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**Exploring Pharmacist Prescribing in
Hospitals in Scotland, with a Focus on
Antimicrobials**

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[B.Pharm. (Hons), MSc (Clinical Pharmacy), PGCert (Research Methods)]

A thesis in partial fulfilment of the requirements of
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for the degree of Doctor of Philosophy

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“One very important aspect of motivation is the willingness to stop and to look at things that no one else has bothered to look at.”

Edward de Bono
(Born in Malta, 1933)

Abstract

This aim of the research was to explore pharmacist prescribing (PP) with a focus on antimicrobials, in hospitals in Scotland.

A mixed-methods approach was used to collect, generate and synthesise data. A systematic review of peer-reviewed published literature on evidence-based roles for the pharmacist as part of an antimicrobial multidisciplinary team, identified roles for pharmacists within the teams but limited evidence relating to outcomes associated with these roles.

Six qualitative focus groups, with 37 hospital pharmacists in 5 Scottish Health Boards, contextualised perceptions of barriers to, and facilitators of, implementation of PP in hospitals. Key themes were: perceived lack of pharmacy management support to take on a prescribing role and little strategic attention paid to PP implementation and sustainability. These issues were discussed in relation to PP in general and not only for antimicrobials. Participants perceived successful implementation of PP to be associated with factors including ward type and patient's clinical condition. None of the pharmacists were prescribing antimicrobials and consequently further studies focused on PP in general.

A scoping exercise, utilising various sources of information, reinforced findings from Phase 1; it highlighted the absence of any national or Health Board frameworks to support implementation of PP in secondary care in Scotland.

Consensus-based research was undertaken, therefore, to provide guidance to facilitate service redesign involving PP in secondary care in Scotland. A Delphi approach undertaken with 40 experts, mainly in strategic posts, resulted in a high level of agreement in areas relating to succession planning, rather than role development; more variability was obtained in areas relating to future orientation of service, competencies required by prescribers and potential development of non-medical prescribing teams. The guidance was developed into a self-assessment toolkit providing an

analytical strategy for implementation and role development of PP in secondary care.

While the results and conclusions generated through this research need to be interpreted with caution, the data generated is an original contribution to the evidence base relating to PP.

Key words: Hospital pharmacy, pharmacists, pharmacist prescribing, antimicrobials, guidelines, guidance, Scotland

Acknowledgements

As an author, this seems to be the most difficult section to write; there are so many people that need to be acknowledged and without whom this thesis would not have been completed and I am so concerned that I will omit someone!

My deepest gratitude goes to my supervisory team; my principal supervisor, Dr Dorothy McCaig, Senior Lecturer, who has been a source of inspiration (both academically and personally) and patiently listened to me, guided and supported me throughout this journey, but especially, when the going was tougher than I would have liked it to be. Many thanks to my other supervisors, Prof Derek Stewart, Dr Bernice West, and Dr Lesley Diack (the latter having stepped in when Dr West left the institution). They all read and re-read numerous drafts and provided me with immense encouragement through regular meetings, providing feedback and guiding the direction and progress of this work.

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through pages of text, going through these with a fine-tooth comb as part of the final proof reading process.

Finally, thanks to my husband Ivan, without whose tremendous support, I am sure this thesis would not have come to completion; for the nagging and for reminding me “to stick with it” and that I am nearly there; my little four-year old son Malcolm, who was involved in this process in his own way while mum could “write her book.” Sorry for not taking you to the park every time it was not raining in Aberdeen, but I promise to make it up once “my book” is finished.

To Ivan, and my little boy, Malcolm
(you will understand what this is all about when you grow up)

External outputs

Results of research described within this thesis have been disseminated through the following outputs. The research has also been presented at a number of University research student symposia, during journal clubs, and locally to other healthcare professionals at teaching days and lunch time meetings held at Aberdeen Royal Infirmary.

Full reports

1. Tonna AP, Stewart D, West B, McCaig D. Pharmacist prescribing in the UK – a literature review of current practice and research. *Journal of Clinical Pharmacy and Therapeutics*. 2007;32:545-56.
2. Tonna AP, Stewart D, McCaig D. An international overview of some pharmacist prescribing models. *Journal of the Malta College of Pharmacy Practice*. 2008;14:20-6.
3. Tonna AP, Stewart D, West B, Gould I, McCaig D. Antimicrobial optimisation in secondary care: the pharmacist as part of a multidisciplinary antimicrobial programme - a literature review. *International Journal of Antimicrobial Agents*. 2008;31:511-7.
4. Tonna AP, Stewart DC, West B, McCaig DJ. Exploring pharmacists' perceptions of the feasibility and value of pharmacist prescribing of antimicrobials in secondary care in Scotland. *International Journal of Pharmacy Practice*. 2010;18:312-19.

Abstracts of conferences

1. Tonna A, Stewart D, West B, McCaig D. Exploring the feasibility and value of pharmacist prescribing of antimicrobials in secondary care. *Pharmacy World and Science*. 2009;31:52. (Poster discussion forum at European Society of Clinical Pharmacists Conference: May, 2007; Edinburgh)

2. Tonna A, Stewart D, West B, McCaig D. Exploring pharmacists' views and perceptions of pharmacist antimicrobial prescribing in secondary care. British Pharmaceutical Conference: September, 2007; Manchester. (Poster)
3. Tonna A, Stewart D, West B, McCaig D. Exploring pharmacists' views and perceptions of pharmacist antimicrobial prescribing in secondary care. The 2008 International Nursing Research Conference: April, 2008; Liverpool. (Oral presentation)
4. Tonna A. The UK Clinical Team Pharmacist Model. The "clinical team" pharmacist: expectations and skills, models and results: May, 2009; Turin. (Oral presentation as invited speaker)
5. Tonna A, Stewart D, Diack L, West B, McCaig D. Developing consensus guidance to facilitate service redesign involving pharmacist prescribing in secondary care in Scotland. International Journal of Pharmacy Practice. 2009; Supplement 2:B28.
(Oral presentation. British Pharmaceutical Conference: September, 2009; Manchester.)
6. Tonna A, Stewart D, West B, McCaig D. Exploring pharmacists' views and perceptions of pharmacist antimicrobial prescribing in secondary care. Celtic Pharmacy Festival: March, 2010; Edinburgh (Poster)
7. Tonna A, Stewart D, West B, McCaig D. Exploring pharmacists' perceptions of the feasibility and value of pharmacist prescribing in secondary care in Scotland. European Association of Hospital Pharmacists: March, 2010; Nice (Poster)
8. Tonna A, Stewart D, Diack L, West B, McCaig D. Developing consensus guidance to facilitate service redesign involving pharmacist prescribing in secondary care in Scotland. European Association of Hospital Pharmacists: March, 2011; Vienna (Poster)

Foreword from the Author

The thesis describes my research work over the past 5 years, or so, where I have tried to explore pharmacist prescribing in Scottish hospitals, with a focus on antimicrobials. This experience has both developed my research abilities, particularly in applying qualitative and consensus data collection and analysis techniques, and contributed to the body of evidence in this emerging research area. It has also strengthened my academic writing skills.

In a way, I have come to this PhD in a round-about way. I first trained as a pharmacist at the University of Malta, followed by a career as a hospital pharmacist. During this period I pursued an MSc in clinical pharmacy at Robert Gordon University, though I was still based in Malta. Once I had completed the MSc, my husband commented that it would soon be time to start my PhD though I did not think so at the time! My husband's career brought us to the UK where after working in a number of cities, we finally settled in Aberdeen. Once here for a number of years, it seemed opportune to start some studies once more with a PhD. I also had a short maternity break during these studies, after which I changed to a part-time student.

Throughout my hospital pharmacy experience, I often noted the misuse and overuse of antimicrobials, particularly in areas such as surgery where patients who were intended for short courses of prophylactic antimicrobials had days of unneeded treatment. Similarly, I could note a lack of knowledge surrounding therapeutic drug monitoring amongst many of the more junior medical staff. I was often very frustrated by all this and the amount of time "wasted" chasing up junior doctors to amend prescriptions and often wondered how much easier it would have been if a prescribing pharmacist could change a patient's dose. This led me to my initial research idea. I was lucky enough to have a supervisory team who accepted my idea and let me explore and shape up my own research, yet guide me without imposing their own ideas. This also

allowed me to take up practice research rather than laboratory based research, which I was less interested in.

Meanwhile, I was also given plenty of opportunities to demonstrate to undergraduate pharmacy students in areas relating mainly to clinical pharmacy, and e-tutor distance learning postgraduate students. These opportunities allowed me to utilise my hospital pharmacy background and provided me with the right set of skills to eventually take up a position as a Lecturer in Clinical Pharmacy, a post which I hold to date.

Throughout the research, I have provided details of background to the research, and have tried to provide a readable text describing my research, its evolution and the context in which I carried it out. The first chapter describes the global problem of antimicrobial resistance, the response to this problem and the potential role of the prescribing pharmacist in optimising antimicrobial use. In the second chapter, I provide a systematic review which explores in more detail and depth the evidence-based role for the hospital pharmacist as part of the antimicrobial multidisciplinary team. Chapters 3 – 5 provide a description of the actual research project which was carried out in three distinct phases using different methods; Phase 1 involved focus group discussions with hospital pharmacists; Phase 2 was a background scoping exercise utilising different sources of information; Phase 3 used a consensus method to develop guidance. Chapter 6 provides a discussion, including the implications of the research for future policy and practice in this area of pharmacist practice together with ideas for future research. In addition, appendices have been provided to illustrate with concrete examples some of the documents referred to in the thesis and to further provide evidence as required.

Key Abbreviations

ABS	Antimicrobial stewardship
AMDT	Antimicrobial Multidisciplinary Team
ATC	Anatomical Therapeutic Chemical Classification
CMP	Clinical Management Plan
DDD	Defined Daily Dose
DOH	Department of Health
EU	European Union
GB	Great Britain
IP	Independent Prescribing
NHS	National Health System
PGD	Patient Group Direction
PP	Pharmacist Prescribing
RPSGB	Royal Pharmaceutical Society of Great Britain
SACAR	Specialist Advisory Committee on Antimicrobial Resistance
SP	Supplementary Prescribing
UK	United Kingdom
WHO	World Health Organisation

TABLE OF CONTENTS

CHAPTER 1	1
AN OVERVIEW OF THE PUBLISHED LITERATURE ON PHARMACIST PRESCRIBING AND POTENTIAL ROLE IN OPTIMISING ANTIMICROBIAL USE	1
1.1 INTRODUCTION	1
1.2 STRATEGIES AIMED AT OPTIMISING ANTIMICROBIAL USE	3
1.2.1 The European Union and prudent use of antimicrobials.....	3
1.2.1.1 The emerging role of the hospital pharmacist identified in strategic documents.....	6
1.2.2 The emerging role of the pharmacist to optimise antimicrobial use in the United Kingdom	10
1.3 PHARMACIST PRESCRIBING.....	17
1.3.1 Models of pharmacist prescribing outwith the United Kingdom.....	17
1.3.1.1 Pharmacist Prescribing in the United States	17
1.3.1.2 Pharmacist Prescribing in South Africa.....	20
1.3.1.3 Pharmacist Prescribing in Canada	20
1.3.1.4 Pharmacist Prescribing in Australia	21
1.3.2 Development of pharmacist prescribing in the United Kingdom.....	22
1.3.3 Implementation and Outcomes of pharmacist prescribing in the United Kingdom	29
1.3.3.1 Descriptive accounts of the application of pharmacist prescribing in the United Kingdom	29
1.3.3.2 Pharmacist prescribing research in the United Kingdom.....	30
1.4 THE ROLE OF THE HOSPITAL PHARMACIST IN IMPROVING ANTIMICROBIAL PRESCRIBING IN THE UNITED KINGDOM.....	54
CHAPTER 2	57
ANTIMICROBIAL OPTIMISATION IN SECONDARY CARE – THE PHARMACIST AS PART OF A MULTIDISCIPLINARY ANTIMICROBIAL PROGRAMME: A SYSTEMATIC LITERATURE REVIEW	57
2.1 INTRODUCTION	57
2.1.1 The role of the pharmacist within multidisciplinary antimicrobial teams.....	57
2.1.2 Evolvement of the antimicrobial multidisciplinary team.....	58
2.2 METHOD	59
2.2.1 Review team	60
2.2.2 Inclusion and exclusion criteria.....	60
2.2.3 Search strategy	60
2.2.4 Screening	61
2.2.5 Quality assessment.....	63
2.3 RESULTS.....	63
2.3.1 Descriptions of multidisciplinary teams	63
2.3.2 Published research involving multidisciplinary teams	70
2.3.2.1 Team members	70
2.3.2.2 Nature of interventions.....	71

2.3.2.3 Study designs	72
2.3.2.4 Outcomes reported	72
2.4 DISCUSSION	89
2.4.1 Strengths and limitations.....	89
2.4.2 Key findings in relation to review research questions.....	89
2.4.3 Discussion of findings and potential future research	91
CHAPTER 3.....	93
FOCUS GROUP DISCUSSIONS	93
3.1 INTRODUCTION	93
3.2 METHODOLOGY	95
3.2.1 An overview of methodological approaches in research.....	95
3.2.2 Choice of method for Phase 1	97
3.2.3 Methods used in qualitative research.....	99
3.2.4 Study Design	99
3.2.4.1 The use of focus groups	99
3.2.4.2 Governance issues.....	102
3.2.4.3 Sampling and recruitment for focus groups.....	103
3.2.4.4 Planning and conducting the focus groups	105
3.2.4.5 Analysing the focus group results	111
3.3 RESULTS.....	118
3.3.1 Introduction	118
3.3.1.1 Demographics of participants	118
3.3.1.2 An overview of the dynamics and interactions within each group .	120
3.3.1.3 Background Survey.....	129
3.3.2 Pharmacists' perceptions of the barriers and challenges towards pharmacist supplementary and independent prescribing in secondary care	131
3.3.2.1 Lack of management support for expanded role	132
3.3.2.2 Current working practices and processes	137
3.3.2.3 Lack of resource and capacity	140
3.3.2.4 Limitations of pharmacist supplementary prescribing	142
3.3.2.5 Concerns relating to pharmacist independent prescribing.....	144
3.3.2.6 Issues within the pharmacy profession	146
3.3.2.7 Concerns relating to other healthcare professionals	149
3.3.2.8 Concerns about patient safety	154
3.3.2.9 Concerns about training of pharmacist prescribers	155
3.3.3 Pharmacists' perceptions of the feasibility of pharmacist supplementary and independent prescribing in secondary care	157
3.3.3.1 Feasibility dependent on environment of practice within secondary care	158
3.3.3.2 Pharmacists' perceptions of advantages of pharmacist prescribing	166
3.3.3.3 Issues with the pharmacy profession.....	170
3.3.3.4 Issues with other healthcare professionals	171
3.4 DISCUSSION	175
3.4.1 Key findings	175
3.4.2 Strengths and limitations.....	176
3.4.3 Discussion of findings and comparison with the literature	178

CHAPTER 4.....	185
BACKGROUND SCOPING EXERCISE	185
4.1 INTRODUCTION	185
4.2 OBJECTIVE 1	187
4.2.1 Follow up of focus group participants	187
4.2.2 Further follow up of participant 10	189
4.3 OBJECTIVE 2	193
4.4 OBJECTIVE 3	195
4.5 DISCUSSION	201
4.5.1 Key findings	201
4.5.2 Strengths and limitations	202
4.5.3 Discussion	203
4.5.4 Conclusion	206
CHAPTER 5.....	207
DEVELOPMENT OF CONSENSUS GUIDANCE TO FACILITATE A SERVICE REDESIGN TO INVOLVE PHARMACIST PRESCRIBING IN SECONDARY CARE	207
5.1 INTRODUCTION	207
5.2 A BRIEF OVERVIEW OF CONSENSUS METHODS	207
5.2.1 The Nominal Group Technique	208
5.2.2 The Delphi Technique	209
5.2.3 Consensus Development Conference	211
5.3 STUDY DESIGN.....	212
5.3.1 Aim and objectives	212
5.3.2 Questionnaire development.....	213
5.3.3 Research Governance.....	226
5.3.4 Process used to achieve consensus	227
5.3.5 Characteristics of a good Delphi and application to this research.....	231
5.4 RESULTS.....	234
5.4.1 Round 1	234
5.4.2 Round 2	248
5.5 DISCUSSION	254
5.5.1 Key findings	254
5.5.2 Strengths and Limitations	255
5.5.3 Comparison with the literature	257
5.5.4 Discussion of findings.....	258
5.5.5 Further research.....	262
5.5.6 Conclusion	262

CHAPTER 6.....	263
GENERAL DISCUSSION	263
6.1 INTRODUCTION	263
6.2 EVOLUTION OF THE RESEARCH PROGRAMME	263
6.3 REVIEW OF KEY FINDINGS.....	270
6.4 DISCUSSION OF METHOD.....	272
6.4.1 Clarifying author bias	272
6.4.2 Focus group discussions	273
6.4.3 Scoping Exercise	275
6.4.4 Delphi study.....	275
6.5 IMPLICATIONS FOR POLICY AND PRACTICE	276
6.5.1 Potential for a pharmacist prescribing role to optimise antimicrobial use	276
6.5.2 A consensus-based analysis guide and action planning tool to facilitate implementation of pharmacist prescribing in Scottish hospitals	277
6.6 FURTHER RESEARCH.....	287
6.7 CONCLUSIONS	289
REFERENCES.....	291

List of Tables

Table 1: A summary of European Union projects aimed at optimising antimicrobial use	8
Table 2: A summary of the development of the role of the pharmacist through United Kingdom strategic documents relating to antimicrobial use	12
Table 3: UK associations that focus on promoting the prudent use of antimicrobials and tackling antimicrobial resistance	16
Table 4: A summary of United Kingdom legislation relating to pharmacist prescribing	28
Table 5: A critical appraisal of questionnaire based surveys exploring pharmacist prescribing	39
Table 6a: A critical appraisal of qualitative based research on pharmacist prescribing	44
Table 6b: A critical appraisal of qualitative based research on pharmacist prescribing (cont)	50
Table 7: Descriptions of programmes run by multidisciplinary teams with pharmacist involvement	66
Table 8: A critical appraisal of trials using an Interrupted Time Series design to measure outcomes of interventions to optimise antimicrobial prescribing through a multidisciplinary team with pharmacy involvement	75
Table 9: A critical appraisal of trials using a Case-Control design to measure outcomes of interventions to optimise antimicrobial prescribing through a multidisciplinary team with pharmacy involvement	83
Table 10: A critical appraisal of trials using a Randomised Controlled Trial design to measure outcomes of interventions to optimise antimicrobial prescribing through a multidisciplinary team with pharmacist involvement	85
Table 11: Initial version of topic guide	108
Table 12: Final version of topic guide	109
Table 13: General demographics, location and participant mix in each focus group	119
Table 14: Characteristics of focus group participants	125

Table 15: Results of background survey	130
Table 16: Categories and themes relating to barriers and challenges towards pharmacist supplementary and independent prescribing in secondary care	132
Table 17: Categories and themes relating to feasibility of pharmacist supplementary and independent prescribing in secondary care	158
Table 18: Clinical examples of chronic conditions where pharmacist antimicrobial prescribing may be feasible	160
Table 19: Prescribing status of focus group participants at Follow up	189
Table 20: A snapshot of pharmacist prescribing in Scotland – May 2008	198
Table 21: Criteria that may facilitate a service redesign involving pharmacist prescribing in secondary care	215

List of Figures

Figure 1: Schematic representation of screening process	62
Figure 2: Schematic representation of evolution of research question and methodology	94
Figure 3: Schematic representation showing both inductive and deductive approaches in quantitative research	96
Figure 4: Schematic representation of method adopted for Phase 1 of the project involving focus groups	117
Figure 5: Schematic representation of evolution of the research following focus group analysis	186
Figure 6: Development of questionnaire	213
Figure 7: A parallel and linked development of overall research aim	266
Figure 8: Factors contributing to evolution of the research	269

Chapter 1

An overview of the published literature on pharmacist prescribing and potential role in optimising antimicrobial use

1.1 Introduction

The focus of this research project was to explore pharmacist prescribing (PP) with a focus on antimicrobialsⁱ in Scottish hospitals. The practice setting was selected as the author has considerable experience as a hospital pharmacy practitioner and has observed numerous cases of antimicrobial misuse and overuse. This has led to a particular interest in this therapeutic area. The practice of non-medical and especially PP has potential to improve this situation.

Section 1.2 provides a review of the literature relating to the emerging role of the pharmacist in optimising antimicrobial use with particular focus on European and United Kingdom (UK) strategic reports. Section 1.3 describes PP, reviewing models of PP in the UK and other countries. Section 1.4 highlights the current role of the hospital pharmacist in optimising antimicrobial use in secondary care.

The wide and extensive use of antimicrobials, both in primary and secondary care, has led to various organisations developing initiatives to optimise antimicrobial use. The World Health Organisation (WHO) Global Strategy for containment of antimicrobial resistance has defined **prudent** prescribing of antimicrobials as: "... the cost-effective use of antimicrobials which maximise clinical therapeutic effect while minimising both drug-related toxicity and the development of antimicrobial resistance," (1) and **appropriate** use of antimicrobials as: "... [the] optimal choice, dosage and duration of antimicrobial therapy and chemoprophylaxis based on defined hospital antibiotic policy, monitoring of antibiotic resistance and up-to-date guidelines." (2) Achieving these may be a challenge where it is necessary to

ⁱ The term "antimicrobial" and "antibiotic" are often used interchangeably in the literature; this review uses the term antimicrobial unless quoting the term as used by the authors' specific publication.

consider both prudent (reducing unnecessary use) and appropriate (ensuring the right antimicrobial, dose, route and length of time while minimising adverse effects and development of resistance) use of antimicrobials. This mammoth task requires multidisciplinary teams with regular and close liaison between all healthcare professionals involved.

There is a complex relationship between the use and consumption of antimicrobials and the development of resistance, with a general view that increased antimicrobial use will lead to an increase in resistance while more prudent and controlled antimicrobial use will slow down the rise in the proportion of resistant strains.(3) However, the evidence for a conclusive relationship between antimicrobial use and development of resistance is surprisingly sparse.(4) More recently, some pioneering studies have been reported in the literature supporting the link between antibiotic use and antibiotic resistance in specific geographical locations. (5-8) Resistance results in increased overall treatment costs due to prolonged illness and resistance to cheaper first-line antimicrobials making it necessary to use more expensive drugs.(1) This problem becomes more urgent due to the lack of development of antimicrobials with novel modes of action. As del Mar describes it, "Antibiotics should be thought of like oil, a non-renewable resource to be carefully husbanded. What we use now cannot be used some time in the future."(9)

Antimicrobial resistance and the threat this brings with it have long been recognised. Inherent antimicrobial resistance existed even before antimicrobials were introduced into medicine; in 1940, Abraham and Chain recognised acquired antimicrobial resistance when, during the development of penicillin, they isolated the enzyme (now termed penicillinase) that destroys penicillin.(10) Due to the international and fast spread of microorganisms in this era of mass travel and global trade, the problem of antimicrobial resistance no longer remains a national one but is a European and global problem requiring international cooperation and a global strategy to avoid going back to the "pre-antibiotic" era. The low quality of poorly formulated or manufactured antimicrobials in the less developed world where often, medications are used after their expiry date, adds to the

complexity of the problem.(11) This has been compounded by factors in secondary care including hospital overcrowding leading to crossinfection, immunosuppression (disease or therapeutic) and the use of more invasive techniques which provide access for easy entry of bacteria into the patient's body.(1)

To support and promote appropriate antimicrobial use as a means of containing antimicrobial resistance, the WHO issued a global strategy which encourages international cooperation.(1) Numerous cases of current practice and barriers to inappropriate antimicrobial prescribing are identified. These include lack of the professional's knowledge and training, lack of diagnostic support, peer pressure and perceptions of patient demands and preferences and lack of enforcement of legislation. Areas for development within hospitals are recommended and include infection control strategies, collation of hospital specific formularies and therapeutic guidelines, and interventions through a coordinated multidisciplinary team with pharmacy representation.

1.2 Strategies aimed at optimising antimicrobial use

1.2.1 The European Union and prudent use of antimicrobials

Concern due to increasing antimicrobial resistance and the need for a more coordinated effort to tackle this led to the organisation of a series of invitational conferences aimed at developing a common strategy to tackle this problem. 'The Microbial Threat', an invitational conference involving numerous stakeholders and aimed to discuss the increasing resistance to antimicrobial agents, was held in Copenhagen in 1998. Final recommendations included increased surveillance to collate data on resistance to micro-organisms on a pan-European basis; collection of data on the supply and consumption of antimicrobial agents; development of a coordinated research programme around antimicrobial resistance; promotion of actions to encourage good practice and prudent use of antimicrobials.(12) The concept of an antimicrobial team, consisting of microbiologists, infectious disease specialists and clinical pharmacists, to

promote rational use of antimicrobials first emerges here. Such teams should cover both primary and secondary care including nursing and residential homes.(13) Teams "... should have the authority to modify antimicrobial prescriptions of individual clinicians in accordance with locally accepted guidelines..." (12)

Assessing the implementation of the Copenhagen recommendations was the aim of a 2001 invitational conference held in Visby, Sweden.(14) Emphasis was made on the need for coordinated multidisciplinary actions, with the major problem of lack of clinical microbiologists highlighted.

