utilising the conceptual model of this thesis, the evidence presented in this PhD is considered within the context of quality of care. A range of perspectives were considered, from the patient perspective through to the provider and funder perspectives, with each perspective offering an opportunity to provide a distinct piece of evidence towards a larger overarching topic of role substitution in general practice.

Conclusion

This thesis provides unique insights into the implementation of role substitution in general practice in Wales. Novel findings across a wide range of roles are presented through the consideration of whole-practice team dynamics to explore the costs and acceptability of role substitution in real-world settings. This thesis challenges the assumption that role substitution will reduce costs. Chapter 2 identified mixed evidence on the cost-effectiveness of role substitution and Chapter 5 demonstrated increased costs in one practice and lower costs in the other practice when increasing their use of role substitution. Though it may seem less costly to employ AHPs in general practice in terms of their unit costs, their consultation lengths may be longer, and they also might be associated with higher patient recall to general practice. The consideration of the thesis findings in relation to role substitution theory highlights the

difficulty of defining and measuring the concept of role substitution in practice. Clearly defined roles, good communication and teamwork are important factors to consider when expanding roles in general practice. If role substitution is not clearly defined and boundaries not fully understood, this will have critical implications on how roles that are substituted, shifted and supplemented can be measured in practice and how this subsequently impacts on quality of services. This thesis utilised routinely collected data to consider the cost implications of role substitution, applying a health economics lens to this topic which in my thesis I acknowledge as an emerging area of interest in this field. The conceptual framework of this thesis provided a helpful structure to consider all of the thesis findings in relation to the dimensions proposed by Maxwell to judge quality of healthcare (Maxwell, 1992). From a health services research perspective, considering the scope of exploration through the conceptual framework has identified areas that this thesis does not fully address and where more work is required.

Role substitution is complex and ever-changing. The approaches used for its successful implementation will vary considerably across practices and decisions must be based on the patient populations in which they serve. This PhD has provided evidence of the advances in role substitution as they are evolving in Wales.

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Appendices (see supplementary document 1)