Recommendations for future actions included a community strategy to ensure data on the use of and resistance to antimicrobials is available community wide. The implementation of prudent use of antimicrobials was again discussed with various recommendations put forward including educational initiatives for health professionals and the general public, setting up and implementing guidelines for appropriate antimicrobial usage covering all aspects of medical care, and the introduction of antimicrobial teams. One recommendation in particular described the input of a specialist antimicrobial pharmacist. "Ideally, the team should consist of an infectious disease physician and/or a clinical microbiologist, a pharmacist with special expertise in antimicrobial agents and a senior nurse." (14)

Antimicrobial use in Europe was the theme for a further 2001 conference held in Brussels where European Surveillance of Antibiotic Consumption (ESAC) project was launched.(15) Recommendations for future research included the validation of indicators of prescribing quality, the development of evidence-based guidelines which could then be translated into indicators of prescribing quality, and the use of Anatomical Therapeutic Classification (ATC)/Defined Daily Doses (DDD) as supported by the WHO. One of the workshops organised focused on interventions in hospitals related to antibiotic use. It was recognised that there was a lack of adequately designed trials measuring the impact of interventions on antibiotic prescribing quality in hospitals. Consequently, better designed studies measuring interventions and identifying barriers to intervention implementation and problems of inappropriate antimicrobial use in

hospitals, were suggested. Recommendations were put forward for both national health authorities and at European level. National health authorities were encouraged to ensure that an antibiotic formulary and guidelines were developed and in place, together with an antimicrobial management team. To aid in implementation, the need for adequate resources in microbiology and infectious disease departments and close liaison with pharmacy were highlighted. On a European level, multi-country cooperation was needed to establish standards of antimicrobial prescribing, to optimise microbiology and infectious diseases services as well as optimising clinical pharmacy services. The establishment of antibiotic prescribing quality indicators was explored during a further workshop in Belgium in 2005.(16) A European Union–United States (EU-US) Transatlantic Task Force was also set up to investigate ways of providing incentives to promote the development of new antibiotics.(17)

The recommendations resulting from these conferences have been supported by European Council recommendations and resolutions. Emphasis was placed on taking a more global view, with the fight against antimicrobial resistance defined as a ‘public health priority’ for all member states.(12,18-20) In 2001, member states were advised to put in place a national strategy for tackling antimicrobial resistance in human medicine which should include a minimum of: surveillance of antimicrobial resistance and use; control and prevention of resistance; education and training; and research.(18,19) This was followed up in 2005 with members of the EU asked to report on the progress of implementing such strategies. Gaps have since emerged and been highlighted in areas around research initiatives, lack of public campaigns and lack of nationally accepted guidelines. In particular, despite the collection of data on antimicrobial use as part of ESAC (See Table 1), it was found to be difficult to link antimicrobial consumption data with clinical indicators.(21)

To further consolidate initiatives in this field at the European level, the European Agency for the Evaluation of Medicinal Products (EMA) has issued a discussion paper on antimicrobial resistance defining actions to be taken.(22) Main points were: providing standard recommendations to

healthcare professionals and patients on the Specific Product Characteristics (SPC), introducing dose recommendations for different infections to overcome inadequate dosing, and cross-referencing between information on the SPC and official guidelines.

1.2.1.1 The emerging role of the hospital pharmacist identified in strategic documents

The Antibiotic Resistance, Prevention and Control [ARPAC], a project that ran from January 2002 to June 2005, aimed at evaluating and harmonising strategies for the prevention and control of antibiotic resistant pathogens in European hospitals.(23) This final report places great emphasis on the impact of hospital pharmacists in rationalising antibiotic prescribing. It concluded that "... there is huge potential in Europe for an increased role for pharmacists..." in measuring and benchmarking antibiotic use, as a key member of Drugs and Therapeutics Committees and as a member of antibiotic teams that visit hospital wards to guide and audit antibiotic therapy. A number of recommendations related to pharmacy and antibiotic use in hospitals are put forward as follows:

- There should be provision of clinical pharmacy services to support antibiotic prescribing
- Pharmacists should form part of Drug and Therapeutics Committees
- Pharmacy departments should be involved in measuring and analysing antibiotic consumption as part of a multidisciplinary team
- Antibiotic pharmacists should be appointed with a hospital wide brief to: review antibiotic orders, design and promote guidelines, implement and run 'switch' programmes and document effectiveness of interventions.(23)

It was recommended that each nation create an educational programme and accreditation for pharmacists to increase the number of specialists available with an expertise in antibiotic prescribing. The report highlights the lack of data and good quality research measuring the effects of interventions on clinical outcome. Further research is required both in

individual countries and on a European level to measure the effect of antibiotic pharmacists on improving and reducing antibiotic prescribing and to investigate the most efficient pharmacy-based intervention.

More recently, the EU has been focusing specifically on antimicrobial stewardship (ABS) in hospitals, with the launch of its “ABS International” project in 2006. Further workshops have been organised to achieve consensus and develop standards for the implementation of ABS in hospitals in the 27 member states.⁽²⁴⁾ Reports describing the projects in different countries have started to emerge.⁽²⁵⁾ The pharmacist is put forward as an essential member of the successful ABS team, with recommendations for further exploration of a potential role for a specialised infectious diseases pharmacist, similar to that seen in the US literature.

Table 1 summarises European Union initiatives aimed at optimising antimicrobial use.

Table 1: A summary of European Union projects aimed at optimising antimicrobial use

Acronym	Full Name	Website	Focus
ARPAC	Antibiotic Resistance, Prevention and Control	www.abdn.ac.uk/arpac	A European commission funded project running from January 2002 to July 2005 and aimed at developing a better understanding of the epidemiology of antibiotic resistance and evaluating and harmonising strategies for the prevention and control of antibiotic resistant pathogens in European hospitals. The final recommendations have been published and there is a strong and important role for the hospital pharmacist.
Originally EARSS Now EARS-NET	European Antimicrobial Resistance Surveillance Network	www.ecdc.europa.eu	A European wide network, launched in January 1999, involving 800 laboratories in 31 countries of national surveillance systems, providing reference data on antimicrobial resistance for public health purposes. It includes collecting data on antimicrobial susceptibility of 7 bacterial isolates, analyses trends in resistance over time and provides guidelines and protocols.
ESAC	European Surveillance of Antimicrobial Consumption	www.esac.ua.ac.be	A network of national surveillance systems aiming to collect reliable and comparable antibiotic consumption data for public health purposes in all European countries.
ESCMID	European Society of Clinical Microbiology and Infectious Diseases	www.escmid.org/	Aims to improve the diagnosis, treatment and prevention of infectious diseases by promoting and supporting research, education and training in the infection disciplines. Runs various study groups such as the ESGNI (European study group on nosocomial infection).

EUCAST	European Committee on Antimicrobial Susceptibility Testing	www.escmid.org/research_projects/eu_cast	Standing ESCMID committee aimed at standardising susceptibility testing in Europe so that comparable results and interpretations are produced.
GRACE	Genomics to combat resistance against antibiotics in community-acquired lower respiratory infection in Europe	www.escmid.org/research_projects/grace	This project was launched on 17 th March 2006 to develop better diagnostic tools such that antibiotic use may be improved. The aim is to move towards having "bedside testing" where one is able to delineate infection from non-infection and viral from bacterial infection.
TROCAR	Translational Research on Combating Antimicrobial Resistance	www.escmid.org/research_projects/trocar	To investigate the epidemiology of new highly variant strains.
ECDC	European Centre for Disease Prevention and Control	www.ecdc.europa.eu	An agency of the EU aimed at protecting human health through the prevention and control of infectious diseases.

1.2.2 The emerging role of the pharmacist to optimise antimicrobial use in the United Kingdom

Concern about the increased resistance to antimicrobials in the UK has been discussed and debated at Government level and has resulted in a number of reports and recommendations, with the first published in 1998.

The 7th Science and Technology Report topic concluded that "... resistance to antibiotics and other anti-infective agents constitutes a major threat to public health and ought to be recognised as such more widely than it is at present." (26) Some examples of good practice referring to hospital pharmacy activities included: monitoring to ensure adherence to a restrictive formulary; checking prescriptions; and providing advice to junior doctors at ward level. The first reference is also made to a specialist antibiotic clinical pharmacist appointed in Hammersmith Hospital leading to a reduced infection rate and annual cost savings of £77,000. No published evidence is however provided to support this statement. In addition, the report highlights that clinical audits indicate that most routine prescribing of antimicrobials is by junior doctors, especially out-of-hours, a factor which might lead to variations in the quality of prescribing.(26) The Government response to this report highlights the importance of prudent antimicrobial use as a main strategy to reduce unnecessary pressure for the emergence of resistance. To encourage prudent antimicrobial use, pharmacists, as part of a multidisciplinary team, should be involved in developing and monitoring adherence to local antimicrobial drug policies.(27) The Path of Least Resistance supports this role of the pharmacist in "... controlling prescribing and identifying inappropriate prescribing". This report gives the role of the hospital pharmacist an added dimension beyond a 'policing' role. Pharmacists are seen as having sufficient knowledge and background to advise prescribers and educate junior doctors.(28) Recommendations set out in these reports were summarised in a Health Service Circular which aimed to highlight actions for the National Health Service (NHS).(29)

The UK Antimicrobial Resistance Strategy and Action Plan endorsed by all UK countries, aimed to provide a focussed approach in line with EU and

WHO strategies. It highlights four main areas of emphasis: surveillance, prudent antimicrobial use in humans and other spheres, the importance of diagnostic and susceptibility testing and public education.(30)

Recommendations for the implementation of this UKwide strategy were published in an interdepartmental report in 2001.(31) This report defines prudent antimicrobial use more comprehensively when compared to the WHO definition as "... the most appropriate way for the treatment or prevention of human infectious diseases, having regard to the diagnosis, evidence of clinical effectiveness, likely benefits, safety, cost and propensity for the emergence of resistance. The most appropriate way implies that the choice, route, dose, frequency and duration of administration have been rigorously determined." Responsibilities to support quality antimicrobial prescribing are assigned to both community and hospital pharmacists who play a key role in monitoring and advising on the appropriate use of antimicrobial therapy. There is support for the development and wide spread implementation of the specialist clinical antimicrobial pharmacist. In these latter documents there is a further shift in the role of the pharmacist, from a 'gate-keeping' role when monitoring and auditing adherence to policies to a more specialist and advisory role.

Strengthening strategies to combat antimicrobial resistance are identified as a priority in the 2002 report *Getting Ahead of the Curve*.(32) This need for high quality prescribing of antimicrobials and surveillance of antimicrobial use resulted in the injection of £12 million (starting in 2003/2004 and continuing for three years) into the NHS in England and Wales.(33) This was aimed at supporting the hospital pharmacy initiative for promoting prudent use of antibiotics and proved to be a turning point, resulting in the recognition and expansion of the specialist antimicrobial pharmacist post. This was further reinforced in the 2003 document *Winning Ways* where clinical pharmacists were assigned a key role in supporting prudent use of antimicrobials.(34) More recently, the role of the specialist antimicrobial pharmacist as part of the multidisciplinary team, was again highlighted in the 2008 document, *Clean, safe care*.(35) Table 2 summarises the development of the role of the antimicrobial pharmacist through UK key documents related to optimising antimicrobial use.

Table 2: A summary of the development of the role of the pharmacist through United Kingdom strategic documents related to optimising antimicrobial use

Document	Endorsing Body	Date	Focus
The Path of Least Resistance (28)	Standing Medical Advisory Committee, Department of Health	1998	Hospital pharmacists control prescribing and identify inappropriate prescribing through checking of adherence to antimicrobial guidelines.
Science and Technology 7 th Report: Resistance to antibiotics and other antimicrobial agents (26)	House of Lords	1998	Hospital pharmacists check prescriptions and advice junior doctors. There is a first reference to a specialist antibiotic clinical pharmacist.
Government Response to science and Technology 7 th Report: Resistance to antibiotics and other antimicrobial agents (27)	UK Parliament	1998	Pharmacists as part of a multidisciplinary team are involved in developing local antimicrobial drug policies depending on resistance patterns and monitoring adherence to them.
HSC 1999/049 Resistance to antibiotics and antimicrobial agents – action for the NHS (29)	NHS Executive	1999	Pharmacists help optimise concordance with antimicrobial agents
UK antimicrobial resistance strategy and action plan (30)	Department of Health	2000	Emphasis on surveillance, prudent antimicrobial use in humans, diagnostic and susceptibility testing and public education but no reference to a specific role for pharmacists
Optimising the clinical use of antimicrobials (31)	Clinical Prescribing Subgroup, Department of Health	2001	Key document with a shift towards a monitoring and advising role for pharmacists who should be members of antimicrobial prescribing groups. Recommendation to introduce specialist clinical pharmacists working exclusively on antimicrobials.
PLCOM 3. Hospital pharmacy initiative for promoting prudent use of antibiotics in hospital (33)	Department of Health	2003	£12 million funding over three years to extend activities related to clinical pharmacy specifically around antimicrobial use. Lead to development of numerous

			posts for specialist antimicrobial pharmacists.
Winning ways. Working together to reduce healthcare associated infection in England (34)	Department of Health	2003	Clinical pharmacists, in collaboration with medical microbiologists and infectious disease physicians, are to provide support for prudent antibiotic prescribing in hospitals.
Healthcare associated infection: What else can the NHS do? (36)	Healthcare Commission	2007	Pharmacists, as part of the antimicrobial team, play a role in development of protocols for appropriate antibiotic use.
Clean, safe care: Reducing infections and saving lives (35)	Department of Health	2008	Role of the specialist antimicrobial pharmacist as part of the multidisciplinary team, are to promote good prescribing practice. This is important to reduce resistance and potential antibiotic-associated complications such as C. difficile.

Numerous agencies, bodies and committees in the UK focus on antimicrobial resistance and the promotion of prudent use of antimicrobials (see Table 3). Among these is the Specialist Advisory Committee on Antimicrobial Resistance (SACAR), set up in 2001 to advise the government on antimicrobial resistance.(37) A prescribing subgroup of SACAR focused specifically on prudent antimicrobial prescribing and oversaw the hospital pharmacy initiative £12 million funding.(38) Preliminary results indicate that due to this funding more than 90% of acute trusts have a specialist member of staff employed, with 90% of these being pharmacists. There remains uncertainty as to how such posts will be funded at the end of this three year initiative.(39) Reports of a snapshot survey aimed at looking into activities that were facilitated as a result of this £12 million fund, indicated that the extra staff appointed were mainly reviewing antimicrobial prescribing guidelines, conducting audit projects, and working more closely with microbiology and infectious diseases departments. These efforts were reducing antibiotic acquisition costs, but no data on clinical and microbiological outcomes was available.(40) SACAR was later replaced in 2007 by the Advisory Committee on Antimicrobial Resistance and Health Acquired Infection (ARHAI).

Antimicrobial resistance has also been on the agenda of the Scottish Executive (now the Scottish Government) Health Department. Following a commitment to the 2000 UKwide strategy, a specific plan for Scotland was published in 2002.(41) The aims were to reduce overall use of antimicrobials, minimise the morbidity and mortality associated with antimicrobial resistance and maintain the effectiveness of antimicrobial agents through surveillance, prudent use of antimicrobials and infection control. Within this strategy, pharmacists are committed to review and monitor local guidelines on antibiotic prescribing. A series of workshops discussed strategies to prevent infections acquired while receiving healthcare.(42) One of the workshops focused on antimicrobial resistance and prescribing and makes recommendations to all NHS Trusts to form multidisciplinary antibiotic prescribing teams with the involvement of pharmacists to take on an educational role. The Right Medicine, which outlines a strategy for pharmaceutical care in Scotland, also highlights the

importance of regular reviews of antibiotic prescribing by pharmacy teams within each ward or unit.(43)

The Scottish Executive promoted the role of the antimicrobial pharmacist in a document published in August 2005 aimed at making recommendations for good antimicrobial practice in acute hospitals.(44) This highlighted various problems including wide variations in antimicrobial prescribing and policy, insufficient liaison between microbiology, clinicians and pharmacists and inadequate supervision of prescribing by junior doctors. A multidisciplinary antimicrobial team is recommended with participation of a lead doctor and pharmacist along with microbiology, infectious diseases and senior management representation. This was re-inforced in 2008 in The Scottish Management of Antimicrobial Resistance Action Plan [ScotMARAP] where the establishment of an antimicrobial team in each health board with a lead antimicrobial pharmacist was once more endorsed.(45) Funding to support the appointment of an antimicrobial pharmacist was highlighted in a Chief Executive letter in the same year.(46)

The practice of PP within the UK has been viewed by some as a natural extension to the role of the hospital pharmacist, including the antimicrobial pharmacist, potentially providing several opportunities for the pharmacist to optimise antimicrobial prescribing.(47,48) The following section aims to describe different models of PP, both within and outwith the UK. This is followed by a focus on the reported role within the UK of the hospital pharmacist in optimising antimicrobial use, with an exploration on whether any of these roles involve PP.

Table 3: United Kingdom associations that focus on promoting the prudent use of antimicrobials and tackling antimicrobial resistance

Acronym	Full Name	Website	Focus
APUA	Alliance for the prudent use of antibiotics	www.tufts.edu/med/apua	Founded in 1981 and set up in 50 countries to strengthen society's defences against infectious diseases by promoting appropriate antimicrobial access and use and controlling resistance on a worldwide basis. UK founded in 2003 in conjunction with BSAC.
BSAC	British Society for Antimicrobial Chemotherapy	www.bsac.org.uk	Set up in 1971. Aims to set standards for antimicrobial susceptibility testing and use, support microbiologists in practice and offer continuing professional development for its members. There is also a separate website related to management of hospital infection.
HCAI & AMR	Department of healthcare acquired infection and antimicrobial resistance	www.hpa.org.uk/infections/about/dir/dir_hcai.htm (weblink no longer active)	Set up in 2001 and falls within the remit of HPA. It is responsible for collecting surveillance data related to healthcare acquired infection and antimicrobial resistance. Replaced by ARHAI as below.
HPA	Health Protection Agency	www.hpa.org.uk/default.htm	Set up in April 2003 in response to Getting ahead of the curve. Offers integrated approach to UK public health and incorporates infectious diseases, chemical radiation and environmental hazards and emergency preparedness.
HIS	Hospital Infection Society	www.his.org.uk	Aims to bring together resources related to hospital associated infection.
SACAR	Standing Advisory Committee on Antimicrobial Resistance	www.dh.gov.uk/ab/Archive/SACAR/index.htm www.dh.gov.uk/ab/ARHAI/index.htm	Set up in 2001 in response to the UK antimicrobial resistance strategy and action plan. Prescribing subgroup oversees the hospital pharmacy initiative. This was later replaced by ARHAI.

1.3 Pharmacist prescribing

1.3.1 Models of pharmacist prescribing outwith the United Kingdom

This section provides an international viewpoint on the models of PP. This allows the reader to compare the different models of PP and its implementation in different countries in relation to the UK. Since PP was pioneered in the US, most of the literature available comes from here. An overview of international PP models is available in the literature.(49)

1.3.1.1 Pharmacist Prescribing in the United States

PP has been driven by a necessity to improve healthcare delivery, with the inability of pharmacists to prescribe resulting in time and cost impediments to the delivery of patient care. There are two models of PP in the United States (US) – dependent or independent authority.(50) Dependent prescribing authority implies that the PP authority is delegated by an independent prescriber, usually a physician, on the basis that the pharmacist is capable of performing the delegated duties. The two have shared responsibility for the patient's overall outcome usually defined through a collaborative drug therapy management (CDTM) agreement where the physician diagnoses and makes treatment decisions and the pharmacist selects, monitors, modifies or discontinues drug therapy as indicated in the agreement. The CDTM may take various forms such as general written protocols, policies or procedures or protocols for each specific patient.(51) Independent prescribing (IP) authority implies that the prescriber is authorised to prescribe all drugs without the supervision of another healthcare professional.(50) The American College of Clinical Pharmacists (ACCP) argues that prescribing within current healthcare systems can no longer be independent due to the complexity of drug regimens. It defines prescribing as encompassing a broader set of activities including selecting, initiating, monitoring, continuing, modifying and administering medications. The role of a pharmacist within a CDTM is consequently advocated since this makes use of the expertise of both the physician and the pharmacist.(52)

The extent of the PP authority depends on whether the setting they are practising is within the remit of state or federal law. The state law, which changes from one state to another, usually favours a model where the pharmacist is a dependent prescriber and therefore prescribing is based on protocols or physician-defined care plans. Many states that have introduced pharmacy prescribing have opted for this model and include California, Kansas, Mississippi, Nevada, New Mexico, North Dakota, Oregon, South Dakota, Texas and Washington.(50) By the end of 2003, 38 states allowed PP for various CDTM (compared to 14 states at the end of 1996).(51) This expansion in PP has been due to further evolution of the healthcare system including greater awareness of patient safety, further data showing improved healthcare outcomes with pharmacist participation, increasing age of the population and increased need for management of chronic diseases and increased patient self-participation and shared responsibility for their healthcare.(51) To ensure greater cohesiveness, it has been recommended that prescribing authority should be obtained on a national level, embracing all areas of pharmacy practice.(53) Examples of dependent prescribing authority may be found in both primary and secondary care. In ambulatory care settings, pharmacists assume responsibility for the management of chronic conditions such as hypertension, asthma, diabetes, hyperlipidaemia and psychiatric disorders.(54) Within a hospital environment, pharmacists may adjust infusions of heparin therapy against a written protocol agreed by a physician or assume responsibility for in and outpatient pain management, including prescribing of adjunct therapy such as antiemetics, antihistamines, laxatives and benzodiazepines.(55) Hospital pharmacists may also be involved in automatic therapeutic substitution to ensure that only drugs on the formulary are prescribed.(55) The American Society of Health Care System Pharmacists (ASHP) has included PP under CDTMs as one of its goals in the 2015 initiative. For hospital inpatients to achieve best use of medicines it aims to have 90% of hospitals having pharmacists manage medication therapy in collaboration with other members of the healthcare team. This also holds for non-hospital patients such as clinic and home-care settings.(56) Independent prescriptive authority at state level is in place in Florida, though pharmacists may only prescribe from a limited formulary and against strict protocols including antiemetic preparations,

antidiarrhoeals and smoking cessation products. (50,52,57) There has, however, been little updating of the formulary and consequently many of the items on the formulary have become over-the-counter medicines.(55) Interestingly, the ACCP does not support pharmacist IP based on (a) the fact that pharmacists are not trained diagnosticians and (b) current and future healthcare systems are moving towards collaboration and a multidisciplinary approach.(52)

The federal government is keener to expand the prescribing authority of the pharmacist and move towards pharmacist IP. This may be implemented within a federal institution irrespective of the state laws and regulations.(50) A directive of the Veteran Affairs (VA) Department lays this down clearly "... Because states cannot regulate the activities of the federal government, or its employees when acting within the scope of their federal employment, except by congressional consent, state laws and regulations relating to medication orders and prescriptions do not affect scope of practice statements under this directive."(58) Within the VA department, clinical pharmacy specialists have worked as independent providers prescribing medicines, reviewing and ordering laboratory tests, performing venepuncture, analysing lab and diagnostic test data, performing physical examinations and assisting in management of medical emergencies, adverse drug reactions, acute and chronic conditions and administering medicines.(59) Total IP authority was pioneered by Florida VA pharmacists in outpatient clinics.(60) This expanded role of the pharmacy specialist has been used as a model for other federal agencies such as the US Army and the Indian Health Service.(50,61) One of the main barriers to PP in the US has been the pharmaceutical industry since pharmacists were perceived as more likely to prescribe generics than doctors.(55) The American College of Physicians and American Society of Internal Medicine have issued a position statement on the expanding role of the pharmacist in which reference is made to PP.(62) This supports physician-directed pharmacist-physician collaborative practice agreements but limits these to the involvement of the pharmacist in patient education and hospital rounds. It categorically states, "... we need to ensure that physicians control prescriptive rights and have the final approval over all patient care decisions." It also comments about

pharmacist IP and does not support this, claiming that there is no evidence that this will benefit the patient and that pharmacists are not trained to initiate therapy. It again emphasises that "This is clearly an area that should remain under physician authority."

Prior to the expansion of this role of the pharmacist, in the early 1980s, studies were undertaken to prove the advantages of pharmacists to a clinical service. This extended role of the pharmacist within a clinical service is now generally accepted as an integral part of healthcare and looking into the cost effectiveness or cost benefit comparisons with physician prescribing is no longer seen as a priority in many institutions.(55) Training for pharmacists to prescribe is not centralised and pharmacist prescribers need to be credentialed within their employing institution.(63)

1.3.1.2 Pharmacist Prescribing in South Africa

Pharmacists working in rural communities in South Africa were previously issued with a permit 22A [12] allowing them to provide prescription only medicines based on their own discretion. This was issued following completion of the Primary Care Drug Therapy Course (PCDT). The aim was to provide a service to patients in rural communities where most patients go to the pharmacy before seeing a doctor and usually have no prescription. At this point, the main barrier towards expanding the number of medicines that may be dispensed by the pharmacist was the medical profession who seemed to show "... fierce and organised resistance." (64)

1.3.1.3 Pharmacist Prescribing in Canada

PP in Canada is limited and varies across provinces. Where PP occurs, this is mainly dependent or delegated prescribing based on a collaborative prescribing model involving an agreement between a pharmacist and a physician.(65) There is a lack of consistency in terms of legislation across Canadian states: some states such as British Columbia, Saskatchewan and Quebec, support independent PP of emergency contraception; some other states allow adapting existing prescriptions, while the broader prescribing privileges for pharmacists are within Alberta.(65 -67) The Canadian Society of Hospital Pharmacists advocates collaborative prescribing within

healthcare facilities arguing that this makes use of the diagnostic expertise of the physician and the pharmacotherapy expertise of the pharmacist.(68) It also claims that this will provide improved patient outcomes and increases the successful and efficient delivery of pharmaceutical care.(69)

1.3.1.4 Pharmacist Prescribing in Australia

PP has been a topic of discussion and debate in Australia with comments that Australia has been slow to catch on to this approach to prescribing.(70) The Society of Hospital Pharmacists of Australia supports extending prescribing rights to pharmacists provided that these are competency based.(71) Extension of the roles of and services provided by pharmacists are being proposed to make better use of the pharmacists' knowledge and improve consumer access to medicines without compromising patient safety.(72) Describing a PP model suitable in an Australian context has been the topic of a published report.(72) Four models of prescribing are proposed which differ depending on the practice setting:

- (a) Medication maintenance – would be based on a collaborative approach to manage patients in residential care facilities where pharmacists review, renew and monitor medication based on a patient-specific plan drawn up by a doctor who is also responsible for initiating therapy.
- (b) Advanced practitioners – this is a hospital based model where pharmacists would be able to prescribe in a supplementary role in designated areas within the hospital. Examples include pre-admission clinics, outpatient clinics, specialist inpatient clinics.
- (c) Protocol management – this would allow pharmacists to prescribe medication according to a defined population based protocol such as anticoagulation clinics
- (d) Pharmacists' formulary – this would allow pharmacists to prescribe medications from a 'pharmacist formulary' and would require current pharmacist only medicines to be incorporated into such a formulary.

Views of hospital pharmacists on PP have been explored through a combination of a questionnaire and a focus group discussion, though the study was limited and involved only 15 hospital pharmacists from one

institution.(73) The pharmacists identified potential areas for implementation of prescribing including repeat prescribing for patients with chronic conditions, adjusting doses according to protocols and prescribing discharge medications. Legal and ethical responsibilities, workload, opposition from physicians and legislation emerged as potential barriers. A wider scale questionnaire based study conducted in New South Wales indicated that the majority of pharmacists who responded supported an expanding PP role, acknowledging that further training was required to take on the role.(74)

1.3.2 Development of pharmacist prescribing in the United Kingdom

The main drive towards the development of non-medical prescribing in the UK, including PP, has been the need to make greater use of the skills and specialisation of different healthcare professionals by creating a more flexible system to prescribe, supply and administer medicines. This has been the focus of the two 'Crown Reports' – the first published in 1998 specifically discussed patient group protocols while the second review in 1999 made recommendations on potential expansion of prescribing roles of healthcare professionals.(75,76) The Department of Health has followed up these recommendations with the non-medical prescribing programme. The ultimate aim is to provide patients with better services, ensuring that safety is not compromised.(77)

The second Crown Report describes two models of prescribing: independent prescribing (IP) and dependent prescribing (later known as supplementary prescribing [SP]). IP occurs when the prescribing practitioner is responsible for patient assessment, diagnosis and clinical management, a definition that was later revised with the implementation of non-medical IP. Dependent prescribing usually involves delegation of authority to a non-medical prescriber from an independent prescriber who is responsible for the initial assessment and diagnosis.(78)

Patient Group Directions

These were initially known as 'patient group protocols' and allowed non-prescribers to supply or administer medicines against a protocol without the

need to identify the patient individually. The then legal uncertainty and lack of consistency in the application of such protocols, both in primary and secondary care needed to be clarified and this was the aim of the first Crown Report.(75) This set out a description of a group protocol and made recommendations about safe practice including criteria for content, development and implementation. It emphasized the importance of ensuring patient safety at any time, concluding that patient group protocols should not replace prescribing on a named patient basis, which is preferred. It may however have a use, in reducing patient waiting times, speeding up patient discharge, avoiding hospitalisation and making better use of professional skills. This report was implemented through Health Services Circular 1998/051.(79) Proposals in the Crown Report were followed up in the consultation document MLX 260 which proposed changes to the legal framework to ensure that any legislative 'loopholes' were dealt with. There is also a change in terminology from 'patient group protocol' to 'patient group direction (PGD)'. The legal definition of a PGD emerges as "...a written instruction for the sale, supply and/or administration of named medicines in an identified clinical situation. It applies to groups of patient who may not be individually identified before presenting for treatment." (80) It clearly defines criteria for a PGD and proposes a list of healthcare professionals (including pharmacists) who may supply under a PGD.(81) Further consultations led to the expansion of healthcare professionals who may prescribe under PGDs.(82,83)

Interestingly, specific guidance on PGDs for antimicrobials has been given. The Department of Health (DOH) states that since resistance to antimicrobials is a public health matter, PGDs for the use of antibiotics should be drawn up very carefully and only with the specialist advice of a microbiologist or public health specialist. PGDs for the use of antibiotics for the management of minor ailments such as viral sore throats should be avoided, and any PGDs using antibiotics should be regularly reviewed and audited.(80,83)

Supplementary Prescribing

The whole framework describing the potential development of SP forms the basis of the final Crown Report Review of Prescribing, Supply and Administration of Medicines. (76) The report argues that change was needed in response to numerous factors including increased professional specialisation, increased knowledge of both patient and carers and their desire to seek advice from a wider range of healthcare professionals and a desire on the part of the patient for seamless care. It goes on further to note that most patients were under the care of multidisciplinary teams and despite the fact that it was not necessarily the doctor who prescribed medication, it was often the doctor who was asked to sign the prescription. In view of these changes, the report, "... recommend(s) that the legal authority to prescribe in the UK, or to authorise supply at NHS expense, should be extended beyond currently authorised prescribers." (76) The concepts and definitions of both 'independent' and 'dependent' prescribing were introduced at this stage. To ensure patient safety, prescribers should keep within their remit of competence and should be familiar with co-morbidities and multiple pathogens.

Following on from the Crown Report, a joint Medicines Control Agency and DOH consultation document was issued in 2002. (84) This proposed changes to the legislation that would permit Prescription-Only-Medicines (POM) to be prescribed by a supplementary prescriber as part of a clinical management plan. It suggests that following diagnosis and overall clinical assessment of a patient, the responsibility including prescribing may be passed on to another professional. There is also a change in terminology from 'dependent prescribing' to 'SP' defined as follows: "A voluntary partnership between the responsible independent prescribing and a supplementary prescriber, to implement an agreed patient specific clinical management plan with the patient's agreement, particularly but not only in relation to prescribing for a specific non-acute medical condition or health need affecting the patient." It was proposed to initially apply this to nurses and pharmacists, with the possibility of later expanding to other healthcare professionals. Many of the responses to this consultation document were positive, however a number of concerns were raised around issues of accountability and indemnity cover

as well as the time involved in drawing up clinical management plans. Unnecessary prescribing of antimicrobials was of particular concern to the Royal College of Pathologists, SACAR and the Public Health Service Board, though this was unlikely to be a problem since most antimicrobials are prescribed in the short term.(85)

Legislation was amended in 2003 to allow SP to come into force through amendment of Section 63 of the Health and Social Care Act 2001.(86) Guidance for implementation in England and Scotland was later issued.(87-89) Emphasis was placed on appropriate training and practitioner accreditation and the Royal Pharmaceutical Society of Great Britain (RPSGB) has produced an outline curriculum for the training of pharmacist SP.(90) This includes a period of learning under the supervision of an independent prescriber. Central to SP is the Clinical Management Plan (CMP), which needs to be drawn up for each individual patient and forms the basis for patient management within the agreed framework between the two healthcare professionals. Detailed guidance and templates have been provided in various sources.(91)

Further amendments to the legislation have enabled expansion of prescribing rights to other healthcare professionals including physiotherapists, radiographers, podiatrists, chiropodists and optometrists. Amendments in April 2005 have also enabled supplementary prescribers to prescribe controlled drugs and unlicensed medications.(86)

Independent Prescribing

The Medicines and Healthcare products Regulatory Authority (MHRA) and DOH jointly produced consultation in 2005 on introducing IP by pharmacists, which broadened the remit of prescribing privileges by the profession. The consultation was again based on the final Crown Report and similar reasons were put forward as those for SP, to support expansion of prescribing responsibilities beyond the medical profession.(92) In this document, the definition of an independent prescriber has been broadened when compared to the initial definition in the Crown Report, to include both diagnosed and undiagnosed conditions as "... a practitioner responsible for

the assessment of patients with undiagnosed or diagnosed conditions and for decisions about the clinical management required, including prescribing." The proposal envisages a number of advantages if prescribing rights were extended to pharmacists including: better use of their skills in pharmacology and therapeutics, greater patient access to medications, a reduction in doctors' workloads and enabling the NHS to reach its targets. A number of options for models of IP were proposed. Respondents were asked to comment on each of these proposals.

- 1) No change
- 2) Prescribing for certain conditions from a limited formulary
- 3) Prescribing for any condition from a limited formulary
- 4) Prescribing for specific conditions from a full formulary
- 5) Prescribing for any condition from a full formulary
- 6) Different approaches for different clinical settings
- 7) A hybrid approach

It is interesting to note that the medical associations responding tended to favour option 1 or 2. Arguments in favour of these included that diagnosis is a very complex process beyond the skills of a pharmacist, commercial interests of community pharmacists may be a concern, a lack of access to the patient record especially in the community, the possibility of over-prescribing antibiotics and a need to separate dispensing and prescribing roles. As one association commented "... extending the role of the pharmacists might undermine the medical degree and remove the central role of the GP [General Practitioner]." (93) Overall, option 5 was the majority choice preferred option with emphasis on a need to have "scope of practice statements" where the prescriber diagnoses and prescribes depending on his/her own skills. None of the medical associations favoured this option with issues around complex diagnosis of multiple conditions and antibiotic prescribing again raised. This is in line with previous policy documents put together by the General Practitioners Committee discussing the future of prescribing.(94,95) In the GPs views, the primary aim of PP is a reduction in GP workload: "Can we give away GP prescribing that we do not want as long as the GP workload goes with it?" (94) There is support

for PP of Over-the-Counter (OTC) and Pharmacy-only (P) medications, including prescribing for patients who are exempt on the NHS, an emphasis on the need to shift more medicines from POM to P, and a need for greater pharmacy involvement in repeat prescribing. Interestingly, there is no reference to the Crown reports and the proposals to expand prescribing privileges of non-medical professions.

Following this consultation, the DOH announced in a press release, that nurse and pharmacist powers will be extended allowing for IP of any condition from a full formulary for nurses and pharmacists. The Secretary of State added that " ...extending prescribing responsibilities is an important part of our commitment to modernise the NHS. By expanding traditional prescribing roles, patients can more easily access the medicines they need from an increased number of highly trained health professionals." (96) As from May 2006 amendment of the Medicines for Human Use (Prescribing) Order allowed independent nurse and PP.(97) Legislation retains a similar definition to IP as that in the MHRA consultation document, and emphasizes that prescribing should be as part of a multidisciplinary team and with a single accessible patient record. Pharmacists may prescribe drugs for any condition from a full formulary with the exception of controlled drugs and unlicensed medications. Emphasis is made on the importance of adequate supervision, audit of practice and continuing professional development. Guidance on the implementation of IP also recommends that apart from exceptional circumstances, the dispensing and prescribing activities should be kept separate.(98) The RPSGB issued an outline curriculum for training programmes to prepare pharmacist prescribers. There was now a need to develop assessment and diagnostic skills needed by a prescriber likely to be prescribing autonomously. There was also emphasis on a need for the pharmacist to be aware of personal limitations and a scope of professional competence.(99) The RPSGB also issued guidance to outline the training needs of supplementary prescribers who will be training to become independent prescribers.(100)

A consultation process was carried out in 2007 to seek views of stakeholders on the IP of controlled drugs by pharmacist and nurse

independent prescribers. (101) Though this consultation recommended a change in legislation, pharmacists and nurses cannot currently independently prescribe controlled drugs since a change to the Misuse of Drugs Regulations, 2001, is still awaited. Further change in legislation in 2009 enable pharmacist and nurse independent prescribers to mix medicines prior to administration in all clinical areas and to prescribe unlicensed medicines. (102-104) Table 4 summarises key developments relating to PP.

Table 4: A summary of UK legislation relating to PP

Year	Development
1999	Crown Report recommended potential expansion of prescribing roles to other healthcare professionals (76)
2003	Section 63 of the Health and Social Act 2001 amended to allow pharmacist SP as part of a CMP (86)
2005	Amendments allowing pharmacists SP of controlled drugs and unlicensed medications as part of a CMP (86)
2006	Amendment of The Medicines for Human Use (Prescribing) Order allowing pharmacist IP of all licensed drugs except controlled drugs (97)
2009	Amendments allowing pharmacists IP of unlicensed medicines and mixing of medicines prior to administration in clinical practice (103,104)

The expansion of prescribing rights to pharmacists has not been met favourably by medical associations, the BMA GP Committee commenting that " This announcement raises patient safety issues and we are extremely concerned that the training provided is not remotely equivalent to the five or six years' training every doctor has undertaken." (105) The BMA's consultants' committee goes even further saying "This is an irresponsible and dangerous move. Patients will suffer." (105) An editorial in a leading medical journal published shortly after the decision was announced argues that it is likely for nurses and pharmacists to prescribe responsibly within their remit of expertise and competence. It does however conclude that the decision to expand pharmacist and nurse prescribing rights might have been taken at a later stage, when more evidence is available to support this. (106) This opinion has been supported by the World Medical Association's General Assembly in 2010. In a statement representing the

opinion of 50 national medical associations, they comment that in the interest of patient safety, "... the physician was the best qualified individual to prescribe independently." (107)

1.3.3 Implementation and Outcomes of pharmacist prescribing in the United Kingdom

This section aims to provide a descriptive account of the application of PP, followed by a critical appraisal of PP primary research in the UK.

1.3.3.1 Descriptive accounts of the application of pharmacist prescribing in the United Kingdom

The following provides an overview of practice settings and areas of care of PP in the UK; most of the information is based on narrative reports and reviews.

February 2004 saw the first pharmacist prescribers to be registered by the Society with the first prescription written by a supplementary prescriber reported in March 2004. (108,109) Following this, there have been reports on the delivery of PP and plans for service development in different healthcare settings which may be divided roughly into four models: community pharmacy, hospital, general practice settings and at the primary/secondary care interface. (110) In some cases, pharmacists had already been making recommendations to doctors, and consequently SP became an extension of previous practices, particularly in a hospital setting. As one pharmacist puts it "We used to write the prescription out and the doctor would sign it...Supplementary prescribing, in a sense, is a way of legalising what the pharmacists did before." (111) All reports in the literature are descriptive narratives of the implementation of pharmacist SP in the different areas of care with no studies measuring the outcomes of PP.

The broad practice of hospital pharmacists lends itself well to PP, with hospital pharmacists having access to patient records and already practicing as part of a multidisciplinary team. (112) Again, most of the reports in the literature are descriptive, commenting on pharmacist implementation of SP

in secondary care, with no robust research design or measure of outcome. For example, one NHS Trust is reported to use the skills of pharmacist prescribers in different care settings, such as the clinical nutrition team, Human Immunodeficiency Virus (HIV) outpatient clinic setting and in critical care where dose adjustment of drugs requiring therapeutic drug monitoring (such as aminoglycosides and vancomycin) is carried out.(111) In another case scenario, PP has been used to improve discharge planning on a cardiac unit.(113) SP outpatient clinics have also been reported in rheumatology.(114)

Supplementary PP within primary care medical practices may be logistically easier than within a community pharmacy setting due to the relatively easier access to both the independent prescriber and patient records.(112) Reports of pharmacist-led clinics in primary care settings include hypertension and clinical risk reduction clinics as well as a menopause and osteoporosis clinic.(115-7) Different reports of improved patient outcomes involving pharmacist SP include a mean reduction in glycosylated haemoglobin, cholesterol and systolic blood pressure following a pharmacist run primary care clinic for patients with uncontrolled type 2 diabetes, and a reduction in waiting time for oncology patients needing amendments to their antiemetic and cytotoxic drug regimens.(118) However, there are no studies measuring the outcomes of PP in these scenarios.

1.3.3.2 Pharmacist prescribing research in the United Kingdom

Studies exploring intra-professional perspectives of pharmacist prescribing

A) Supplementary prescribing

Early experiences of pharmacist SP were explored through a cross-sectional survey, with a piloted and validated postal questionnaire sent to all pharmacist prescribers, (n=488 after removing the pilot sample of 30) registered in June 2005 in Great Britain.(119) This was the first such large scale study and therefore crucial in providing baseline information on early implementation of SP. The authors obtained a response rate of 401 (82.3%) with respondents representing hospital, community and primary care settings. 48.6% of respondents self-reported practicing SP, with practitioners in primary care settings most likely to be implementing SP

compared to those in community or hospital pharmacies. Prescriptions had been mainly written for cardiovascular medications. Participants identified job satisfaction, increased self confidence, greater recognition and time savings as benefits of implementing SP. Financial and organisational problems, a general lack of awareness of the pharmacist's role and restrictions due to the clinical management plan emerged as the main barriers to PP. Results from an open question in this same survey were reported separately.(120) Interestingly, SP emerged as a natural extension of the pharmacist roles particularly in hospital and primary care settings. "Supplementary prescribing has little changed my practice – it has legalised what I did anyway." (120) The legally required CMPs were considered to be restrictive and time consuming, with pharmacists commenting that it may be easier to write up a prescription and get the independent prescriber to sign it, rather than complete a CMP. Consequently, independent PP was perceived as a potential solution to this problem.

Hobson et al's report was a questionnaire based national survey, designed to explore the implementation of pharmacist SP in England.(121) Previously validated and piloted questionnaires were sent out to pharmacists (n=151 secondary care trusts; n=273 primary care trusts) in both primary and secondary care who would oversee implementation of pharmacist SP. Results (response rate=68% for both surveys) indicated that the number of supplementary prescribers tended to be higher the bigger the NHS Trust or size of hospital. Total parenteral nutrition (TPN) or clinical nutrition was identified as the speciality with most supplementary prescribers. Other clinical areas where pharmacists were being trained to be supplementary prescribers included HIV, cystic fibrosis and surgery/orthopaedics. Interestingly, there were more secondary care pharmacist prescribers than primary care pharmacist prescribers possibly since in primary care, prescribing is often being used to set up a new service whereas in secondary care it is being used to "... legitimize services already being provided." (121) This differs from conclusions drawn by George et al, where pharmacists in primary care settings were most likely to be implementing prescribing. This is possibly due to the fact that the latter questionnaires have been sent out to the practising pharmacists rather than the

pharmacists implementing the prescribing.(119) Different geographies may also have contributed to these differences with George et al having included Great Britain while Hobson et al included only England.

In a small-scale study, Warchal et al used a piloted questionnaire (n=63; response rate=60.4%) and telephone interviews (n=10) to explore supplementary prescribers' attitudes and experiences related to their extended roles, with 30% of pharmacists then on the register invited to participate.(122) Pharmacists were asked reasons for introducing SP, with the majority indicating a wish to make better use of existing skills and to benefit patients. Barriers to prescribing were mainly related to the infrastructure, and included availability of computer generated prescriptions, lack of remuneration for the new role and a lack of continued support. Hospital pharmacists encountered fewer barriers than primary care or community pharmacists, mainly due to the availability of patient notes and pre-existing supportive infrastructure. Most of the respondents (n=81.6%) intended to become independent prescribers within the next five years and hence develop their role as opportunities and training became available.

Tully et al explored pharmacists' views and experiences towards the change in responsibility and accountability as part of SP. (123) This was achieved by conducting a pair of interviews with 8 participants who practised mainly in secondary care; the first was pre-training, and the second 6-8 months after completing training to qualify as a SP. At the first interview, most pharmacists were enthusiastic and optimistic to supplementary prescribe seeing this as an opportunity to regularise their work and provide a smoother service. Post-training, a number of barriers most of which were highlighted in other research, emerge. The CMP as a requirement of SP and the lack of staff to sustain the service, were the main concerns. Again, as in other research, the participants were keen to move on to independently prescribe.

Results of another UKwide study exploring the views of pharmacist supplementary prescribers on their current and potential future roles as

prescribers, have been reported by Weiss et al. (124) Semi-structured interviews were conducted with a UKwide purposive sample of 23 pharmacists, practising in both primary and secondary care settings. While some pharmacists felt that SP was no change to their previous practice, other pharmacists felt it increased their professional status. Concerns were raised about ways of ensuring that prescribing was within the individual's competency. Pharmacists also highlighted the importance of ensuring effective communication within a team if the prescribing process was being broken down. As in other research, participants were not comfortable in their own clinical examination and diagnostic skills.

Tables 5, 6a and 6b present a critical appraisal of these publications.

B) Independent Prescribing

As may be expected, being such a novel topic, there is little evidence exploring pharmacists' awareness, views and attitudes on being independent prescribers. George et al aimed to explore this in a sample (n=500) of Scottish community pharmacists, who were sent a validated and piloted questionnaire. (125) A 43.4% response rate was reported. The respondents appeared to be well informed and 91.2% knew about proposals for pharmacists to become independent prescribers. Interestingly, though 80.5% reported being happy to be independent prescribers, only 53.5% believed that it was their professional duty to do so. Participants perceived better patient access to medications as the main advantage of pharmacist IP. As expected, pharmacists who were already supplementary prescribers and "leading edge practitioners" were more likely to embrace the idea of pharmacist IP (the original Crown Report definition was used in this study rather than the broader definition later incorporated in the final legislation – see Section 1.3.2). Though this study provides some valuable insight, it is limited to community pharmacists in Scotland; it would be interesting to explore the willingness of pharmacists to take on IP in other areas of practice throughout the UK.

C) Impact of pharmacist prescribing on patient care

Few UK studies in the literature measure the impact of the pharmacist supplementary prescriber on patient care. A small-scale, single-site trial has been reported and seeks to measure the outcome of PP in an intensive care unit (ICU). A retrospective trial of before and after SP was carried out to determine the level of adherence to guidelines of pharmacist supplementary prescribers with doctor prescribers of anti-infective agents in haemofiltered patients.(126) Results showed that 53.7% of prescriptions issued by doctors adhered to guidelines while 100% of the prescriptions issued by supplementary prescribers were appropriate. Though a single-centre small-scale non-randomised trial, it shows that PP may impact positively on acute care. In a separate commentary, the author highlights problems encountered on ICU, which are common to other areas of secondary care, with emphasis on the fact that proposed changes to patient's medications agreed and discussed during the ward round were not implemented by doctors. Reasons may include doctors forgetting, considering other matters as a priority or a lack of understanding. The author argues that due to the mainly drug-focused activities of the pharmacists, PP is a natural extension of the pharmacist role and consequently PP was introduced in this practice setting to optimise patient care.(127)

Studies exploring inter-professional perspectives of pharmacist prescribing One study (128) aimed to determine the factors that would enable or inhibit implementation of non-medical prescribing, focusing on the attitudes of key stakeholders to non-medical prescribing. Data were generated through a number of semi-structured interviews with stakeholders (medical staff, pharmacists and nurses) working in a secondary care environment. Though medical staff accepted PP, they were only prepared to do this within set boundaries and protocols within which pharmacists could prescribe. They expressed concern around pharmacist IP, even if this involved "more simple" cases including prescribing of analgesics and switching antimicrobials from the intravenous to the oral route. When compared to nurses, pharmacists were seen as being disadvantaged in that they did not have enough patient contact to know the patients well enough to be able to prescribe safely. A concern about the pharmacist's lack of diagnostic skills was also raised. This study raises issues on potential barriers which may

arise due to the encroachment of traditional roles with the advent of non-medical IP.

These barriers were also highlighted in other research (129) that involved focus group discussions and interviews with pharmacists who were enrolled on a SP course, and medical staff who had agreed to act as their mentors during their SP training. This research aimed to explore pharmacists' and mentors' views on the introduction of pharmacist supplementary prescribers and thus recruited participants in different practice settings, prior to them embarking on their training programme. Again, the mentors felt that SP was the more appropriate process for PP since it set the barriers within which they would be able to prescribe. Issues were raised also about the lack of pharmacist diagnostic skills that are required as part of IP. Despite these difficulties, both pharmacists and mentors believed that pharmacist SP is likely to improve overall patient care. The same participants were followed up 12 months after the pharmacists qualified. (130) Most pharmacists who were actively prescribing worked in a hospital setting. Participants believed that optimal settings for PP were outpatient clinics or chronic diseases that are protocol-driven. Both pharmacists and their mentors felt that pharmacist SP enabled pharmacists to progress professionally and to gain confidence in their skills, with a strong mentor-pharmacist relationship making it more likely for the pharmacist SP to be successful. Pharmacists perceived a degree of professional encroachment by both nurses and doctors, with these other healthcare professionals feeling threatened by the pharmacists' new role. Other barriers included the paperwork involved in implementing CMPs and a lack of pharmacy resource to maintain the service. Pharmacists believed that progression to IP was the way forward, though both pharmacists and mentors believed that pharmacists would be likely to independently prescribe if a diagnosis had already been made, and where the condition is protocol-driven.

Pharmacist prescribers participating in research conducted by Stewart et al. were also eager to take on IP in the future, though doctors, particularly in a primary care setting, were concerned about the lack of pharmacist diagnostic skills. This study adopted a case-analysis approach and

interviews were conducted with pharmacist supplementary prescribers, doctors who were their linked independent prescribers and patients.(131) Pharmacists viewed SP as "... a natural extension to their advisory role, almost legalising their current practice." Patients were initially apprehensive about having a pharmacist consultation but provided positive feedback following their experiences. All stakeholders felt that patient outcomes were positive following the introduction of pharmacist SP. Healthcare professionals perceived enhanced teamwork to be the main benefit while a lack of support together with patient demands were reported to be the main challenges of pharmacist SP.

A study, focusing in a primary care setting, aimed to explore pharmacists' and GPs' perceptions on the potential effect of pharmacist SP on professional boundaries.(132) Pharmacists included in this research were early adopters and commented that it was through their own initiative that they had identified an area within which they could prescribe. As in other research, they felt that a pre-existing strong working relationship with the GP practice was likely to ensure more successful implementation of pharmacist SP. A good level of patient acceptance was reported by both GPs and pharmacists; however there were mixed reactions and views as to whether a pharmacist SP was threatening the medical prescriber's professional identity.

Further details and a critical appraisal are at Tables 5, 6a and 6b.

Studies exploring patient perspectives of pharmacist prescribing
One small-scale study has aimed to evaluate patients' perceptions of a pharmacist-led SP hypertension clinic.(133) A self-administered piloted questionnaire was sent to all patients (n=127) who had been invited to attend the clinic, including those who had refused the appointment. 57% of respondents felt the standard of care was better than previous care and 86% indicated that they could make an appointment more easily. Patients who refused the appointment indicated that they would like to continue with their present GP or nurse rather than a pharmacist. Others said that they were given an inconvenient appointment date or time. This study may be

viewed as an audit of the service provided; no statistical analysis was performed and the author states that the questionnaire was aimed at finding ways to improve the current service being offered. As with all questionnaire based studies, non respondent bias may be a disadvantage since the non respondents may be patients who felt they had a negative experience of the clinic. However, it does indicate that there was a general acceptance of patients for non-medical prescribing.

Another small-scale study (134) as part of a larger case-based study, (131) aimed at exploring patients' perspectives of pharmacist SP in Scotland. This involved distributing pre-piloted questionnaires based on previous research, to patients (n=180) as they attended their appointments with a pharmacist SP mainly in community settings (further detail of the settings has been provided in Table 6a below). A response rate of 57.2% (n=103) was achieved and the main conditions managed by the pharmacists were hypertension and asthma. Though around 89% of patients were totally satisfied with their consultation, 65% still preferred to consult a doctor. A broader study aimed to determine views on attitudes of the Scottish general public on non-medical prescribing, with a focus on PP through a postal pre-piloted questionnaire. (135) A 34.6% (n=1728) response rate is reported. 56.6% of respondents were aware that a healthcare professional other than a doctor could prescribe their medication, with greatest awareness of the pharmacist's role. Television and newspapers were the main source of this information. Patients were comfortable mainly with a PP a medicine previously prescribed only by a doctor, with just over half supporting a prescribing role for a pharmacist. Concerns were raised about the lack of diagnostic skills of the pharmacist and a lack of privacy in a pharmacy. Overall, patients appeared to accept a prescribing role for a pharmacist though, prescribing a smaller range of medicines than doctors and if a diagnosis had been made by a doctor.

A recently published study aimed to explore patients' perceptions of the capability of a pharmacist to be a non-medical prescriber; it also explores any preferences patients may have between consulting a pharmacist or a nurse. (136) This was achieved by conducting semi-structured interviews in

primary and secondary care settings, with both patients who had experience of a PP and those who did not. Patients perceived pharmacists to have an inferior knowledge to doctors and nurses with a lack of patient awareness of pharmacist length of training. They suggest that they would trust a pharmacist more once a relationship has been established. Discussions focused mainly around community pharmacies, with numerous concerns relating to clinical governance and confidentiality in community pharmacies expressed. The findings of this study somewhat contradict those by Stewart et al (135) described above; these differences in findings may be attributed to different geographical areas and different methods employed in the studies.

A critical appraisal of the studies may be found at Tables 5, 6a and 6b

Table 5: A critical appraisal of questionnaire based surveys exploring pharmacist prescribing (137,138)
(note this table is 5 pages long)

Criteria	George et al 2006 (125)	George et al 2006 (119)	George et al 2006 (120)	Hobson et al 2006 (121)	Stewart et al 2009 (135)
Study population and survey sample					
Study population clearly defined and appropriate	A random sample from all community pharmacies in Scotland n=500	All pharmacist supplementary prescribers registered in June 2005 n=518	All pharmacist supplementary prescribers registered in June 2005 n=518	All chief pharmacists in primary (PCT) and secondary care trusts (SCT) in England (n=271) and (n=143)	A random sample of members of the general public (n=5000) aged 18 or over obtained from the UK electoral roll
Sampling strategy Ex stratified, randomized, sequential, inclusion and exclusion criteria	Randomized using random numbers	Not applicable since all prescribers were included	Not applicable since all prescribers were included	Not applicable since all chief pharmacists were included	Random sample but method for randomization not described
Sample size determined beforehand with a suitable description of how this was achieved	n=500 but no information provided on how sample size was determined or what proportion of community pharmacies this included	Not applicable; no sampling required	Not applicable; no sampling required	Not applicable; no sampling required	n=5000 but no information provided on how sample size was determined
How the survey was conducted Ex face-to-face interviews; telephone interviews;	Mailed questionnaire addressed to the managing	Mailed questionnaire	Mailed questionnaire	Mailed questionnaire; SCT questionnaires	Mailed questionnaire

mailed questionnaire	pharmacist			were addressed to the chief pharmacists; PCT questionnaires were addressed to the PCT pharmacist or pharmaceutical advisor	
How the response rate was maximised	Two questionnaire reminders sent to non-respondents at 4-weekly intervals	Three reminders sent to non-respondents at 2-weekly intervals	Three reminders sent to non-respondents at 2-weekly intervals	Second mailing of questionnaire after 3 weeks; follow up telephone call after 4 weeks to SCT, mailing to PCT; last mailing after 3 weeks	Two questionnaire reminders sent to non-respondents at 4-weekly intervals
Response rate including a description of participants who were unsuitable for research or refused to take part	n = 217 (43.4%)	n = 401 (82.2%)	n = 401 (82.2%) but only about 1/3 completed the open question	n = 68% for both surveys	n = 1728 (34.6%); n = 343 (6.9%) returned undelivered due to addressee moving
Description and discussion of any potential response bias	Considered; authors discuss the possibility that most respondents who had an interest in IP were more likely to respond	Not discussed; but unlikely to be any response bias due to the high response rate	Considered	Not discussed	Considered; authors discuss the possibility that non-respondents had little interest in the topic

Questionnaire					
A description of the questionnaire development Ex what process was used to create the questionnaire, was a literature search done to identify key areas, were previous questionnaires adapted or combined	Provided; this was based on policy documents	Not provided	Not provided	Provided; informed by a literature review, interviews with policy makers and academic pharmacists and a focus group.	Provided; this was informed by the current literature
Reliability testing; assessing reproducibility and consistency	Not described	Described	Not described	Not described	Described; limitations of the study relating to test-retest reliability are highlighted
Content or face validity testing	Done by an expert panel of practitioners and researchers	Done by four experts	Done by four experts in non-medical prescribing	Done	Done by an expert panel of academic pharmacy practitioners and researchers
Piloting	Done by sending to 30 random pharmacists; some minimal changes followed	Done by sending to 30 pharmacists selected randomly; some minor revisions followed	Done by sending to 30 pharmacists selected randomly; some minor revisions followed	Done by sending to 17 SCT pharmacists and 30 PCT pharmacists; some minor revisions followed	Done by sending to 500 members of the public; some minimal changes followed.

A description of the questionnaire content Ex the number of questions/items, open or close ended questions	Clearly described	Clearly described	Clearly described	Clearly described	Clearly described
Analysis					
What sort of analysis was carried out and was this appropriate? Ex correct statistical tests for quantitative answers; qualitative analysis for open ended questions	Statistical tests were presented for quantitative answers; content analysis performed for qualitative analysis but not presented in this paper	Statistical tests were presented for quantitative answers; no details are provided on analysis of open questions	Descriptive statistics provided; statistical tests were not presented for quantitative answers; content analysis of open question provided here with adequate thematic description and illustrative quotes	Descriptive statistics provided; statistical tests were presented for quantitative answers	Statistical tests were presented for quantitative answers; key themes identified through open question presented but no discussion of derivation of these themes.
Results					
Reporting of all relevant data to include	Provided	Provided	Provided	Provided	Provided
Reporting of both significant and non-significant results	Provided	Provided	Not applicable	Provided	Provided
Adequate reporting of qualitative results	Not available	Not available	Provided	Not available	Partially provided

Discussion					
The results in relation to the objectives of the study	Discussed	Discussed	Discussed	Discussed	Discussed
Possible interpretations	Discussed	Discussed	Discussed	Discussed	Discussed
Comparisons with other studies	Discussed but few studies to compare with	Discussed but few studies to compare with	Discussed but few studies to compare with	Not discussed, but few studies to compare with	Discussed but authors acknowledge that few studies to compare with
Strengths and limitations	Discussed	Discussed	Discussed	Discussed	Discussed
Future research	Not included	Discussed	Discussed	Not discussed	Discussed

Table 6a: A critical appraisal of qualitative based research on pharmacist prescribing (139)
(note this table is 6 pages long)

Criteria	Warchal et al (122)	Buckley et al (128)	Lloyd et al (129)	Tann et al (132)	Stewart et al (131)
Research design					
Justification by authors of research design to address the aims of the research	No	No	No	No	No
Is a qualitative method appropriate	Yes – a mixed method used here where participants were sent a questionnaire containing both open and closed questions; answers were then validated through a telephone interview. It aims to explore the attitudes of pharmacist supplementary prescribers to their training and extended roles	Yes – aims to explore the attitudes of stakeholders to non-medical prescribing	Yes – aims to explore the context and views of pharmacist supplementary prescribers and their mentors	Yes – aims to explore the perceptions of GPs and pharmacists of SP	Yes – a mixed method involving interviews, video recording and a questionnaire used as part of a qualitative case-study approach. Only the interviews are reported in this paper. Questionnaires distributed to the patients are reported elsewhere. (134)

Sampling of participants					
Sampling strategy Ex purposive, theoretical, exclusion and inclusion criteria	Purposive sampling; only pharmacists known to have completed the course were recruited. However no details provided as to why the specific participants were invited to participate. Demographics of participants provided.	Purposive sampling; no details provided of the characteristics of participants included	Purposive sampling; demographics of participants provided	Purposive sampling; no details provided of characteristics of participants. However, a comprehensive background provided on the GP practices where participants practised.	Purposive sampling; a comprehensive account is provided on how the 10 case study sites were generated.
Was the sampling in line with the research aims	Yes	Yes	Yes	Yes	Yes
Any justification of sample size Ex limited sample, data saturation	Not provided	Not provided	Yes	Not provided	Not provided
Any discussions provided around participant recruitment Ex have any refused	Provided	Not provided	Provided	Provided	Provided
Were participants selected the most	Yes, though there is no discussion	Details of participants not	Yes	Yes	Yes

appropriate to provide the type of knowledge sought by the study	around how these participants were sampled from all the supplementary prescribers	provided so cannot be determined			
Data generation					
Method for data generation clear Ex focus group, interviews	Clear. Questionnaire and telephone interviews	Clear. Semi-structured interviews	Clear. A combination of focus groups and semi-structured interviews	Clear. A combination of focus groups and interviews	Clear. Telephone interview
Method for data generation explicit including development and piloting Ex has topic guide been used	Provided	Not provided	Provided	Not provided though the topics discussed were highlighted	Provided
Setting for data collection clear	Yes – participants provided a mix of hospital, primary care and community pharmacy settings.	Yes – a secondary care trust	Yes – pharmacists and their mentors prior to starting training as supplementary prescribers. Involved hospital, community and primary care pharmacy settings.	Yes – three practices within two primary care trusts with a high proportion of pharmacist SPs.	Yes – participants provided a spectrum of both geographical location within Scotland and pharmacy settings, though only one case was hospital based.
Justification of methods chosen	Not provided	Not provided	Not provided	Not provided	Not provided
Consideration of who collects the	Not provided	Not provided	Provided	Not provided	Provided

data					
Any modification of methods during the study and why	None	None	None	None	None
Clear format of the data collected Ex transcripts, audio-recordings, video-recordings	Clear. Questionnaire; transcripts from telephone interviews were recorded manually	Clear. Audiorecordings of interviews which were then fully transcribed	Clear. Audiorecordings of discussions and interviews which were then fully transcribed	Clear. Audiorecorded with detailed field notes taken	Clear. Audiorecorded and transcribed verbatim
Discussion around data saturation	Not provided	Not provided	Provided	Not provided	Provided
Reflexivityⁱⁱ					
Researcher bias and potential influence considered at the planning stage of the research Ex formulation of research questions	Not discussed	Not discussed	Discussed	Not discussed	Not discussed
Researcher bias and potential influence considered during the data collection	Not discussed	Not discussed	Discussed	Not discussed	Not discussed
Ethical issues					
Consideration of ethical issues that the study may have	Not discussed	Ethical approval sought; all participants and	Ethical approval sought; all participants and	Ethical approval sought: all participants and	Ethical approval sought: all participants and

ⁱⁱ This involves answering the question “Has the relationship between researcher and participants been adequately observed?”

arisen and steps taken to deal with these		quotes provided are anonymised			
Data analysis					
Clear description of analysis process used or framework applied	No	Yes	Yes	Yes	Yes
Clear description of derivation of themes and categories from data	No	Yes	Yes	Yes	Yes
Provision of sufficient data to support findings	Yes	Yes	Yes	Yes	Yes
Consideration of any contradictory data that may have arisen	Yes	Yes	Yes	Yes	Yes
Researcher bias and potential influence considered during the data analysis	Not discussed	Not discussed	Yes	Yes, though not discussed	Yes, though not discussed
Results					
Results are clear and explicit	Yes	Yes	Yes	Yes	Yes
Evidence provided both for and against the researcher's	Yes	Yes	Yes	Yes	Yes

arguments					
Consideration of issues around credibility Ex triangulation, more than one analyst	Discussed	Not discussed	Discussed	Discussed	Discussed
Discussion					
The results in relation to the original research question	Considered	Considered	Considered	Considered	Considered
The results in relation to the current literature	Provided though limited by lack of literature available	Provided	Provided	Considered	Considered
Issues around transferability and application of research	Provided	Provided	Provided	Provided	Provided
Future research	Provided	Provided	Provided	Not provided	Provided
Conclusion appropriate to research aim	Yes	Yes	Yes	Yes	Yes

Table 6b: A critical appraisal of qualitative based research on pharmacist prescribing (cont.) (139)
(note this table is 4 pages long)

Criteria	Hobson et al (136)	Tully et al (123)	Weiss MC et al (124)
Research design			
Justification by authors of research design to address the aims of the research	No	Yes	No
Is a qualitative method appropriate	Yes – aims to explore patients’ perceptions of capability of pharmacist to prescribe and whether patients had any preferences between consulting a pharmacist or a nurse and why	Yes – aims to explore pharmacists’ views and experiences towards the change in responsibility and accountability as part of SP	Yes – aims to explore pharmacists’ views on their current and potential future role as a prescriber
Sampling of participants			
Sampling strategy Ex purposive, theoretical, exclusion and inclusion criteria	Purposive sampling – this included 4 sites in primary and secondary care where a pharmacist was actively prescribing. Randomization used to select patients. Both patients who had experience of a PP and those who did not were recruited to allow comparisons to be made. Demographics of patients provided	Purposive sampling but no details provided of the participants with exception of setting and geographical location	Purposive sampling – a sample of pharmacists from all the UK who were on the SP register at the time of the study

Was the sampling in line with the research aims	Yes	Yes	Yes
Any justification of sample size Ex limited sample, data saturation	Yes – patients were recruited until data saturation was achieved	Not provided	Not provided
Any discussions provided around participant recruitment Ex have any refused	Not provided	Not provided	Provided
Were participants selected the most appropriate to provide the type of knowledge sought by the study	Yes	Yes	Yes
Data generation			
Method for data generation clear Ex focus group, interviews	Clear. Semi-structured interviews	Clear. Semi-structured interviews	Clear. Semi-structured interviews and case studies; only the interviews are reported here
Method for data generation explicit including development and piloting Ex has topic guide been used	Provided	Partially provided – some detail given on focus of interviews but nothing on development or use of a topic guide	Not Provided
Setting for data collection clear	Yes – both primary and secondary care	Yes – mainly secondary care	Yes – both primary and secondary care
Justification of methods chosen	Not provided	Not provided	Not provided
Consideration of who collects the data	Not provided	Not provided	Not provided
Any modification of methods during the study and why	None	None	None
Clear format of the data collected Ex transcripts, audio-recordings, video-recordings	Yes – interviews were audio-tape recorded and transcribed	Yes – interviews were audio-tape recorded and transcribed	Yes – interviews were audio-tape recorded and transcribed

Discussion around data saturation	Provided	Provided	Not provided
Reflexivity			
Researcher bias and potential influence considered at the planning stage of the research Ex formulation of research questions	Not discussed	Not discussed	Not discussed
Researcher bias and potential influence considered during the data collection	Not discussed	Not discussed	Not discussed
Ethical issues			
Consideration of ethical issues that the study may have arisen and steps taken to deal with these	Ethical approval sought; all participants and quotes provided are anonymised	Ethical approval sought; all participants and quotes provided are anonymised	Ethical approval sought; all participants and quotes provided are anonymised
Data analysis			
Clear description of analysis process used or framework applied	Yes	Yes	Yes
Clear description of derivation of themes and categories from data	Yes	Yes	Yes
Provision of sufficient data to support findings	Yes	Yes	Yes
Consideration of any contradictory data that may have arisen	Yes	Yes	Yes
Researcher bias and potential influence considered during the data analysis	Not discussed	Not discussed	Not discussed

Results			
Results are clear and explicit	Yes	Yes	Yes
Evidence provided both for and against the researcher's arguments	Yes	Yes	Yes
Consideration of issues around credibility Ex triangulation, more than one analyst	Not discussed	Not discussed	Not discussed
Discussion			
The results in relation to the original research question	Considered	Considered	Considered
The results in relation to the current literature	Provided	Provided	Provided
Issues around transferability and application of research	Provided	Provided	Provided
Future research	Provided	Provided	Provided
Conclusion appropriate to research aim	Yes	Yes	Yes

1.4 The role of the hospital pharmacist in improving antimicrobial prescribing in the United Kingdom

The potential value of the hospital pharmacist in improving antimicrobial prescribing has been described in the literature. Overall, many publications describe the pharmacist's intervention with few controlled trials evaluating the outcomes of such interventions. Trials often tended to focus on economic evaluations with little or no evaluation of clinical or patient outcomes. Further details are in Chapter 2. This section will describe the role within the UK of the hospital pharmacist, including the antimicrobial pharmacist, in improving antimicrobial prescribing and will explore whether there is a potential for PP to enhance this role.

In his commentary on the role of the hospital pharmacist in antimicrobial management, Cooke encourages the collaboration of the pharmacist with the microbiologists and other clinicians.⁽³⁸⁾ The potential role of hospital pharmacists has been described in various papers and includes:

(38,48,140,141)

- Promoting guidelines, formularies and policies using guidance from SACAR to ensure consistency in content and quality
- Encouraging prescribers to use systemic medication rather than topical medication due to increased resistance with the latter
- Taking the lead in intravenous to oral switching where appropriate
- Ensuring appropriate duration of treatment using various strategies such as automatic stops
- Using pharmacokinetic knowledge to ensure optimal antimicrobial dosing in individual patients
- Ensuring appropriate administration of antimicrobials required for surgical prophylaxis
- Resistance monitoring and sensitivity possibly with selective reporting in collaboration with microbiology departments
- Preparation of intravenous antimicrobials

- Encouraging the development of information technology (IT) prescribing support systems with links to local antimicrobial sensitivity profiles
- Leading on educational initiatives to train prescribers including running formal training initiatives, education during ward rounds and providing feedback following audits
- Ensuring patient safety by monitoring for allergies
- Providing information on the safe use of antimicrobials in specific clinical situations such as in organ dysfunction, pregnancy and breast feeding.

The need to have increased pharmacy involvement and the increased complexity and specialization in this field have led to the development of specialist posts with a dedicated full time antimicrobial pharmacist [also referred to as an infectious diseases, antibiotic or infection management pharmacist]. This role has been promoted by the £12 million funding provided over three years by the DOH, as part of a pharmacy initiative to promote the prudent use of antibiotics in England. (33) Hand comments that these pharmacists are likely to have a consulting role with daily duties including providing advice on management of patients with infections, monitoring antibiotic therapy and ensuring compliance with Trusts' antibiotic prescribing policies. (142) In larger hospitals, an expanding role for the pharmacist may imply a more managerial role where the antimicrobial pharmacist advises through a team of ward-based clinical pharmacists. (47) It was reported that the proportion of hospitals with an antimicrobial pharmacist increased from 6% in 2000 to 88% in 2005 following this funding. (143) The broader spectrum of activities will vary depending upon the needs of the hospital but may also include education of different healthcare professionals, participating in forums and committees, monitoring and auditing antibiotic use and maintaining prescribing control systems. Hand comments that education " ...is likely to be the most effective, although time consuming use of a microbiology pharmacist's time." (142) A cross-sectional survey demonstrated that these are the most common responsibilities of antimicrobial pharmacists. To promote best practice, share experiences and provide educational support, the United Kingdom Clinical Pharmacists Association (UKCPA) has a special interest

group networking antimicrobial pharmacists. Other pharmacists working in specialities where antimicrobial prescribing is crucial to patient care such as surgery and critical care, also have access to this group.(144-5) To date, there is little evidence reporting the effects of interventions of antimicrobial specialist pharmacists or other models on prescribing control.(39)

It is likely that with the introduction of supplementary and independent prescribing, the role of the antimicrobial pharmacist in the UK may expand.(47-8) This will need the pharmacist to move away from the traditional gate keeping role to a more supportive role. When discussing this, Weller et al comment that doctors "... need to see the benefits of advice and support from the pharmacist, rather than viewing them as a policy enforcer." (47) Pharmacists are likely to be at least as knowledgeable as junior doctors and are likely to be more familiar with local guidelines and policies, given that junior doctors spend little time within a given speciality.(47) Implementation of SP has provided the pharmacist with a wide range of opportunities such as automatic stop orders or oral switches without the need to consult a clinician. Interestingly, these are roles which pharmacists, on their own or as members of a multidisciplinary team, have taken on before the introduction of SP and are the focus of a systematic review described in Chapter 2.

Chapter 2

Antimicrobial optimisation in secondary care – the pharmacist as part of a multidisciplinary antimicrobial programme: a systematic literature review

2.1 Introduction

2.1.1 The role of the pharmacist within multidisciplinary antimicrobial teams

Traditionally, the pharmacist has often been placed as an enforcer of guidelines, with a “policing” role. This has been reinforced by the findings of a systematic review describing interventions to improve antibiotic prescribing practices for hospital inpatients.(146) Studies included in the review depended on a pharmacist as a deliverer of the intervention (22/66 studies). While the systematic review revealed that physicians tend to lead even more restrictive stewardship practices than pharmacists, the interventions made by pharmacists were predominantly persuasive and included education, guideline development, reminders to physicians and clinical audit and feedback. The literature indicates a desire by pharmacists to move away from this “antibiotic policing” role to one where the pharmacist is a “co-therapist.” (147) Setting up antimicrobial multidisciplinary teams (AMDT) with pharmacist involvement, has been one approach to breaking down the barriers between traditional healthcare professional roles. Programmes involving AMDT appear to be the way forward when attempting to implement strategies aimed at optimising antimicrobial use in secondary care.(144,148-152) When discussing such a multidisciplinary approach to antimicrobial stewardship, Paskovaty et al have summarised requirements to ensure its success: obtaining baseline information such as antimicrobial expenditure and resistance patterns to understand the background of the institution; selecting strategies to implement the antimicrobial stewardship that are tailored according to the needs of the institution; determining team members and their roles and responsibilities; establishing support of hospital administration both in terms of funding and in terms of team empowerment; building good relationships with other clinicians to facilitate acceptance of

recommendations; providing feedback to prescribers as well as conducting clinical audits with feedback to monitor effectiveness of programme.(148)

A report by Schentag et al described a pioneering programme with pharmacist involvement, driven to follow up expensive empiric regimens following the availability of cultures and sensitivity reports by streamlining and shortening of the antimicrobial treatment.(153) Two specialist clinical pharmacists led the intervention with the support of infectious diseases (ID) physicians and microbiology. The usual patient management with empiric treatment of antimicrobials was initiated; cultures were then reviewed by the pharmacists following approximately 48 hours and any changes were proposed by discussion with the prescribers. Types of interventions included dosage adjustments, conversion from intravenous (IV) to oral medication and earlier discontinuation of antimicrobial therapy. The authors reported a high physician acceptance rate and cost savings that covered the costs of the personnel required. Better patient outcomes were also reported though no evidence was given to support this. The report did not give details of pre-intervention data and there was no comparison between pre- and post-intervention variables. Interestingly, the pharmacists made recommendations to the prescribers, but did not automatically make any changes to treatment and consequently it was at the discretion of the prescriber whether or not to change treatment.

2.1.2 Evolvement of the antimicrobial multidisciplinary team

The concept of a multidisciplinary team to improve antimicrobial prescribing and ultimately reduce antimicrobial resistance and improve patient safety, was introduced by the Infectious Diseases Society of America (IDSA) which recommended the establishment of "Antimicrobial Agents Teams" within hospitals.(154) This team is responsible for ensuring optimal use of antimicrobialsⁱⁱⁱ within the institution and would be led by an (ID) physician. Other team members recommended by IDSA are an infection control practitioner, clinical microbiologist and clinical pharmacist, with the latter having a relatively limited role and being responsible for providing information related to addition or deletion of antimicrobials from the

ⁱⁱⁱ The term "antimicrobial" and "antibiotic" are often used interchangeably in the literature; this review quotes the term as used by the authors in the specific publication being referred to.

hospital formulary. This concept of an antimicrobial multidisciplinary team was reinforced in subsequent IDSA position statements of 1997 and 2007, the latter referring to “Antimicrobial stewardship teams”. The 2007 guidance places the clinical pharmacist as key personnel within the team together with the ID physician, also making recommendations that the pharmacist should have training in infectious diseases.(152,155) This has been viewed by many as a change in position compared to previous guidelines.(156)

The recommendation to introduce antimicrobial multidisciplinary teams as a way to optimise antimicrobial use has also been echoed by the EU and introduced in Copenhagen in 1998. Antimicrobial teams aimed at promoting the rational use of antimicrobials and, consisting of microbiologists, ID specialists and clinical pharmacists should be in place in both primary and secondary care settings and “... should have the authority to modify antimicrobial prescriptions of individual clinicians in accordance with locally accepted guidelines.” (12) Recommendations have also been made within the UK and have been described in Section 1.2.2.

The aim of the review being described here is to achieve the following objectives through a systematic literature review:

- a) To explore the evidence based clinical role of the pharmacist in optimising antimicrobial use when working within a multidisciplinary antimicrobial team in secondary care
- b) To determine the published outcomes of interventions to optimise antimicrobial prescribing through a multidisciplinary team with pharmacy involvement

2.2 Method

The method for this systematic literature review reflects updated guidance published by the Centre for Reviews and Dissemination, University of York.(157)

2.2.1 Review team

The review team was made up of AT and DS. Where agreement was not reached, it was planned to involve a 3rd person DM, in the discussions; however this was not necessary. A consultant microbiologist with expertise in antimicrobial stewardship and antimicrobial policies was an advisor to the team.

2.2.2 Inclusion and exclusion criteria

The inclusion criteria were as follows:

- ✓ Full text papers published in peer reviewed journals. Where only abstracts or letters were retrievable, the authors were contacted to determine whether full texts had been published. Papers that were not available as full text were discarded since it is difficult to appraise studies where no full text is available
- ✓ English language
- ✓ Papers reporting both descriptive accounts and primary research involving a multidisciplinary antimicrobial team with pharmacy involvement. Descriptive accounts were included since it was not expected to find many trials.
- ✓ Papers involving interventions targeting hospital inpatients.

Papers where there was either no multidisciplinary team or where the pharmacist had no role within the intervention were excluded. Papers involving interventions targeted at residents in community or ambulatory care settings were also discarded.

2.2.3 Search strategy

The databases Medline (through Pubmed), International Pharmaceutical Abstracts (IPA) and Embase were searched between the years 1995-2006. Medline and Embase are the databases most commonly used and recommended for healthcare interventions. (157) However, not all pharmacy literature is captured in these databases; consequently, though there is significant overlap between the databases, IPA was also included to broaden the pharmacy literature covered. The search was conducted in early 2007 and was started at 1995 to enable identification of literature some years

before the Crown Report was published in 1999 and would therefore identify any changes in practice due to introduction of pharmacist SP.

The following search words were used: antibiotics, antimicrobials, anti-bacterials, antiinfectives, pharmacists, outcomes, interventions, multidisciplinary, hospital, microbiology, infection management, antibiotic stewardship, antibiotic support team, antibiotic optimisation and antibiotic control programmes. The search words were used in different combinations. A detail of the number of hits obtained for each combination is at Appendix 2.1.

The bibliography lists of published reviews (4,146,148) were searched for any other relevant papers and the reference lists of included papers were also searched for any other relevant material. However, no papers were identified in this manner.

2.2.4 Screening

A total of 761 hits were obtained through the Medline search, 697 through the IPA search and 530 through Embase. Sixty one papers were identified as potentially relevant on the basis of their title and abstract. Initial screening resulted in 27 abstracts discarded because full papers were not available despite contacting authors as necessary. Thirty four full papers were retrieved for full paper screening. Ten were discarded because they were either descriptions of programmes in ambulatory care, or were programmes with no pharmacy involvement. Twenty four full publications were included in this review. A schematic representation of the screening process is at Figure 1.

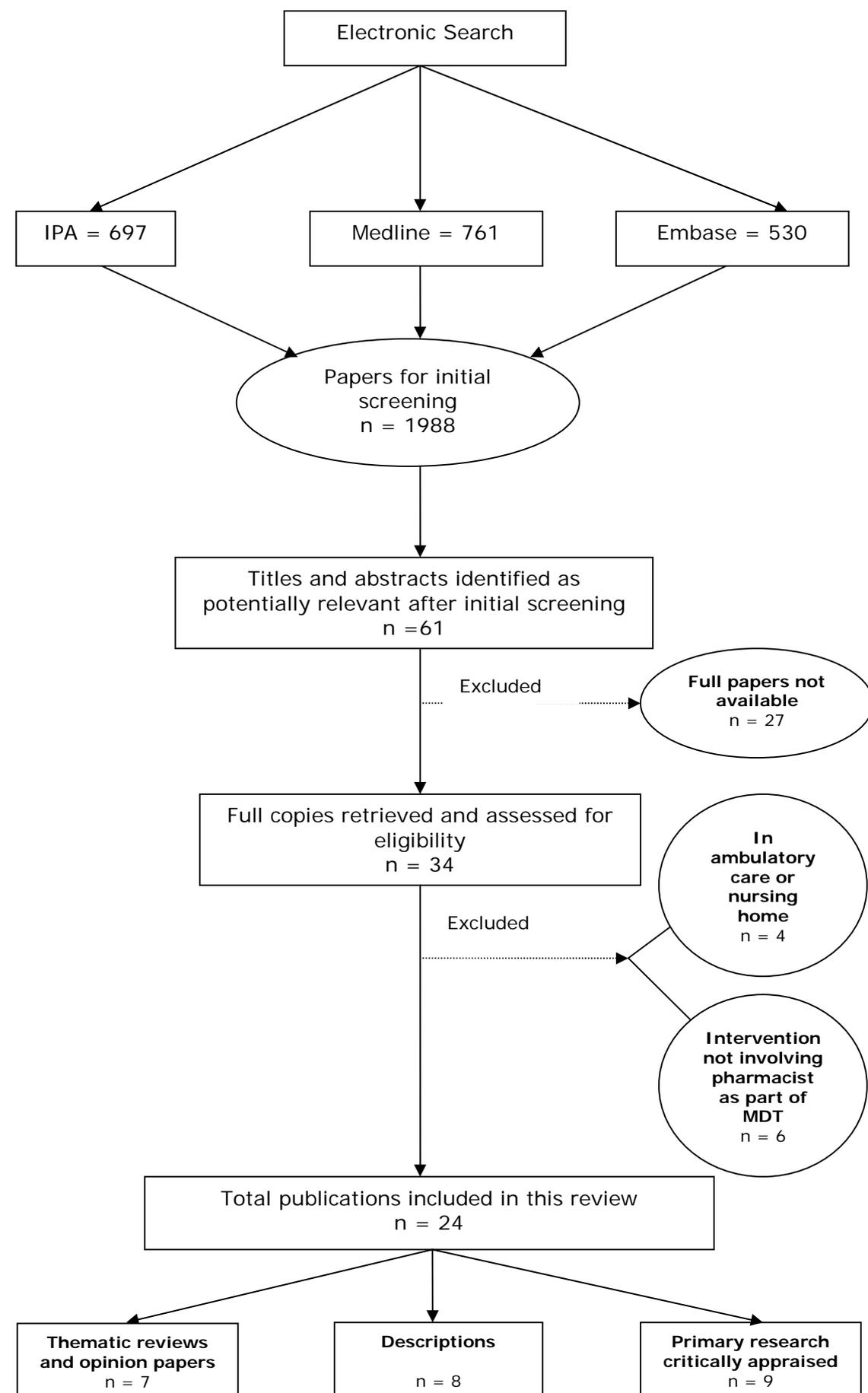


Figure 1: Schematic representation of screening process

2.2.5 Quality assessment

Papers were reviewed for quality by AT and DS using standard criteria for critical appraisal published in the literature. Where available, criteria published as part of the Critical Skills Appraisal Programme (CASP) were used. In the case of Randomised Control Trials, some additional criteria were obtained from the CONSORT statement. No CASP criteria were available for Interrupted Time Series studies and therefore criteria available through the Cochrane Effective Practice and Organisation of Care Group were used. Details of all criteria used are found in the results section below.(158-160)

2.3 Results

2.3.1 Descriptions of multidisciplinary teams

This section summarises descriptions of different programmes aimed at optimising antimicrobial use within various institutions and run by multidisciplinary teams. The publications (eight descriptions) offered insight and experiences into the team structure, the running, and the different strategies adopted, thus offering some valuable information. However, many of the findings reported are descriptive and do not employ any standard research methods to measure the impact of the interventions made. Table 7 is a summary of these descriptive reports and accompanies the text below.

Many of the team approaches reported originate from the UK. A West London model described such a team with a strong pharmacy input, the team being chaired by a chief pharmacist and the specialist ID pharmacist acting as secretary to this group.(161) The group identified a set of seven key elements that were considered vital to ensure successful antibiotic stewardship. These included strong leadership, dedicated individuals with responsibility for leading on antibiotic use, adequate resources and education and training. This has led to the appointment of an ID pharmacist with a high clinical profile and defined responsibilities, with regular attendance of microbiology led ward rounds and weekly educational meetings. The ID pharmacist has a major role in education and training in areas beyond the traditional boundaries such as training of phlebotomy staff

to ensure adequate sampling for therapeutic drug monitoring. Ward clinical pharmacists have been included in the agenda and liaise closely with the ID pharmacist to discuss the management of individual patients. Though no evidence was given to support the statement, the authors reported that the ID pharmacist post has led to reduced costs and better quality of antibiotic prescribing. A successful multidisciplinary approach to promote the prudent use of antimicrobials has also been reported in Manchester.(162) This pharmacist and microbiologist led strategy was multifaceted and consisted of three main elements: education and training mainly directed at junior doctors; restriction of certain IV antibiotics with selective microbiological reporting and switching of IV-to-oral antibiotics by pharmacists through a patient group direction; and monitoring, including drug expenditure, drug usage data and point prevalence data. This approach was described as reducing the number of patients on IV therapy inappropriately and keeping antimicrobial consumptions and costs down despite predictions for these to rise. Interestingly, this is one of the few reports where the pharmacist is actually making changes to patient's medication (IV-to-oral switching) rather than just making recommendations. The success of these strategies led the Trust to plan future developments which included a joint antibiotic pharmacist and microbiologist ward round on all general wards. Collaboration between clinical pharmacists^{iv} and the microbiology department was the mainstay of a programme piloted over 7 months in Ipswich.(163) The clinical pharmacists here, on a daily basis, referred patients requiring a review of their antimicrobial treatment to the AMDT and used specific criteria. The specialist clinical pharmacist and a microbiologist daily reviewed these patients, documenting any recommendations where changes in treatment were required and giving feedback to the referring clinical pharmacist. The programme was well received with 92 reviews carried out requiring 52 interventions. No descriptions of outcomes of the programme are provided. Similar collaboration between clinical pharmacists and microbiology has also been set up in Southampton and a three month observational study has been reported.(164) A high rate of acceptance was observed (100% on care for the elderly wards and 95% on medical wards)

^{iv} The clinical pharmacist is responsible for the rational and optimal use of drugs in all healthcare settings. In secondary care, the clinical pharmacist is usually mainly ward-based and may also be referred to in some literature as a ward pharmacist.

and the authors estimated a cost savings after deducting the costs associated with the team's intervention. More recently, reports indicated that pharmacy technicians were also involved in multidisciplinary teams and have been given key roles in monitoring antimicrobial use and the set up of audits.(165)

Team approaches as part of antimicrobial management programmes have also been reported and described outside the UK, and particularly in the US.(147,166-168) Different methods of patient identification were reported ranging from daily screening of patients on IV antimicrobials through the pharmacy system to referral of the patients by other clinical ward pharmacists. Many of the teams were established in response to increased costs, and financial outcomes were mainly reported. The interventions made by the antimicrobial teams were claimed to have improved quality of prescribing and patient care with no negative patient outcomes; however, there was often little evidence to back these statements. Further detail is found in the table below. Other descriptions have involved a multidisciplinary approach to optimising antimicrobial use in a specific area of care, for example optimising antibiotic prophylaxis of surgical-site infections.(169) Unfortunately, insufficient information is provided both about the team composition and outcomes of such interventions, making them difficult to evaluate.

Table 7: Descriptions of programmes run by multidisciplinary teams with pharmacist involvement

Author Year Country	Site	Professionals involved in team ^v	Description of programme	Findings reported ^{vi}
Lee et al, 1995, US (147)	Hospital but further details not provided	Pharmacists ID physicians	Clinical pharmacists identified and reviewed all patients on antimicrobials, using the institution's guidance as a reference point. Patients requiring intervention were referred to the team who made the necessary recommendations to the prescribing physician.	A 16% decrease in antimicrobial costs No adverse effects on hospital length of stay or readmission rates
Burke et al, 1995, US (167)	310-bed university teaching hospital	ID physicians Clinical pharmacists Microbiologist Nurses	Not clearly described. A description of the set up and running of the team is provided rather than a description of the way the programme was run.	A decrease in antimicrobial costs A decrease in length of stay for patients with pneumonia A reduction in mortality for patients with pneumonia
Lacy et al, 1997, US (166)	760-bed tertiary community teaching hospital	Pharmacists ID specialists	Pharmacists identified and assessed appropriateness of all patients receiving IV antimicrobial therapy with the help of a computer programme algorithm. This occurred both at the dispensary and on wards. Patients requiring interventions were discussed with ID specialists and recommendations made to the prescribing physician who also made changes in treatment.	Acceptance rate for recommendations is 95% A decrease in antimicrobial purchases A decrease length of stay for patients with pneumonia
Cooke et al, 2004, UK (161)	1000-bed tertiary	Chief pharmacist ID pharmacist	Multi-faceted programme involving numerous activities. ID pharmacist had a high profile with a	Authors reported a significant impact on cost

^v Descriptive term used here is as used at source

^{vi} These are the findings reported by the authors; there is often little evidence to support these and hence have been classified in this review as descriptive reports

	teaching hospital on two sites	Microbiologists Infection control Clinical pharmacists	consultant role and regularly attended ID ward rounds and educational meetings and activities for different members of the multidisciplinary team. Clinical pharmacists were involved and worked together with the ID pharmacists referring any patients who needed further intervention, and participated in the implementation of antibiotic policies and collected data for audits and point prevalence studies.	and quality of antimicrobial prescribing
Pasquale et al, 2004, US (168)	996-bed network consisting of 3 sites	ID physicians Clinical pharmacist	Multi-faceted programme initially involving the drawing up and dissemination of guidelines. Patients on IV antibiotics were identified daily through the hospitals' computer system and reviewed by a pharmacist for inappropriate antibiotic use. Patients on antibiotics that were already restricted and therefore required the approval of an ID physician were excluded. Patients on inappropriate antibiotic use were referred back to the ID physician and recommendations made to the prescriber.	77% of interventions made were accepted. Interventions mainly involved IV-to-oral switch for levofloxacin [a case-control evaluation on this reported elsewhere in this review], modification of IV therapy dose, duration and frequency, and changing an antibiotic to improve cover Estimated reduction in costs reported
Williams et al, 2005, UK (162)	900-bed university teaching hospital	Clinical pharmacists Microbiologist	Multi-faceted programme initially involving the drawing up and dissemination of antibiotic guidelines with some IV antibiotics being restricted and requiring microbiology approval. Selective microbiological reporting together with daily reviews of all patients on IV antibiotics by the clinical pharmacists and medical teams was launched concurrently. A policy was introduced where pharmacists were allowed to switch patients with respiratory infection from IV-to-oral medication using a patient group directive. An education and	Reduction in the number of patients on IV antibiotics for more than 48 hours Reduction in number of patients on inappropriate IV antibiotics when compared to the NHS trust policy Reduction in rise of the annual antibiotic expenditure

			training campaign was run by microbiology and pharmacy with various methods used for dissemination of the guidelines. Regular audits and point prevalence studies were planned to monitor achievements.	
Cheeseman M, 2006, UK (163)	800-bed district general hospital	Clinical pharmacists Microbiologist	Clinical pharmacists referred patients requiring review of their antimicrobial treatment to a pharmacy-microbiology team, on a daily basis. The latter reviewed these patients making any recommendations required and documenting these in the patient notes; feedback was also provided to the referring pharmacist.	Project piloted over 7 months – 92 reviews requiring 52 interventions; the most common intervention was inappropriate choice of antimicrobials No further outcomes were reported
Weeks C, 2006, UK (164)	University teaching hospital. Service provided on 208 beds in medicine and a 90 bed Care of the Elderly unit	Clinical pharmacist Microbiologist	Clinical pharmacists referred patients requiring review of their antimicrobial treatment to a pharmacy-microbiology team – patients prescribed intravenous and second line antibiotics were referred. The microbiologist reviewed treatment making use of any relevant pathology data and made any changes required in the medication. The pharmacist ensured that the recommendations adhered to the hospital formulary and had taken the individual patient parameters into consideration.	The authors provide an observational study over a 3 month period. 69 patients seen in care for the elderly and 263 in medicine. Stopping antimicrobials and narrowing the focus of therapy were the most common interventions. Changing IV-to-oral medication was more common in medicine compared to Care of the Elderly. A high acceptance rate was reported. No differences in mortality or length of stay were noted. An estimated reduction in

				costs was made after having deducted the costs for the team.
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2.3.2 Published research involving multidisciplinary teams

A number of trials have been published aimed at reporting the outcomes of multidisciplinary teams with pharmacy involvement as an intervention with the goal of improving antimicrobial prescribing in hospital inpatients. Nine studies were identified; five from the US, one from Canada, one from Switzerland, one from France and one from Argentina.

The primary aim of most interventions was to optimise antimicrobial prescribing. The initial perception in most cases was that antimicrobial overuse was a common practice in the institution. Reducing associated costs through rationalisation of antimicrobials was a major driving force in most studies; many set out to prove the cost effectiveness of the AMDT to hospital management. Further details of the studies together with a critical appraisal approach have been summarised in Tables 8, 9 and 10 below.

2.3.2.1 Team members

The core members of the team were the ID physician and clinical pharmacist with the team having dedicated and protected time for antibiotic management. Often a partnership between the team members was reported with shared responsibilities when assessing individual cases and in ensuring appropriateness of antimicrobial prescribing. The pharmacist on the team was involved in:

- Prescriber education on a one-to-one basis by making written or verbal recommendations following identification of inappropriate antimicrobial prescribing (170-174)
- Making recommendations to switch IV therapy to oral therapy as appropriate (168,175)
- Running therapeutic interchange programmes (175)
- Enforcing restriction policies when these were in place (173,175,176)

The role of the pharmacist could not be determined in one study.(177)

2.3.2.2 Nature of interventions

Different programmes were reported in the trials, many of which were tailored to the specific institution and may be grouped according to the nature of the intervention as described below. The classification used here is adapted from Paskovaty et al.(148) Other classifications of interventions have also been described elsewhere in the literature.(146)

Clinical Pathways: These involved the development of peer reviewed guidelines followed by dissemination and educational programmes. Lutters et al report such an intervention specifically targeted at management of urinary tract and respiratory tract infections in a geriatric hospital.(170)

Post-prescribing evaluation combined with clinical pathways where the appropriateness of the initial antimicrobial prescribed was assessed against hospital guidelines and any other laboratory data available. This allowed streamlining where broad empiric therapy was narrowed according to the individual patient's needs with recommendations for changes made by the antimicrobial team. Various studies describe such an intervention. Carling et al report post-prescribing evaluation with prescriptions for specific parenteral antibiotics evaluated by the team for adherence to the institution's guidelines.(171) Recommendations were then made to the prescribers as required. Similar interventions were reported by Gums et al, Fraser et al and Bantar et al, with patients screened to ensure appropriate antimicrobial therapy and written and verbal recommendations made to prescribers where changes were appropriate.(172,174,177) Other studies report screening of parenteral antimicrobial treatment against guidelines making recommendations where conversion to oral treatment was appropriate.(168,175) Salama et al also report automatic interchanges by pharmacy staff to facilitate adherence to the institution's guidelines.(175)

Clinical pathways combined with restriction policies: Here, second line agents were restricted and required prior approval by members of the team. The choice of antibiotics restricted was based most commonly on costs.(173,175,176) Likely impact of the antibiotics on bacterial ecology (176), and the adverse effect profile (173) were other factors taken into

consideration. Pharmacists within the AMDT and the dispensary were the principal providers of this programme, often validating the prescription, issuing approvals where appropriate and making recommendations as necessary. (173,175)

2.3.2.3 Study designs

All trials were single site and the hospital bed capacity varied between 250-772 beds. The sites were tertiary teaching hospitals, community hospitals or geriatric care hospitals. Most of the studies were interrupted time series (n=4) with audit points pre and post intervention (170-1,175 -6); two (172,174) were randomised controlled trials; one was a comparative study with no randomization (173); one was mainly a descriptive study but included a small-scale case control trial (168); one an uncontrolled before after study. (177) A critical appraisal of the trial design is summarised in Tables 8, 9 and 10.

2.3.2.4 Outcomes reported

Most of the trials were economically driven and initiated to achieve a cost saving for the institution. When reporting outcomes, few trials have taken the cost of the intervention into account and most trials have not considered the impact on patient outcomes.

Drug related outcomes

These outcomes were related to appropriate antimicrobial prescribing; for example, the prescribing of a recommended antimicrobial at the appropriate dosage or duration for a specific condition usually as indicated by the institution's formulary. Most trials measured the adherence of prescriptions to guidelines and preset criteria such as adjustment of dose if the patient had organ dysfunction. Saizy-Calleart et al report that following the intervention, there was an initial reduction in the number of inappropriate prescriptions, followed by a rise until a constant level was reached. (176) Other studies indicate that adherence with guidelines increased following the intervention with a reduction in the number of recommendations necessary (171); it was not possible to determine the impact of the intervention in one study since no pre-intervention data were available. (170) In a comparative study, Gross et al aimed to compare the

recommendations made by the AMDT (8am to 5pm) to the ID fellows who provided the service out-of-hours (5pm to 11pm) and at weekends.(173) The AMDT was more likely to adhere to guidelines compared to 75% of recommendations made by the ID fellows. Fraser et al measured the need for re-administration of antimicrobials after 7 days, arguing that this was a measure of the efficacy of the antimicrobial prescribed, and consequently, of appropriateness of choice and reported a reduced need for re-administration in the intervention group as compared to the control group.(174)

Microbiological outcomes

These outcomes were related to the prevalence of antibiotic resistant bacteria and reported only in few trials. A maintenance or improvement in bacterial susceptibility was reported and further details are available at Tables 8, 9 and 10.(171,176,177)

Indicators of clinical outcomes

These included the length of hospital stay, inpatient mortality and 28 day mortality. A reduction in hospital length of stay was reported following introduction of the intervention though this was not always statistically significant.(172,174,177) Recommendations made by the AMDT were more likely to result in a clinical cure both when compared to the advice given by ID fellows, and when compared to a historical control group. (173,168) Again these reported differences were not always statistically significant. A reduction in the need for parenteral antibiotics emerged though again this was not always statistically significant.(168,174) Gums et al also identify a reduction in the number of both non-intensive care unit (statistically significant) and intensive care unit beds (not statistically significant) together with a non statistically significant reduction in mortality in the intervention group.(172)

Financial outcomes

These included the healthcare resource costs, including the costs involved in implementation of the intervention. Economic benefits were reported in all trials, and related to a reduction in use of antibiotics, use of cheaper therapeutic equivalents or earlier IV-to-oral conversions. Not all differences

were statistically significant. The cost of the intervention made was not always considered as outlined in Tables 8, 9 and 10.

Table 8: A critical appraisal of trials using an Interrupted Time Series^{vii} design to measure outcomes of interventions to optimise antimicrobial prescribing through a multidisciplinary team with pharmacy involvement (1996 – 2006) (158) (note this table is 8 pages long)

Criteria	Salama et al Canada 1996 (175)	Saizy-Callaert et al France 2003 (176)	Carling et al USA 2003 (171)	Lutters et al Switzerland 2004 (170)
Objectives of the programme (as stated by authors)	"To increase the quality of antimicrobial prescribing and to control runaway costs of antimicrobial therapy"	"To rationalise antibiotic usage, based on a participatory approach and aimed at obtaining a durable change in prescribing practices"	"To minimise the inappropriate use of third-generation cephalosporins"	"A comprehensive educational antibiotic management programme designed to improve antibiotic use and reduce treatment costs in elderly patients with suspected urinary or respiratory tract infections"
Site description				
Number of sites	Single site	Single site	Single site	Single site
Setting	465-bed university tertiary care teaching hospital	600-bed teaching hospital	Medium size community teaching hospital (exact bed capacity not specified)	304-bed teaching geriatric hospital
Nature of intervention				
Intervention as described by the authors	Initially during the 12 month pre-intervention period: Streamlining of the	Programme combined: Developing local prescribing guidelines based on consensus and	A prospective antibiotic monitoring procedure where adherence to hospital	Phase I; a baseline phase lasting 12 months during which antibiotic utilization

^{vii} Interrupted time series designs are multiple observations over time which are interrupted usually by an intervention or treatment. Long time series require at least 20 observations; short time series need to have at least three pre and three post-intervention observations and involve multiple t-tests, analysis of variance or repeated measures analysis to protect against threats of internal validity.

	<p>antimicrobial hospital formulary Automatic 3 day stop order for all antimicrobials Clinical antimicrobial guidelines that were disseminated using various methods</p> <p>Then the intervention consisted of the development of a multidisciplinary antimicrobial use programme with: Automatic therapeutic interchanges with nine possible interchanges identified Antimicrobial restriction policy restricting eight antimicrobials; these were only permitted for use in approved indications Intravenous to oral switch encouraged for specific antimicrobials</p>	<p>disseminated through a pocket size guide</p> <p>An antimicrobial restriction policy for the most expensive antibiotics and those most likely to affect resistance patterns; these could be prescribed on a named patient prescription by a senior hospital doctor, were validated by pharmacy and supplied for 48-72 hours to encourage review</p> <p>Regular assessment of antibiotic prescriptions to ensure adherence to guidelines</p> <p>Training and information provided to prescribers</p>	<p>recommendations for specific parenteral antibiotics is assessed using a standard data collection tool. Prescribers are given individual written and verbal feedback and recommendations</p> <p>Evaluations and feedback are made by an ID specialist and a clinical pharmacist specialising in infectious diseases</p>	<p>reviews were performed Phase II – lasted 9 months and involved development of evidence-based guidelines in collaboration with physicians</p> <p>Phase III – intervention over 9 months consisted of an intensive educational programme during which guidelines were disseminated through cards and lectures. Weekly ward rounds were held by the MDT to assess compliance with guidelines and provide physician feedback</p> <p>Phase IV – a 6 month post intervention phase during which physicians received only guidelines</p>
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Professionals involved in team	Physicians, pharmacists, nurses, hospital administration	Pharmacist, bacteriologist, ID physician	Clinical pharmacist, ID physician	ID physician, pharmacist and pharmacologist
Study design				
Number of observations pre-intervention	13 observations performed monthly over 12 months	Only available for economic outcome: annual antiinfectives expenditure data provided for 3 years pre-intervention	Antibiotic use: annual values for DDD/1,000 patient beds measured for 3 years pre-intervention; each individual value is not provided Antibiotic costs: annual values of cost of parenteral antibiotics per 1,000 patient days measured and provided as above Annual incidence of all resistant pathogens provided for 3 years pre-intervention	One point prevalence study was carried out per trimester; 7 observations carried out pre-intervention; 3 observations during the intervention
Number of observations post-intervention	29 observations performed monthly over 30 months	Adherence of prescription to guidelines: 6 observations where data was collected over a one month period; these are not at regular intervals Economic outcome: annual expenditure data for 4 years post-intervention Trends in bacterial	Antibiotic use: annual values for DDD/1,000 patient beds measured for 7 years post-intervention but again individual values are not provided Antibiotic costs: annual values of cost of parenteral antibiotics per 1,000 patient days	2 point prevalence studies carried out post-intervention, one per trimester

		resistance: annual trends for 4 years post-intervention	provided Annual incidence of resistant pathogens provided for 7 years post-intervention Adherence of prescriptions to guidelines; annual number of interventions made measured for 7 years post-intervention but individual values not provided	
Clearly defined point when intervention occurred	Clearly described: intervention launched and month specified following collection of baseline data over a 13 month period	Clearly described: intervention launched between baseline year and first year when post-intervention data collected	Clearly described	Clearly described: intervention launched at Phase III of trial
Patient recruitment				
Selection of patients	Not clear	All patients receiving an antibiotic in all departments; no details provided on type of patients	All patients on parenteral third generation cephalosporins, aztreonam, parenteral fluoroquinolones and imipenem	All patients receiving at least one antimicrobial on day of study; details of patient characteristics are provided
Inclusion and exclusion criteria	Not clear	Patients with HIV were excluded	As above	Not clear
Control group if any	Not included	Not included	Not included	Not included
Number of patients	Not specified	Total over 4 years: 1221	Not specified	Total number of records screened 3,383. 680 included

				since receiving at least one antibiotic agent
Method of determination	Not clear	Way in which patients were identified not clear	Way in which patients were identified not clear	Way in which patients were identified not clear
Outcomes measured	Monthly usage patterns of restricted antimicrobials Antimicrobial costs as a % of total drug costs and the total antibiotic cost	Adherence of prescriptions to guidelines; where no guidelines available, appropriateness was assessed by experts Antimicrobial cost as a % of total drug expenditure and per hospital patient Trends in bacterial resistance for MRSA, EPESB, CRP ^{viii}	Antibiotic use expressed as DDD/1,000 patient beds Antibiotic expenditure expressed as parenteral antibiotic use per 1000 patient beds Incidence of Clostridium difficile, ceftazidime resistant enterobacteriaceae, MRSA and vancomycin resistant enterococci Assessment of adherence of prescriptions to guidelines for antibiotics specified above	Total antimicrobial use Assessment of prescriptions against guidelines during ward rounds; these were classified as total, partial, none or ascertainment impossible Antibiotic costs – measured by cumulative antibiotic costs for all patients receiving an antimicrobial on point prevalence day
Results				
Description	Monthly use of restricted antibiotics reduced or remained the same; sharpest drop in use of ceftazidime, imipenem and vancomycin	Number of inappropriate prescriptions first fell, then rose and remained constant Both the antimicrobial cost as a % of total expenditure and the cost per hospital patient fell	Use of third generation cephalosporins and aztreonam decreased; use of other antibiotics remained stable Reduction in costs Reduction in incidence of Clostridium difficile and	Results are not provided for each of the 12 point prevalence studies conducted but have been grouped and totals are provided for each Phase and comparisons provided

^{viii} MRSA: Methicillin-resistant Staphylococcus aureus; EPESB: Enterobacteriaceae producing extended spectrum β -lactamases; CRP: ceftazidime-resistant pseudomonas

	Both the antimicrobial expenditure as a % of total drug costs and the total antibiotic costs fell	Incidence of EPESB fell; MRSA and CRP remained constant	ceftazidime resistant enterobacteriaecae, but no changes in incidence of other pathogens Compliance with guidelines increased and number of interventions required decreased	between Phase I and IV Total number of antibiotics prescribed fell Cumulative daily antibiotic costs for all surveyed patients fell 75% of prescriptions assessed for adherence to guidelines complied totally. This was only performed during Phase III of the study
Statistics used	No multiple t-tests, analysis of variance or repeated measures analysis included	Fisher's exact test and Chi-squared; no multiple t-tests, analysis of variance or repeated measures analysis included	Multiple test analysis used	Proportions compared using Fisher's exact test and Chi-squared; means compared using analysis of variance and Kruskal-Wallis test; trends analysed using regression
Statistical significance	Not done	Incidence of EPESB fell significantly over the four years but no pre-intervention data to compare this with (p<0.001) Expenditure costs per patient fell significantly between 1994 and 2000 (p<0.001)	Reduction in antibiotic use was statistically significant (p <0.001) Reduction in incidence of Clostridium difficile (p=0.002) and ceftazidime resistant enterobacteriaecae was statistically significant (p=0.02)	Both the total number of prescriptions and cumulative daily costs fell significantly when comparing Phase I with Phase IV (P<0.001) It is not possible to compare pre- and post-adherence to guidelines since this performed only in Phase III

Quality criteria				
Intervention is independent of other changes	Not clear	Done: number of HIV patients fell significantly over the study period and were therefore not included; other parameters such as bed stay remained the same	Not clear	Not clear
Intervention is unlikely to affect data collection	Not clear	Not clear	Not clear	Not clear
Blinded assessment of primary outcome (authors state specifically that the primary outcome variables were assessed blindly or outcome variables are objective)	Done	Done for all outcomes except when assessing adherence of prescription to guidelines	Done for all outcomes except when assessing adherence of prescription to guidelines	Done with antibiotic use and costs Not done when assessing adherence to guidelines
Completeness of data set (dataset should cover 80-100% of the total number of participants or episodes of care in the study)	Not applicable since the number of patients included has not been specified	Done	Not applicable since the number of patients included has not been specified	Done
Reliability of outcome measures (if two or more raters have at least 90% agreement or kappa ≥ 0.8 or if outcome obtained from an automated system)	Done – antimicrobial usage and costs are being measured	Done when antimicrobial usage, costs and trends in bacterial resistance are being measured Not done when assessing adherence of prescription to guidelines	Done when antimicrobial usage, costs and trends in resistant pathogens measured. Not done when assessing adherence of prescription to guidelines	Done when antibiotic use and costs are being measured Not done when assessing adherence of prescription to guidelines
Comments	Does not involve a specialised MDT but a hospital wide multidisciplinary	Information about pre-intervention not given for all outcome measures	Costs of programme have been considered by authors but no details around this costing are	The study objectives indicate that the aim is to assess the impact of guidelines targeting

	<p>programme with pharmacy participation.</p> <p>Though reference is made to quality of antimicrobial prescribing as one of the objectives, there are no details of how these were measured and if the programme had any impact.</p> <p>Cost analysis does not include cost of the interventions.</p>	<p>Though authors comment that the intervention required a large initial investment, this is not costed when taking into account cost savings.</p> <p>One of the few studies that considers resistance patterns.</p>	<p>provided.</p> <p>One of the few studies where follow up is over a prolonged period of time, indicating the possible sustainability of a long programme.</p> <p>One of the few studies that puts emphasis on resistance patterns.</p>	<p>urinary tract infections and respiratory tract infections; yet all patients on antimicrobials are included in each of the point prevalence surveys conducted.</p> <p>Cost analysis does not include cost of educational programme.</p> <p>Despite no intensive educational ward rounds during Phase 4, the reduction in antibiotic use was sustained.</p>
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Table 9: A critical appraisal of trials using a Case-Control design to measure outcomes of interventions to optimise antimicrobial prescribing through a multidisciplinary team with pharmacy involvement (1996 – 2006) (160)

Criteria	Pasquale et al US 2004 (168)
Objectives of the programme (as stated by authors)	"To assess the interventions of an Antibiotic Support Team related to the IV-to-oral switch of levofloxacin"
Site description	
Number of sites	3
Setting	963-bed network spread over 3 sites; intervention made on one site; bed capacity here not specified
Nature of intervention	
Intervention as described by the authors	Patients started on an IV antibiotic within the last 24 hours were identified and assessed by a pharmacist for appropriateness of antibiotic use against set guidelines. The pharmacist evaluated patients who were on an IV antibiotic to determine whether they were suitable for an IV-to-oral switch. Where the antibiotic prescribed was not according to the guidelines, the pharmacist referred to the ID physician. When necessary, recommendations for changes in treatment were made to the prescribing physician
Professionals involved in team	A clinical pharmacist and an ID physician
Patient recruitment	
Selection of cases and method of recruitment	Patients (n=22) started on IV levofloxacin for the treatment of community acquired pneumonia (CAP) between March-November 2000 were identified through the hospital computer system for review by the team
Selection of controls and method of recruitment	Patients (n=26) started on IV levofloxacin for the treatment of CAP between March-November 1999 were recruited retrospectively. Further details on recruitment are not provided
Inclusion and exclusion criteria	Patients in obstetrics and gynaecology units, special care nursery, in the haemodialysis unit, on a one-dose prophylactic antibiotic or who had a consultation with an ID specialist were excluded from review by the Antibiotic Support Team. However, it is not clear whether these patients were also excluded from this case-control study. Patients on initial IV levofloxacin and a diagnosis on CAP were included
Number of patients included in case and control groups	
Method of determination	Cases were selected through the hospital computer system during the study. It is not clear how controls were selected

Were there sufficient numbers included in the two groups Ex use of a power calculation	Not specified
Matching of case and controls	These were matched based on demographics and the severity of illness of the CAP using a published score system. The authors report that there was no statistically significant difference between the two groups, but details of the statistical methods used here is not provided
Validity and reliability of recorded data for historical controls	Not considered
Outcomes measured	Clinical outcomes were classified into positive, negative or neutral. A description of each is provided. Duration of antibiotic therapy Length of hospital stay
Results	
Description	More positive clinical outcomes were recorded for the cases compared to controls (91% compared to 88%) Fewer days of IV therapy in case compared to controls (1.6 days compared to 2.9 days) Length of stay was 0.4 days less for case compared to controls
Statistics used (including consideration of any confounding variables)	Clinical outcomes not statistically comparable; $P < 0.005$ when comparing IV therapy and $P = 0.375$ when comparing length of stay. However details of statistics used not provided; confounding variables not considered
Quality criteria	
Blinded assessment of primary outcome (authors state specifically that the primary outcome variables were assessed blindly or outcome variables are objective)	Duration of therapy and length of stay objective outcomes. No information provided about determination of clinical outcomes.
Completeness of data set (dataset should cover 80-100% of the total number of participants or episodes of care in the study)	All included
Reliability of outcome measures (if two or more raters have at least 90% agreement or kappa ≥ 0.8 or if outcome obtained from an automated system)	Not specified
Comments	This small-scale case-control study is part of a wider study aimed at determining the nature of interventions of an Antibiotic Support Team. Most of the paper reports a descriptive study about the nature of the interventions made by this team. Numerous criteria required to ensure the robustness of the study are not provided in the report. It is therefore not possible to conclude whether they were considered by the authors when designing the trial

Table 10: A critical appraisal of trials using a Randomized Control Trial design to measure outcomes of interventions to optimise antimicrobial prescribing through a multidisciplinary team with pharmacy involvement (1996 – 2006) (159,178,179) (note this table is 4 pages long)

Criteria	Fraser et al US 1997 (174)	Gums et al US 1999 (172)
Objectives of the programme (as stated by authors)	"To evaluate (the) clinical, microbiological and economic effectiveness" of "a case-oriented education approach"	"To test the hypothesis that a timely consult from a multidisciplinary antimicrobial therapy team would improve the quality of care, reduce patient charges, and result in net savings to the hospital"
Site description		
Number of sites	One	One
Setting	600-bed tertiary care teaching hospital	275-bed community hospital
Nature of intervention		
Intervention as described by the authors; where the intervention was administered	The MDT prospectively reviewed all the patient medical records using a systematic approach at baseline, on alternate days and until 3 days after treatment with antibiotics was discontinued. Where recommendations were made, these were left in the patient notes.	After two hours of randomization, the prescriber received relevant recommendations from the team; these were placed in the patient's chart and telephoned or faxed if urgent.
Professionals involved in team	ID fellow Clinical pharmacist	ID physician Clinical pharmacy fellow Microbiology laboratory personnel
Patient recruitment		
Method for identification of patients	Through pharmacy records; adult inpatients on 1 of 10 specified parenteral antibiotics for 3 or more consecutive days were included	Through various methods including screening of charts, reviewing of aminoglycoside and vancomycin levels and daily screening of culture and sensitivity reports
Method for generation of the randomization schedule (Ex table of numbers, computer generated)	Computer generated random number table	Not specified
Method for implementation of the randomization sequence (Ex numbered envelopes)	Not specified	Not specified

Who has implemented the randomization	Not specified	Not specified
Matching of patients in intervention and control group; supply of baseline information for both groups	Baseline information for both groups supplied; no details supplied on methods used to match patients in both groups	Achieved though stratification of randomization according to infectious diseases category such that 2 patients in each category were in each arm of the trial; relevant baseline information for both groups supplied
Any differences reported between the two groups	None	None
Inclusion and exclusion criteria	Clearly defined	Clearly defined
Method of determination of number of patients in each group	Not specified	Not specified
Were there sufficient numbers included in the two groups ex use of a power calculation	Not specified	Not specified
Blinding		
Was blinding conducted; were participants, staff or study personnel blinded	Not specified	Only staff in the control group were blinded
Outcomes measured	Antibiotic costs and length of parenteral treatment; need for readministration of antibiotics after 7 days; length of patient stay	Primary outcome: length of stay (LOS) after randomization Secondary outcomes: economic evaluation and survival
Results		
Description	A decrease in antibiotic costs and length of parenteral treatment; a decrease in the need for readministration of antibiotics within 7 days; a decrease in LOS in the intervention group	A decrease in LOS after randomization; a reduced number of both ICU and non-ICU days; overall reduction in patient charges; reduced mortality in intervention group
Statistics used (including consideration of any confounding variables)	Chi-squared and t-tests were performed for normal distributions; nonparametric variables for others; Multivariable linear regression was performed to account for any variables	t-test and Chi-squared were used to determine any differences in baseline variables; Weibull regression was used to compare all intervention and control group end point medians; Fisher's exact test was used to compare mortality
Statistical significance	Decreased costs	Decreased LOS (p =

	(p<0.04) and decreased need for readministration of antibiotics (p=0.02) were SS; decreased duration of parenteral treatment (p=0.08) and decreased LOS (p=0.11) not SS	0.0001) and number of ICU days (p=0.0001) were statistically significant (SS); SS reduction in patient charges (p=0.008); no SS in non-ICU bed days (p=0.081) and in survival (p=0.175)
Were all participants who entered the trial accounted for; if there were withdrawals, is a description provided giving reasons why	Yes 252 patients were recruited with 260 reviews performed; one patient was excluded since he was readmitted after less than 31 days; 31 were excluded because ID were involved in a consultation; 3 were excluded because contact was made with the prescribers to ensure patient safety	Yes 272 patients were recruited; withdrawals clearly defined (20); a further 14 patients were excluded from the analysis because the prescribers did not accept the team intervention
Quality criteria		
Blinded assessment of primary outcome (authors state specifically that the primary outcome variables were assessed blindly or outcome variables are objective)	Yes – all outcomes reported were objective	Yes – all primary outcomes reported were objective
Completeness of data set (dataset should cover 80-100% of the total number of participants or episodes of care in the study)	Yes	Yes
Reliability of outcome measures (if two or more raters have at least 90% agreement or kappa ≥0.8 or if outcome obtained from an automated system)	Yes – all outcomes measured came through automated systems	Yes – all outcomes measured came through automated systems
Methods used to enhance the quality of measurements (Ex multiple observations; training of assessors)	Not available	Not available
Discussion		
External validity of the trial findings	Not provided	Not provided
Interpretation of results including consideration of potential bias and imprecision	Provided with a clear discussion about the limitations of this study	Provided – but bias and imprecision not considered
Comments	A pioneering study involving an RCT. Economic outcomes do	One of the few RCTs within this area; an attempt to link both

	<p>not take costs of the intervention into consideration. Mainly an economic driven trial with little consideration for patient outcomes despite evaluation of clinical and microbiological outcomes being initial aims. The authors consider the need for readministration of antibiotics after 7 days and LOS as indirect measures of response to antibiotic treatment.</p>	<p>patient outcomes through optimisation of antimicrobial use, with economic outcomes, with the latter taken into consideration to obtain evidence to present to management. Economic evaluation takes cost of intervention into consideration</p>
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2.4 Discussion

2.4.1 Strengths and limitations

This review adds to the current body of literature since it is the first review specifically considering the role of the hospital pharmacist within the AMDT. The method used follows updated guidance published by the Centre of Review and Dissemination updated guidance (157) and methods for establishing the review team, the inclusion and exclusion criteria, the search strategy and screening process and the quality assessment have been carefully considered to ensure a robust process has been employed. An expert in the topic was external advisor to the team. It is exhaustive in that it has considered both descriptive reports and primary research about the topic, though it has not considered grey literature and papers that were not in English.

2.4.2 Key findings in relation to review research questions

The paucity of data available, the small-scale, single-site nature of the trials and the study quality made it difficult to draw any finite conclusions about outcomes following interventions by an AMDT. Only two of the studies were randomised controlled trials and most were conducted over short time-scales making it difficult to draw any conclusions about sustainability of the projects. The study design often did not consider the cost of the intervention, and there is a focus on cost containment with little consideration for microbiological or patient outcomes. Only positive outcomes were reported with no publications making any reference to possible negative outcomes.

Bearing in mind the above comments on the quantity and quality of the published reports (both descriptive and evaluative) a crucial role was identified for the pharmacist as part of a multidisciplinary programme that may be considered as follows:

(a) A role for the dispensary pharmacist who often screened initial antimicrobial requests. This was particularly important where restriction policies were being applied.

(b) A role for the general clinical pharmacist who was often on the ward and in an ideal position to identify those patients with specific pharmaceutical needs and give feedback to the specialist pharmacist. Other roles included guideline development, formulary management, IV-to-oral conversions and evaluations of programme outcomes through monitoring of drug usage.

(c) The pharmacist who had undergone specialist training in infectious diseases and antimicrobials and was an integral part of the antimicrobial team. In collaboration with other professionals within the team, the pharmacist was involved in streamlining empiric treatment following availability of microbiology reports, reviewing more complex patients referred to by the ward clinical pharmacist, participating in educational meetings and attending ward rounds.

Interestingly, the pharmacist was only making changes to the patient's medication in two papers: an IV-to-oral switch led by a patient group direction (see section 1.2.2), and an automatic therapeutic interchange where the physician was notified that the change had been made. (162, 175)

Of the nine evaluative trials identified, most were economically driven due to the institution's spiralling costs relating mainly to antimicrobial expenditure and the cost savings following implementation of the AMDT are the only outcome reported; most set out to prove to hospital management the cost-effectiveness of an AMDT with little or no consideration of the costs required to set up the AMDT and the intervention made as part of the programme. The effect of the AMDT on antibiotic usage is difficult to compare due to lack of standardisation of the units of measurement. The few trials that considered patient outcomes mainly used the length of hospital stay as a marker of effectiveness (172,177); this may however be imprecise as an outcome measure making it difficult to interpret the data.(4) It is not possible to draw any conclusions as to how the teams had any effect on bacterial resistance due to the lack of data available.

2.4.3 Discussion of findings and potential future research

Clinical pathways followed by post-prescribing evaluations by the AMDT, was the programme most commonly established in the trials identified. This involved establishing clinical guidelines and providing feedback to prescribers on adherence to the guidelines. This allowed for the streamlining of patients' treatment through recommendations rather than restrictions and may reflect the institutions' desire to move away from control and policing in an effort to rationalise antimicrobial treatment. All trials reported are single site and it is therefore difficult to extrapolate findings from one institution to another. The lack of benchmarking in relation to the hospital demographics (Ex teaching, number of surgeries, number of acute admissions) do not allow generalisability of the findings. It is not possible to determine which of the interventions is likely to be most effective since institutions tailored a programme most likely to be effective in the given institution. None of the trials were directly comparing the interventions made by the AMDT, so it is not possible to conclude which may be a more effective intervention. Besides, many of the programmes reported come from the US and the different healthcare systems make it impossible to generalise findings and extrapolate to other healthcare systems due to the different practices and resistance patterns within different institutions and countries. This has also been highlighted by other reviews. (146,148)

To build more robust evidence supporting the most suitable intervention to optimise antimicrobial use and the role of the pharmacist within such teams, there is a need for further research as also concluded in other reviews. (4,146,148,180) Some examples of potential areas of research include:

- Trials over a longer period of time to determine which intervention is the most sustainable
- Trials which address the current deficiencies in methods to enhance external validity such as standardising the units of measurement of antimicrobials (Ex using the defined daily doses) and defining hospital demographics

- Trials which address the impact of teams on patient and microbiological outcomes, mainly resistance patterns.

Pharmacists may potentially be involved in optimising antimicrobial use through PP, a role which has not been reported in the published literature. The growing responsibilities of the pharmacist to enable PP allow pharmacists to potentially expand on their current roles within hospitals including that as part of AMDT. The advent of pharmacist IP enables them to proactively start or change a patient's treatment without the need to first contact a physician and this may include optimisation of antimicrobial treatment. This is likely to reduce the time required for writing up prescriptions providing quicker access of the appropriate medication to patients. Antimicrobial treatment may lend itself to such expanding roles, for example, IV-to-oral switch in accordance with clinical guidance and the patient's clinical status, streamlining antimicrobial treatment following availability of culture and sensitivity reporting or prescribing antimicrobials in accordance with evidence-based guidelines as part of surgical prophylaxis. The growing problem of antimicrobial resistance makes it likely that new ways of practice need to be explored in the future to help optimise antimicrobial use in hospitals. This may include PP. There is little primary research on PP in hospitals, and no research was identified that focuses on a specific drug including antimicrobials. The following research project aims to explore PP in Scottish hospitals, with a focus on antimicrobials. Results of the research may help policy makers who are looking for novel ways of integrating the pharmacist prescriber as part of the AMDT.

Chapter 3

Focus group discussions

3.1 Introduction

There has been considerable evolution of the research aims and methodology when comparing the original research proposal to the aims and objectives in this Phase 1 of the research. The main sources of information and influence in this were the literature review and discussion with the supervisory team. Figure 2 shows the approach taken and the way in which both the research question and methodology evolved.

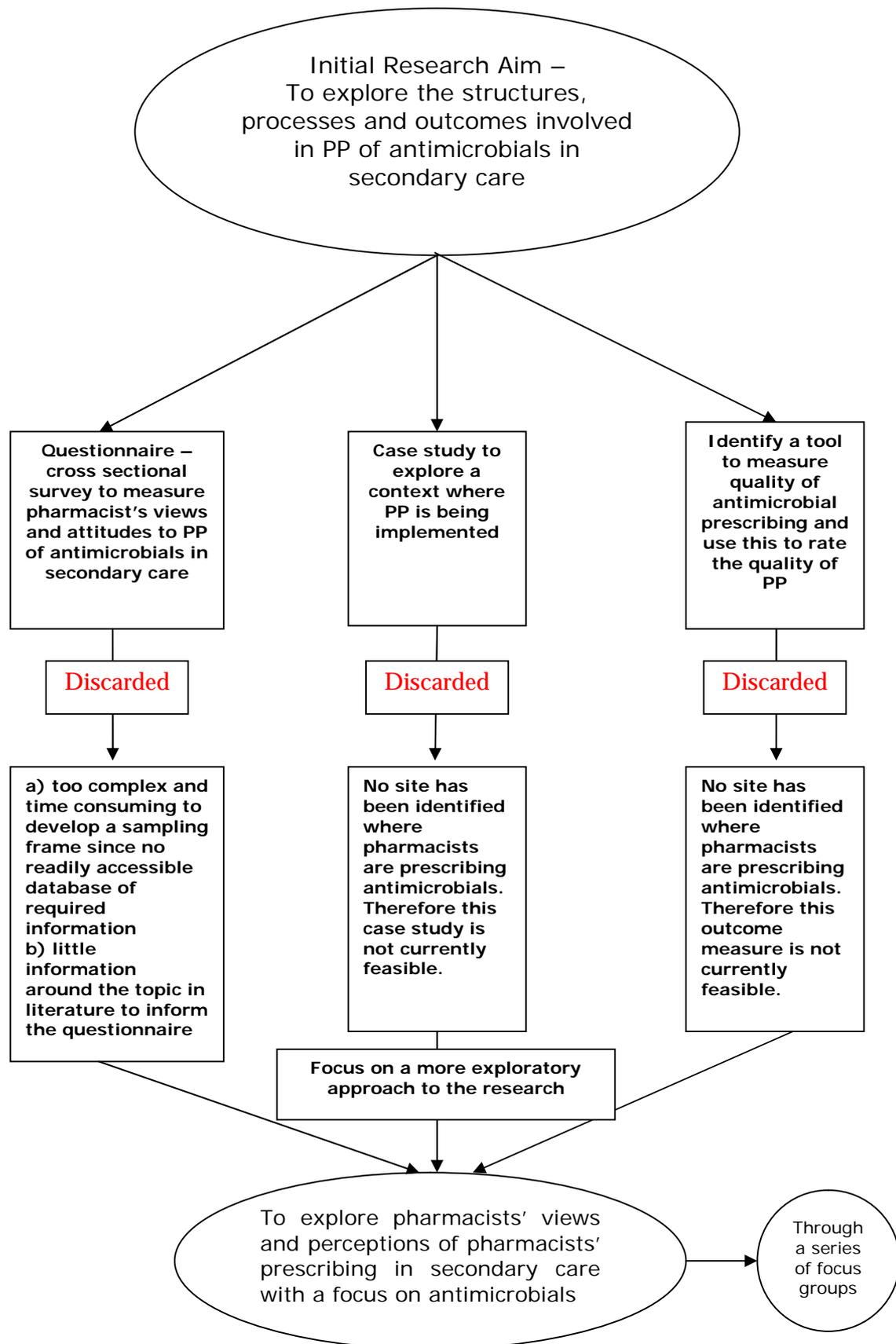


Figure 2: Schematic representation of evolution of research aim and methodology

3.2 Methodology

3.2.1 An overview of methodological approaches in research

Traditionally, there have been two key approaches in research: the quantitative approach dealing with numbers and statistics and the qualitative approach focusing on words and text. (181) This section briefly compares the distinctive theoretical frameworks on which each is based. Rather than being a comprehensive discussion of each method, emphasis is placed on aspects that are of relevance to this research.

Authors have argued that qualitative research, unlike quantitative research, is interested in idealism rather than realism. (182) This implies that it tries to determine what people's perception of reality is. Conversely, quantitative research is based on realism, with scientists claiming that it is possible to state objective truths about the material world. Critics of quantitative research claim that this is not possible; science actually produces the best conclusions in the current historical context and with the tools presently available. The natural versus artificial debate has also emerged with qualitative research linked to the natural, and quantitative to the artificial, implying that the latter deals only with experimental work. The different methods of reasoning involved in qualitative and quantitative methods have been broadly classified as inductive and deductive respectively. The deductive approach in quantitative methodology starts with a broad theory that is proven or disproved through observation in an experimental environment. Conversely, qualitative methods take the opposite approach, and start with observation to generate theories and are thus more exploratory in nature. The latter tends to develop concepts while the former tends to develop indicators. (181, 182) This may be shown graphically as follows: (183)

Deductive approach:

Theory → Hypothesis → Experimentation → Confirmation

Inductive approach:

Observation → Pattern → Tentative hypothesis → Theory

It is easy to visualise that a circular process may be drawn up and that any form of research is actually a combination of deductive and inductive processes as shown in Figure 3.(183)

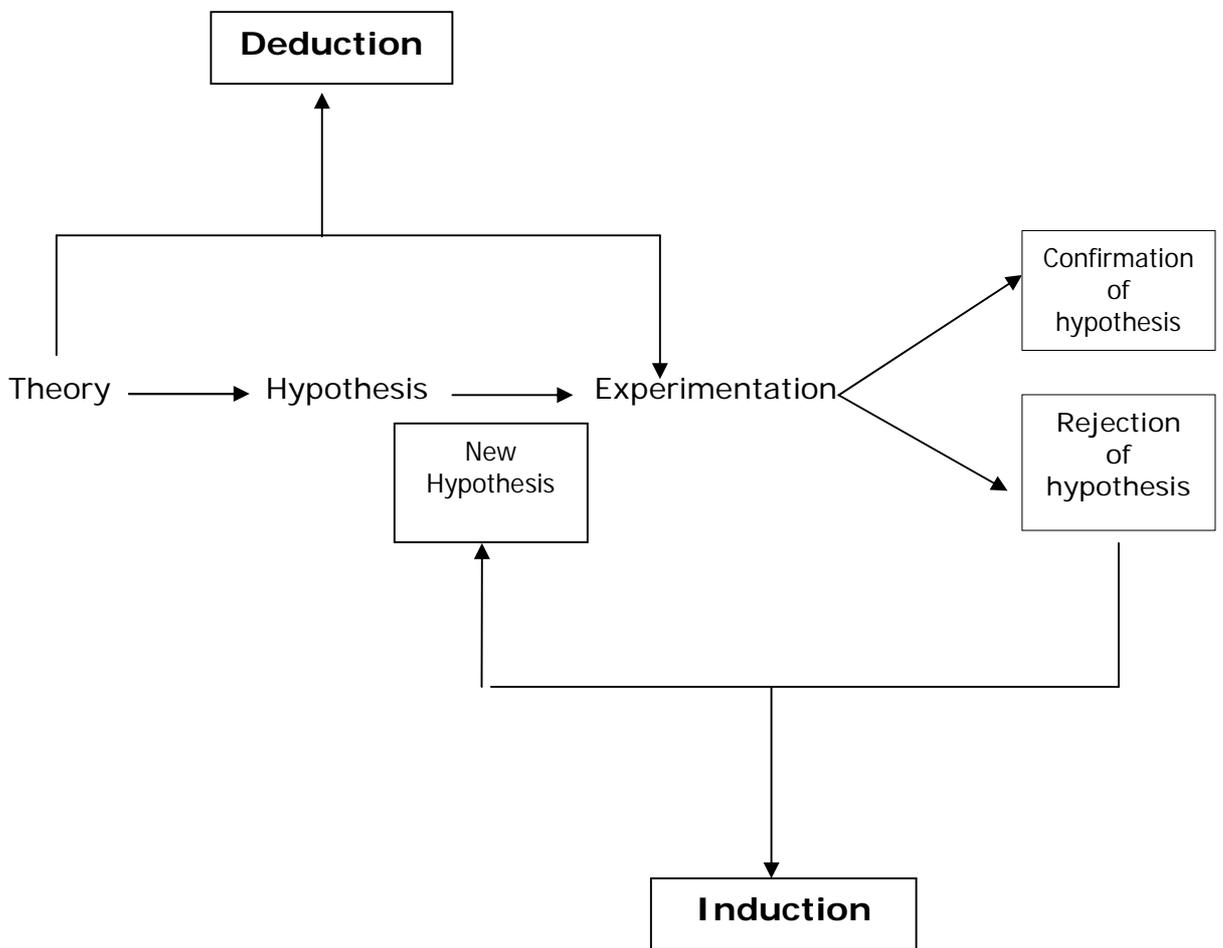


Figure 3: Schematic representation showing both inductive and deductive approaches in quantitative research

3.2.2 Choice of method for Phase 1

The aim of Phase 1 of the project was:

To explore pharmacists' views and perceptions of pharmacists' prescribing in secondary care with a focus on antimicrobials.

The research objectives for Phase 1 of the project were to explore:

- To what extent pharmacists were using their prescribing privileges
- Pharmacists' perceptions of the usefulness of PP in practice with a focus on antimicrobials
- Pharmacists' perceptions of the potential barriers towards PP in secondary care with a focus on antimicrobials.

A schematic representation of development of methods for Phase 1 is at Figure 2. This phase of the research aimed to explore participants' views and perceptions, and is consequently more interested in answering the "why" rather than "what" is happening around PP in secondary care. The research aim cannot be answered using numbers or statistics, but the in-depth and rich descriptions characteristic of qualitative research are required to illustrate views and perceptions. It would be difficult to capture these using a survey questionnaire with "yes" and "no" or "tick-box" answers. An alternative would be an open-ended questionnaire; however this would assume the agreement of participants to fill this appropriately and would likely be very time-consuming on their part. Besides, such a questionnaire was unlikely to give the sufficient depth required and consequently, a qualitative method was likely to access data and information inaccessible to quantitative methods. Due to the originality of the subject being researched, there is little information available in the literature to guide the development of quantitative research tools, and consequently this research may be viewed as being exploratory; again qualitative research is the more appropriate in such a case scenario, since this will generate information for subsequent explanatory or predictive research.(182) The choice of research method was therefore made on the basis of which is the more appropriate to achieve the project aim and which

is more likely to produce the most answers to the questions being asked, rather than on the basis that one form of research is superior to another. As Hammersley is quoted in Murphy "... which of these approaches is most appropriate should depend on our purposes, and the stage that our research has reached, not on paradigmatic commitments." (182)

Considering the above, a qualitative methodology may offer a number of advantages as a research method here over quantitative research namely (181,182):

- Since it is an iterative process, there is a constant interplay between data collection and data analysis and consequently the design of the study emerges as the research progresses in response to earlier observations. This is of particular relevance to this research since findings in Phase 1 of the project will inform later phases.
- Viewing events and actions from the perspective of those being studied; this allows use of methods such as focus groups and in-depth interviews, which allow the researcher to be as close as possible to the participants rather than putting forward the researcher's ideas as in a survey questionnaire. This is especially important in this research due to the lack of literature and information about the topic to inform the development of a questionnaire. The research also aims to capture views and attitudes, which may be more effectively achieved by the use of a qualitative methodology. Bryman as described in Murphy, uses the following description "The quantitative researcher adopts the posture of an outsider looking in on the social world...Among qualitative researchers there is an urge to 'get close'...to be an insider...by getting close to their subjects and becoming an insider they can view the world as a participant in that setting." (182) This may however also pose certain problems mainly for the researcher to leave behind all ideas and prejudices and analyse and investigate the participants' views as a point of departure. It is therefore imperative that the researcher clearly illustrates how he or she has arrived at the

interpretation of the actions of others. The process used is examined in more detail in Section 3.2.4 below.

3.2.3 Methods used in qualitative research

Methods in qualitative research may be divided into those where data are naturally occurring and those where data are generated. The naturally occurring include observation (which may be covert or overt), document analysis (which may be both formal or informal such as diaries or letters) and conversation analysis. This is of particular use where behaviour and interactions need to be explored in the natural environment of the group being studied. Analysis relies heavily on the researcher's interpretation of what is being observed or read. (184) Generated data include in-depth interviews and focus groups. Such methods involve the participant's reconstruction of attitudes, beliefs, behaviour or other aspects that are being investigated; they are a unique source of information in understanding participants' own perspectives of the phenomenon being investigated relying heavily on their own interpretation, though this may be further interpreted by the researcher. (184)

3.2.4 Study Design

3.2.4.1 The use of focus groups

Generated data methods of collection were considered to be more appropriate than naturally occurring since they would provide insight into the pharmacists' perceptions together with their own interpretation into why they held these views and perceptions. The research aim and questions were explored through focus group discussions with hospital pharmacists. Kitzinger comments that focus groups have been shown to be an effective way of exploring the attitudes of staff within a health service and were therefore a suitable choice for this research. (185)

The focus group method is a form of group interview first introduced by Merton et al, where a moderator guides the interview by asking a number of focused questions, and participants within the small group discussing those topics raised by the moderator, asking each other questions and commenting on each others' experiences and points of view. (181,185) The

discussion within the group is therefore the generated data in focus groups. Participants are usually selected because they come from a similar background or have shared a similar life experience. Morgan recommends having six to ten participants in each group; it may be more practical to have smaller groups if the participants are likely to have a lot to contribute. A typical focus group lasts about 90 minutes. (186,187) The number of groups conducted varies immensely in the literature with one project reporting up to 52 conducted groups. (181) Usually, the higher the level of diversity within each group, the more ideas generated and consequently the more focus groups are needed. It is normally recommended to conduct groups until theoretical saturation is reached, where no new ideas are generated and where the moderator feels confident that he/she may predict what the next group will discuss. (181) Focus groups are usually audio-recorded and transcribed with transcription-based analysis, though there have been reports of note-based and memory-based analysis. A transcript-based analysis is recommended since it allows capturing of the group dynamics with knowledge of "who is saying what." (181,187)

Focus groups were preferred over in-depth interviews for Phase 1 of the research for the following reasons: (181,184,187,188)

- A focus group design would allow participants to probe each other's reasons for holding certain views and ideas rather than just a question-answer as would occur in a normal interview; consequently participants may influence each other's response. In this context, it would enable discussion between participants who are supplementary prescribers or training to become prescribers, and those who are not supplementary prescribers. It would also stimulate discussion between pharmacists working in different specialities.
- Arguing and discussion between the members of the group may result in a more realistic result than just an interview. Again, having mixed groups would enable probing and a better understanding of any differences that may exist between different areas where pharmacists were practising. However, this may lead to a problem

with dynamics within the group which need to be effectively managed by the moderator.

- May be regarded as more “naturalistic” when compared to interviews; in real life people rarely build up ideas, work or function in isolation but rather in groups. This may be of particular relevance here since all the group participants are already part of an existing work group.
- Individual’s responses are usually more spontaneous; being away from the interview question-answer design, participants in a focus group will only answer the question if they feel strongly and have a definite feeling about the subject not because they have to.
- Since the focus is on the group rather than the individual, participants may feel more secure since what is being said will not necessarily be attributed to the individual but rather to the group. Focus groups therefore enable inclusion and contribution from people who would otherwise not participate if a one-to-one interview were held.

The following approaches were adopted to enhance a systematic approach in this research.

- The moderator who was also the author and analysed the data was trained prior to embarking on the project and attended courses relating both to qualitative methods and the data management software NVIVO.
- A topic guide was used to provide a systematic approach, yet allowing the participants to discuss issues.
- All discussions were recorded and transcribed “ad verbatim” by the moderator/author. This allowed for capture of data that would not be possible to write down and helped with a rigorous analysis.
- Where possible, an assistant moderator was present to take further notes where relevant.
- A clear account was provided of the process used to collect and analyse the data.

- Inter-rater reliability checks were incorporated in the analysis process to ensure that another researcher came to the same conclusions when using raw data.

Each is discussed in further detail below.

3.2.4.2 Governance issues

The project was approved by the ethical review panel of the School of Pharmacy. Since NHS personnel were involved as participants, ethics approval was sought through the Multi-centre research ethics committee for Scotland (MREC). The full submission is in Appendix 3.1. MREC advised that the project did not need to be reviewed by an NHS ethics committee since it involved only staff and not patients and did not involve an intervention. This reply may be found at Appendix 3.2. However, Research and Development (RandD) approval was obtained for each acute organisation where a focus group was to be conducted. This was at times a very lengthy process with applications taking up to three months to be processed. Overall, it took 7 months to obtain all the necessary approvals. An example of an obtained approval is at Appendix 3.3.

Acute chief pharmacists in the selected NHS health boards were initially approached and given a brief overview of the project and asked whether they would be willing to participate, with all agreeing to participate. They were then asked to provide a list of all senior pharmacists who were Grade D and above, their speciality and whether or not they were supplementary prescribers or in the process of completing the course. Pharmacists were then stratified by the main variables of prescribing status, and clinical area; where possible, one pharmacist was selected per group to ensure as far as possible representation of the main variables identified above. In the rare circumstance where two pharmacists worked within one speciality, one pharmacist was approached, this being organised blindly. Participants were sent a recruitment pack which included: an invitation letter, some background information about the study and a consent form (see Appendix 3.4). Participants could withdraw from the study at any point. The author stored all the signed consent forms in a locked drawer.

Media cards with focus group recordings were stored in a locked drawer separate from the consent forms. These will be destroyed once the research is completed. To ensure participant anonymity, all transcriptions were carried out by the author who was also the moderator at all focus group discussions. Only anonymised transcripts were available as paper copies and distributed to other members of the supervisory group for review. When inputting data into NVIVO (data management programme), only the anonymised data were entered. Storage of all information is on a password protected laptop. Any electronic or paper data will be destroyed once the research has been written up.

3.2.4.3 Sampling and recruitment for focus groups

Choice of locations

Sampling of locations was purposive, with the aim of including representation from health boards where specialised ID units were present, and representation from health boards where such services were not available. It was also aimed to have health boards with a mix of rural and urban catchment areas. To achieve this variation, the following health boards were recruited. Four health boards with specialised ID units were included in the study. These had ID units within large teaching hospitals with tertiary referral services, offering a mix of urban and rural location. Two health boards were selected since there were no specialised ID units present and no ID consultants within these health boards. Due to their geographic location they also provided representation of the more rural areas both having one main district general hospital.

The health boards were recruited largely in order of when RandD approval was granted. Unfortunately, a focus group discussion was not conducted in one of the district general hospitals due to a delay in research governance.

Recruitment of participants

Sampling was purposive, with the intention of including representation from ward based clinical senior pharmacists (usually Grade D or over, though this was changing with the NHS 'Agenda for change' programme) who were supplementary prescribers (or in stages of their SP course) or not, hospital pharmacists working in different specialities (eg critical care, surgery, respiratory, orthopaedics, diabetes and endocrine) where antimicrobial prescribing is essential to patient care. Specialities with no ward based activities, such as medicines information and quality assurance, were excluded from the sample. Senior pharmacists were included in the study rather than more junior grades since it was more likely for this grade of pharmacists to have sufficient work experience within an area to be specialist pharmacists and to have a better understanding of the role, if any, of PP within that area. Having a mix of practitioners working in different specialities would allow identification of any relevant distinctions between different, but typical, settings/areas and individuals' perceptions of PP. The sampling frame therefore included all pharmacists falling within these categories. Mixing the groups, particularly with respect to different prescribing status, would potentially be able to generate more discussion. To allow for a discussion involving 'hands on' current practitioners, pharmacists who were higher up in management and chief pharmacists were purposely omitted at this stage of the research. Together with the recruitment pack, participants were sent a background survey which they were asked to complete if they agreed to participate in the study. The latter was aimed to obtain more details about the pharmacist's experience with the speciality PP of antimicrobials within the department. The survey was reviewed for face and content validity by the same experts reviewing the topic guide as described below. It was aimed to have 6-8 participants in each group rather than run larger groups with 10 or more participants. This would allow for a well balanced discussion where all participants have time to air their views; it would be unlikely for the participants to have enough time to express their views if a larger group was convened.(186) Krueger goes on to comment that groups of more than 10 participants greatly limit the amount of input from each individual, restrict the flow of ideas and on a more practical level, are difficult to assemble and moderate.(189) It would

also have been unlikely to be able to recruit more than 10 participants from each site. Signed consent forms were returned in a provided stamped and addressed envelope prior to participation in the focus groups.

3.2.4.4 Planning and conducting the focus groups

Choice of moderator

The author was the moderator and led all the group discussions. To ensure efficacy of group moderation, the author attended various focus groups organised by the school to observe the proceedings. Subsequently, the author attended a week long specialised training programme focusing on qualitative methodologies, with focus group moderation being one of the topics covered.^{ix} She also familiarised herself with specialised literature to gain further insight into group dynamics and conducting focus groups.

The moderator had no association with any organisations where the focus groups were carried out. Having the author as moderator was a major advantage since this ensured that the moderator was familiar with the project aims. Efforts were made to minimise moderator bias as recommended by Stewart et al: a standard introduction was used (Appendix 3.5), which was the same for all focus groups; personal bias was minimised by not only welcoming and reinforcing points of view with which the author was in agreement but also other emerging ideas; questions asked aimed to explore both the potential and the barriers of the topic under investigation; and welcoming and reinforcing points of view that were not consistent with themes that emerged from previous focus groups.(188) Since the moderator was neutral and the research was not being carried out on behalf of any sponsor, reinforcing points of view likely to be pleasing to the client were not applicable in this case. Having the author present at all focus groups allowed the "gist" and "feel" of the group to be captured; qualities that would have been missed if only the transcript was used for analysis.

Krueger recommends having an assistant moderator present at every focus group as part of a systematic approach, acting as an extra pair of eyes and observing and noting the participants' body language throughout the

^{ix}Social Research Association Course held in Edinburgh in March 2006

discussion. He also goes on to acknowledge that very often it is not possible to have an assistant moderator in the private setting mainly due to financial constraints.(190) Where available, an assistant moderator accompanied the author with a standard field note reporting form based on the literature used for note taking. (Appendix 3.6) The assistant moderators were also provided with a checklist to enable rating of the moderator and ensure continual development and improvement of the moderating skills.(190) Presence of the assistant moderator therefore provided intermittent validity to check the process being used and to offer insight into the groups. This exercise was particularly valuable during the initial groups. Due to logistical problems, it was not always possible to have an assistant moderator available at all focus groups. Where no assistant moderator was available, two recorders were used to ensure efficient recording of the group discussion. When assistant moderators participated, neutrality was also ensured. All assistant moderators were from the school of pharmacy and were not involved in teaching any courses that the participants were likely to be undertaking.

Development of the topic guide

To ensure that a consistent and systematic approach was taken when asking the participants questions and to ensure that all the study objectives were covered, a topic guide was developed. When drawing up the topic guide, a questioning approach was taken rather than a list of topics to be explored during the focus group. The questioning route produces more efficient analysis because it minimises subtle differences in questions.(191) However, it may produce a lack of spontaneity when the questions are being asked. Rather than having a "rolling interview guide" where the questions were changed depending on answers to previous focus groups, consistency in the questions was kept across groups and enabling a more systematic approach to the analysis.(188,189) A more "moderately" structured approach was taken when developing the questions for the topic guide; the questions aimed to answer the specific research objectives but at the same time explore participants' views about the topic.(186) The aim was to have a balance between the author's focus and the group's interests.

The first questions were aimed to be biographical and related to the participants' own prescribing status; this was viewed as a way of creating a relaxed group dynamic and get the discussion started, particularly since the groups were being audio-recorded. The questions were developed to flow from the more general to the more specific questions. An initial set of questions was developed by the author as at Table 11. This was then reviewed for face and content validity, by the three members of the supervisory team, two academics, one with a special interest in non-medical prescribing and another with an expertise in qualitative research methods and two academics external to the university. The reviewers were asked to comment about the readability of the questions and the extent to which the questions answered the research objectives. The questions were also circulated to a national infection management interest group coordinated by the UKCPA; however only one response was obtained, with other members commenting that they found it difficult to critique mainly due to a lack of familiarity with qualitative research methods. The final version of the topic guide used is at Table 12.

Table 11: Initial version of topic guide

TOPIC GUIDE FOR FOCUS GROUPS DISCUSSION

1. I wonder whether we may start by having a brief introduction from each participant including speciality and whether or not supplementary prescriber or on the course. Is supplementary prescribing (SP) used in the day-to-day job? Are there any plans for those who are not supplementary prescribers to become SPs as part of future objectives?
2. Does your department support and encourage PP?
[Prompts: finance course; provide study leave to attend residentials; allow for study time; provide a framework to apply PP in practice; provide current job cover to take SP forward]
3. Is there a role for pharmacist supplementary prescribing of antimicrobials in secondary care?
[Prompts: pharmacist adequate knowledge and background to prescribe antimicrobials especially compared to HOs and SHOs and registrars in some specialities; better quality use of medicine; better medicines management; ever discussed the potential of pharmacist antimicrobial prescribing with colleagues or clinicians]
4. Are you prescribing antimicrobials as part of your day-to-day job? Is there any other PP antimicrobials within the department and if yes what speciality? Do you have any specific clinical management plans drawn up specifically for antimicrobials or any patient group directions eg IV-to-oral switches?
5. If you are prescribing antimicrobials what has been the feedback from:
a) doctors b) nurses c) patients [any differences between if on acute ward or chronic conditions as an outpatient eg HIV or cystic fibrosis] d) other colleagues
[Prompts: more holistic care of patients; ensure patient concordance; ensure patient have a better understanding of their condition and why antimicrobials are needed; improve patient discharge process; patients having a longer appointment time at an out-patient clinic]
6. Do you feel more comfortable writing prescriptions for antimicrobials for a) diagnosed conditions b) undiagnosed conditions
7. Are there any benefits which you have already seen or any potential benefits of PP of antimicrobials?
[Prompts: closing gap in current patient care; ability to save time chasing doctors; filling in a gap that a medical practitioner may have left; improved continuity of care; increase pharmacist profile and job satisfaction within the working environment]
8. Are there any barriers, problems or potential problems that may arise if PP antimicrobials?
[Prompts: stepping over the traditional inter-professional boundaries eg doctors and nurse practitioners; shortage of hospital pharmacist and increased workload; separation of prescribing/dispensing tasks which may be especially a problem in rural areas; problem with not having the pharmacist for 7 days and possible disruption of service; problems with indemnity/increased liability; setting up of clinical management plans for individual patients on acute wards where there is a constantly changing clinical background]
9. Is there anything that has been missed or that anyone would like to add?

Table 12: Final version of topic guide

TOPIC GUIDE FOR FOCUS GROUPS DISCUSSION

1. I wonder whether we may start by having a brief introduction from each participant including speciality, and whether or not a supplementary prescriber or on the course.

THEN, for those who are not supplementary prescribers, are there any short-term plans to become SPs as part of future objectives?

2. For those who are supplementary prescribers, to what extent is this being used in the day-to-day job?

THEN if SP is not being implemented what are the reasons for this?

3. For everyone, moving onto antimicrobials, what are your thoughts on pharmacist SP of antimicrobials in secondary care?

Consider different patient groups:

- a. intensive care
- b. respiratory
- c. elective surgery
- d. orthopaedics, trauma
- e. dosing of antimicrobials in renal patients
- f. outpatients/inpatients as chronic/acute conditions

4. Have you ever discussed the possibility of pharmacist antimicrobial prescribing with colleagues or clinicians?

THEN for anyone already prescribing antimicrobials what has been the feedback from other healthcare professionals, colleagues or patients.

Now moving onto PP (both supplementary and independent). With independent prescribing, there is no need for a CMP and a pharmacist may prescribe both if the doctor has diagnosed a condition or can diagnose and prescribe.

5. In a hospital environment, what is the feasibility of a PP when

- a. a diagnosis has been made
THEN, b. when a pharmacist has to diagnose and then prescribe

6. What is the value of both pharmacist antimicrobial supplementary prescribing and independent prescribing in secondary care?

- If we start with
- a) the positive thoughts
 - b) the negative thoughts

7. What attitude does pharmacy management have towards pharmacist SP of antimicrobials?

8. Are there any barriers, problems or potential problems that may arise if pharmacist is

- a) supplementary prescribing antimicrobials
- b) independent prescribing antimicrobials

9. Is there anything anyone would like to add?

After conducting the first focus group, it was felt that giving examples as in question 3 may be leading; a minor change was therefore made and these examples were omitted in the subsequent focus groups. Participants during the first focus group were also asked to summarise the results of the discussion in one written sentence. This was however dropped since the participants felt that this was very difficult to complete and express; besides, on analysis, this did not help to gain a better understanding of the discussion.

Prior to asking any questions on the topic guide, there was a brief introduction where the participants were given reasons why they had been chosen to participate, were reminded that the discussions were being recorded, and were asked not to speak over each other. It was also emphasized that the aim of the groups was to stimulate discussion rather than reach consensus. The focus groups were held within the hospital premises, since this location was suitable for the participants. Many of the groups were held over lunch breaks with lunch provided by the university; the lunch offered an opportunity for the moderator to interact and get to know the participants. The seating arrangement was similar for most groups with a circular seating arrangement adopted for most groups; where possible the moderator avoided sitting at the head of the table to create a more informal environment. On average, the focus groups lasted around 60 minutes (40-70 minutes) and were conducted between July 2006 and January 2007.

Audio-recording and transcriptions

Transcript-based analysis is usually the most rigorous form of analysis and therefore, though time consuming, was opted for in this project. To ensure a complete, thorough and systematic capturing of data, all focus groups were digitally audio-recorded, with the participants' consent, and transcribed "ad verbatim." This systematic approach allowed reconstruction of critical parts of the focus groups during the analysis phase.(189) All transcriptions were prepared by the author to ensure "immersion" in the data. All audio-recordings were securely kept until the writing up stage and were then destroyed. Audio-recordings were heard only by the author, who

was also present at the focus groups. They were anonymised following transcribing and only the anonymised versions were used for data analysis.

3.2.4.5 Analysing the focus group results

Approach to analysis

There are no clearly agreed rules or procedures as to the correct approach to analysis of qualitative data with variations occurring depending on the traditions of the discipline, the main focus and the aims of analysis.(184)

This is emphasized by Patton who makes the following comment: "Do your very best with your full intellect to fairly represent the data and communicate what the data reveal given the purpose of the study." (192)

The objective of the analysis in this research was to have a better understanding of the participants' views and perceptions towards PP in secondary care in terms of: the current use of prescribing skills and the perceived opportunities, feasibility, challenges and barriers of PP in secondary care with a focus on antimicrobials. The themes were initially identified through a narrative analysis and were very loose terms based on the participants' own views. The author tried to understand the way the account was constructed and the meaning of the "story" that the participants were relating and trying to put forward. Content analysis was then carried out to understand the way the theme was presented and frequency of occurrence. The use of a combination of approaches has been reported in the literature and often there is not one clear cut approach but a crossing of boundaries.(184) A thematic summary was then drawn up to produce a descriptive account of each focus group. A 'cross-sectional' approach was adopted in that the same themes were applied to the whole dataset, initially manually and then computer-assisted, such that chunks of data representing a theme were placed together. Use of a cross-sectional approach has been criticised since it may produce a separation of the theme from the context; other authors have however commented that this is the advantage of using such an approach and is the only way of understanding and interpreting data.(184) There has also been much debate around the use of computer-assisted software; those in favour of their use have included consistency of approach, ease of linking and easier

conceptualisation of data and theory building as advantages. Reported disadvantages have been a removal from context, a way of trying to put “scientific method” into qualitative research, an over-emphasis on counting rather than other forms of analysis, and a temptation to take a “shortcut.” (184,189) The latter has been overcome in this project by initially building a manual thematic index followed by a descriptive account of each group. Following this, data were entered into NVIVO7 such that chunks of text where a specific theme emerged were grouped together. This therefore gave the facility to help organise data across the whole group using “software for data administration and archiving.” (184) The complete transcripts were entered into the software package and though anonymised, the author could identify who was speaking through the coding system used, helping to keep the analysis in context. (189) The author attended a training course on the use of NVIVO organised by the University in December 2006.

The analytical process and tools used

Ritchie et al have summarised the required features of an analytical tool as follows, recommending that the process chosen should have all of the features: (184)

- Remains grounded in the data with constant and frequent re-visiting of data and quick and easy access to the original data
- Permits captured synthesis allowing data reduction without loss of meaning of the original text
- Facilitates and displays ordering such that the data may be inspected in blocks that are related to the specific subject
- Permits within and between case searches
- Allows systematic and comprehensive coverage of the dataset implying that the same method is applied across the whole of the dataset
- Permits flexibility allowing additions or amendments at any point in the analysis
- Allows transparency to others.

The actual process may be viewed as taking the form of an “analytic hierarchy” made up of 3 stages: data management, descriptive accounts and explanatory accounts. (184) The whole process is an iterative process implying that this is not a linear approach or a sequential process as in quantitative data analysis, but rather each of the steps is revisited at different stages of the analysis. Murphy similarly described the analysis process as involving both the data management, which allow data reduction and consequently allow data to be handled more efficiently, and the procedures where the relationships and features are identified. (182) These processes usually occur simultaneously as the data progresses. Murphy goes on to describe theoretical sensitivity, which involves the element of individuality in qualitative research, both in terms of the setting studied and in terms of the researchers. Therefore, though one may include thorough descriptions of methods used, one cannot completely standardise methods for qualitative analysis.

Data management involves sorting and reducing the data making them more manageable through generation of themes followed by labelling and sorting of all the text, manually or computer-aided. Descriptive accounts make use of the synthesized data to prepare a description. At this point, it is important to keep referring to the words used by the participants and to the content of people’s accounts. The researcher may then move on to develop typologies as a way of classification and segmentation of different characteristics emerging. Explanatory accounts usually occur at a later stage and involve building explanations and trying to answer any pattern and outcomes in data that are observed. It is important that the whole process used is clear such that other readers and other researchers may view the logic of construction of conclusions.

To aid in the analytical process in this research, the analysis tool ‘framework’ was used, a method developed in the UK in the 1980s at the National Centre for Social Research by Ritchie and Lewis. It is a matrix-based analytical method and was selected since it facilitates rigorous and transparent data management ensuring that all steps involved can be systematically conducted and can be viewed and assessed by researchers

other than the primary analyst. (184,193) The framework method was also considered to be the most suitable since the research was led by pre-defined objectives and a “semi-structured” topic guide was used to facilitate the focus groups, thus giving the research more structure at the start than would be typical of qualitative research. The author also attended a specialised course (as previously specified) that used the ‘framework’ tool and therefore felt more confident with this method. There are five main stages to this approach: (193)

- Familiarisation: involves immersion in the raw data. In this case, the author collecting the data was also the analyst and was therefore already relatively familiar with the data. Furthermore, to aid in the process, the author transcribed the audio recordings herself and read these transcripts over and over again.
- Identifying a thematic framework. The end product was a detailed list of themes – effectively an ‘index’ which could then be applied to the whole text.
- Indexing – Applying the thematic framework to the whole text systematically. The term ‘indexing’ rather than ‘coding’ is being used since it is fitting the index into the text without any interpretation as coding would imply.
- Charting – Rearranging the data according to the appropriate part of the framework to which they relate. This is done by synthesising the material into charts sorted out by the themes. This ensures that there is no ‘context stripping.’
- Mapping and interpretation – using the charts to find associations and provide descriptions and explanations.

Due to the recent development of this method of analysis, there is little critique of this in the literature.

A more detailed step-by-step breakdown of the method used for analysis is found below.

- 1 The transcript for the first focus group was read and recurring themes and ideas were identified. Examples include clinical management plan as a limitation of pharmacist SP.
- 2 The themes were sorted and grouped under a smaller number of categories building the thematic index or framework. This was reviewed as more themes emerged. Throughout this process, the language was kept as close as possible to that used by the participants with little reference to the literature i.e. the process was "grounded in the data."

Barriers to PP

Category	Limitations of pharmacist SP
Themes	Clinical Management Plan

- 3 The transcript was then labelled and this involved an indexing process where the themes and concepts were applied to different parts of the data i.e. which theme is being mentioned in which part of the data.
- 4 This was initially done manually with notes written in the margins on the transcript, and then electronically using NVIVO7. Where sections of the data fitted into more than one theme, these were 'multi-indexed.'
- 5 The above was repeated for each focus group transcription. New themes were added on as they emerged from each focus group. As the data was understood better, themes were also collapsed to create broader categories. Data saturation was eventually reached when no more new themes emerged. Different versions of the thematic index and the final version generated through NVIVO7 are at Appendix 3.7 and 3.8.
- 6 The data were sorted by category and theme electronically such that all the material falling under a specific theme was organised together. To keep the data within context, though the data were anonymised, the author was able to identify which participant said what. Also the texts were labelled to know the context i.e. which focus group the data originated from.

During all the above processes involved in data management, there were regular discussions with the supervisory team as an “auditing” process.

- 7 All the data on a specific theme within each focus group were brought together. This would allow for a comparison of that theme across groups.
- 8 This step was repeated by another author and compared to obtain feedback and check for concordance. This inter-rater reliability constituted the “audit” element used throughout the project and aimed to improve the consistency of the analysis.(193) The initial focus group analysed was reviewed by 2 other researchers and served as a validity check.
- 9 The transcripts were re-read while listening to the recording and the frequency, extensiveness and intensity of comments were noted.
- 10 The indexed transcripts, together with the information as organised within NVIVO were used to perform across group content analysis and write up the results.

Data selection and presentation

This is a comprehensive output where a detailed and extensive portrayal of the findings is presented. The report is a descriptive account telling the ‘story’ and taking into account all views, even atypical ones. The structure of the report is that of the emerging themes. There is use of verbatim passages to contextualise what is in the narrative text. Using verbatim quotations helps to clarify links between data, interpretation and conclusion, and strengthens the validity and credibility of findings.(194) Bowling also comments that when using a narrative format “Data need to be presented so that their richness is not lost.” Quotations have been selected to illustrate the divergence of opinion and more than one quote is provided if there were different perspectives. Each quote has an “identity tag” which highlights the key characteristics of the speaker.

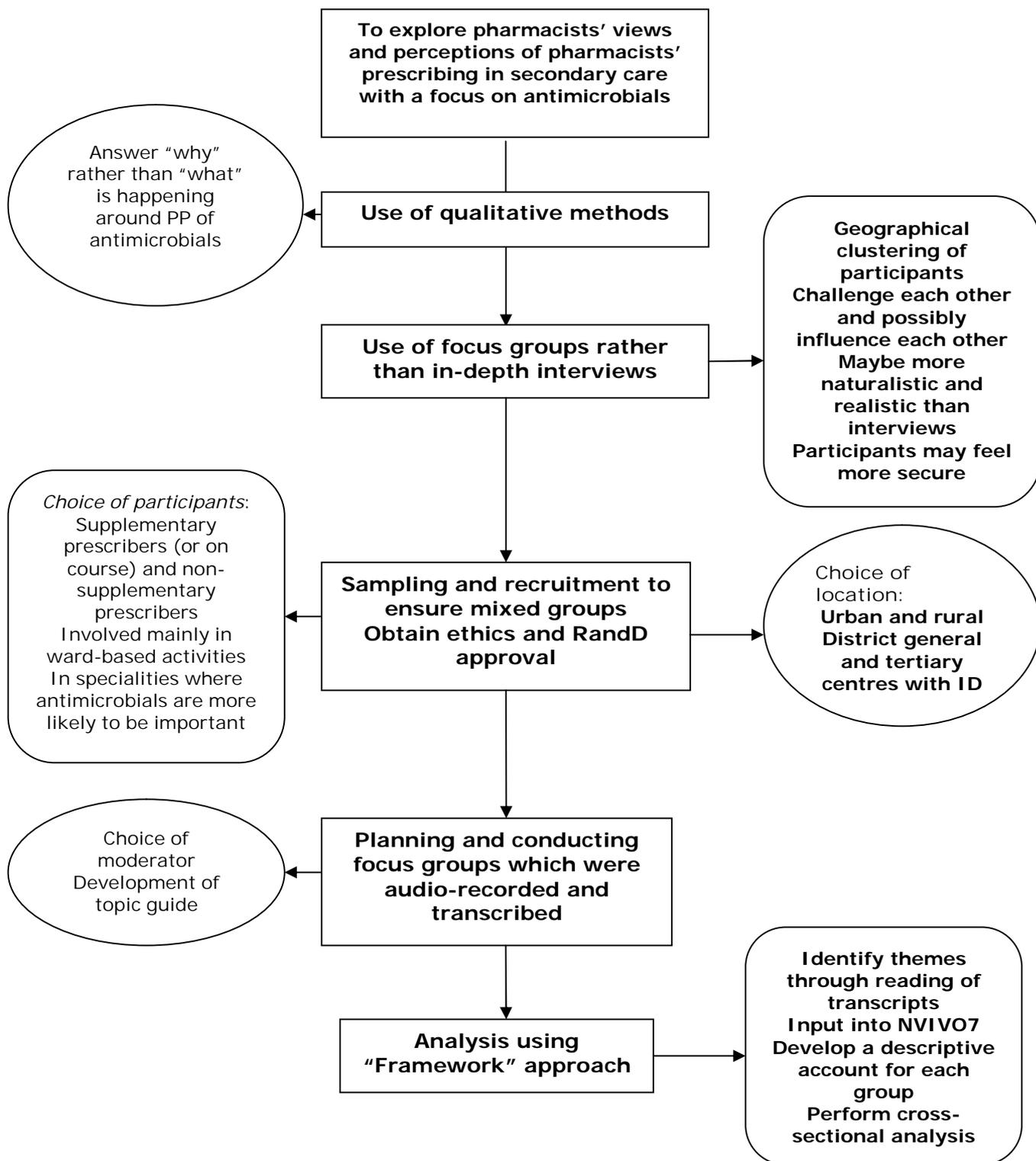


Figure 4: Schematic representation of methodology adopted for Phase 1 of the project involving focus groups

3.3 Results

3.3.1 Introduction

3.3.1.1 Demographics of participants

A total of 56 pharmacists were approached with 39 pharmacists consenting to participate and 37 of whom actually participated in one of the six focus groups. The main reasons for non-participation were lack of availability due to being off work or due to other work commitments. Two pharmacists could not participate in the final discussion despite having consented, due to other urgent work commitments that had to be dealt with at the time. Table 13 provides some information about the overall mix of each group, also providing details about the demographics and services offered at each focus group location. Though it would have been ideal to provide information about the population covered by each health board where a focus group was held, this was not provided to help ensure participant anonymity.

Table 13: General demographics, location and participant mix in each focus group

	Services Offered	No of pharmacists invited	No of pharmacists consented	No of pharmacists participating	No of supplementary prescribers
1	District general hospital with no ID unit; 577 beds	11	6	6	4 and 1 in training
2	Tertiary centre with an ID unit & 2 antimicrobial pharmacists; 1000 beds	10	6	6	1 in training
3	Tertiary centre with no ID unit; >900 beds	10	7	6	3
4	Tertiary centre with an ID unit and an ID pharmacist; 800 beds	10	7	7	2 in training
5	Tertiary centre with an ID unit and an ID pharmacist; 900 beds	8	7	7	4 and 1 in training
6	Tertiary centre with an ID unit; a number of specialised pharmacists; 932 beds	6	6	5	2 and 1 in training

Of the 37 participants, 32 were female and 19 were supplementary prescribers or undertaking training; they had been in practice for an average of 14 years and had been in their current speciality for an average of 6.3 years. Table 14 provides details about the characteristics of the participants. To protect the participants and ensure anonymity, participants for all the six focus groups have been grouped into one table and numbered consecutively in order of recruitment.

3.3.1.2 An overview of the dynamics and interactions within each group

As discussed in greater detail in the methodology section (Section 3.2), a number of processes were used to capture the dynamics and interactions within each group. The author was the moderator, thus allowing for the “feel” and the “gist” of each group to be captured, rather than just basing analysis on a written transcript. The moderator was neutral to the organisation, had not worked in any of the secondary care environments where the groups were run, and did not personally know any of the participants helping to develop a more objective perspective. Where available, an assistant moderator participated, acting as an extra pair of eyes to observe the participants’ body language throughout the discussion, making notes using a standard field note reporting form. The assistant moderator then acted as a validity check by reading the descriptions generated for each group. This section aims to describe the dynamics and interactions captured within the group. There is no attempt at content analysis here.

Location 1

All questions within the topic guide were covered during a focus group that lasted approximately 67 minutes. Overall, the group tended to have more lengthy discussions around the feasibility and value of PP rather than the barriers and challenges. The group was in agreement throughout with no areas of conflict or disagreement identified.

Participant 1 was a “middle management” pharmacist and consequently gave valuable insight into higher pharmacy management issues and associated bureaucracy areas of which the other group participants may

have been less aware. Being a clinical team leader, he brought this experience to the group and informing the discussion about how the PP had developed. It proved very difficult to stimulate participant 2 into the discussion despite encouragement from the moderator. Participants 3 and 4 did not participate extensively, but did on occasion raise issues they considered relevant. Participant 5 was a clear opinion leader voicing issues about changes within the department. The issues of potential changes within the department were discussed by this participant but she does not appear to be professionally threatened by any of the changes.

Location 2

All questions within the topic guide were covered during a focus group that lasted approximately 70 minutes. The discussion tended to focus more on barriers and challenges of PP rather than the feasibility and value. Overall all members of the group gave their views and opinions about the topic throughout the discussion, and being audio-recorded did not seem to hinder them from voicing their opinion about issues that were possibly sensitive. They were in agreement with no conflicting issues arising.

The group was very cooperative, and the participants were keenly willing to identify and move to another venue when the room originally booked turned out to be double booked. Participants 7 and 9 had very strong opinions and views about the subject. However, they did not try and dominate or influence other members of the group.

Location 3

All questions within the topic guide were covered during a focus group that lasted approximately 70 minutes. Overall all members of the group voiced their views and opinions about the topics under discussion. There were no clearly dominant personalities and no key areas of disagreement. It was a very lively discussion with members of the group asking each other questions and probing for further information. The group did not appear to bias in favour of, or against PP of antimicrobials; both the feasibility and value and the barriers were equally discussed, though there seemed to be greater discussion around the challenges and logistical issues of

implementing PP. Overall, the group seemed to have considerable amount of experience. The participants were in agreement most of the time, and discussed areas where they disagreed. The latter focused mainly around roles, responsibilities and experiences involving other members of the multidisciplinary team. There was little need for intervention from the moderator. Recording the discussion did not appear to hinder participants from voicing their opinion and sometimes using colloquial language. The discussion was sometimes difficult to transcribe since the group members tended to speak over each other.

Participants 15 and 18 were very strong opinion leaders, though they did not dominate or overpower other members of the group. Participant 13 was regularly called out of the room having to respond to bleeps, though she did participate in the discussion.

Location 4

The focus group lasted approximately 40 minutes, a shorter discussion group compared to the other groups, and in that respect was not typical of other focus groups conducted. All questions in the topic guide were covered in about 20 minutes; the moderator then asked some more questions, using a "rolling interview guide," which were related to themes emerging from the previous groups. Prompts were sometimes used to try and encourage participation. Interestingly, not all participants were consistent in their points of view throughout the discussion; for example, participant 19 initially indicated that she felt there was no role for PP of antimicrobials in her speciality but then later goes on to identify potential areas for pharmacist optimisation of antimicrobial treatment. This inconsistency may be related to participants being influenced by one another during the discussion, and help to produce the rich and complex data linked to focus groups.

There were no dominating personalities and none of the group members were strong opinion leaders. Participant 23 did not participate much in the discussion, possibly because she felt that the potential of PP of

antimicrobials was not very relevant to her area of practice i.e. palliative care.

Location 5

All questions within the topic guide were covered during a focus group that lasted approximately 60 minutes. The discussion was lively with some members of the group agreeing strongly to PP, and others feeling that PP was not part of the role of the ward based clinical pharmacist. There were areas of disagreement during the discussion, most of which were not resolved, but resulted in participants speaking over each other or trying to convert one another to their point of view.

There were some complex dynamics in this group that were observed and documented by the assistant moderator. These are described as follows:

Participants 26 and 27 were very confident and engaged in conversation and discussion throughout. Both were assertive without being aggressive. Participant 28 had a very strong and dominant personality, often trying to convert others to his point of view. This was expressed through his body language which was at times observed to be aggressive and he interrupted and tried to shut down other speakers (particularly participants 26 and 27) who did not always agree with his point of view. Participants 31 and 32 did not contribute much to the discussion and did not appear to be confident and at ease within this particular group. Both participants were specifically offered an opportunity to contribute to the group, and participant 32 did participate more in the discussion following this, though she still remained ill-at-ease.

Location 6

All questions within the topic guide were covered during a focus group that lasted approximately 50 minutes. The focus group initially took the format of a group interview, with the participants taking it in turns to respond to questions asked by the moderator; but this soon developed into a discussion with the participants asking one another questions. Generally the pharmacists recounted their own experiences and thoughts adding on to

what the other participants were describing. The group did not appear to bias in favour of or against PP, with both the feasibility and value and the barriers to prescribing discussed.

Overall the discussion was a balanced discussion with all members of the group giving their views and opinions about the topic, with no dominant personalities and with no real areas of disagreement. There was no attempt by any member of the group to influence other members. Most of the members of the group were antimicrobial or infectious diseases pharmacists, and in this respect they were different from other focus groups held previously that were more heterogeneous. This led to the discussion being focused around antimicrobials and antimicrobial utilisation with little or no reference to other specialities.

Table 14: Characteristics of focus group participants

Participant	Sex	Speciality	Years as pharmacist	Years in speciality	SP status	Use of prescribing skills in day-to-day job
1	M	Medicine/Managerial	18	16	Yes	Through a diabetes clinic where patients are referred for control of hypertension; antihypertensive medication is prescribed according to the British Hypertension Society Guidelines 2004 and the local joint formulary
2	F	Medicine	18	5	Yes	As above
3	F	Sterile Production	22	6	On a SP course	Eventually planning to prescribe TPN for patients. Participant feels that "there is a definite need for the service in the hospital"
4	F	Woman and child health	17	10	No	
5	F	Surgery and Anaesthesia	12	5	Yes	Running of an abdominal aortic aneurysm clinic in collaboration with a nurse, aimed at optimising cardiovascular risk factor control. This may involve prescribing of statins, aspirin and beta blockers. Prescribing is against local protocols developed by the cardiologists and vascular surgeons
6	F	Renal	5	2	Yes	Not currently; but planning to prescribe once protocols have been established in areas related to anaemia associated with renal disease and renal bone disease

Participant	Sex	Speciality	Years as pharmacist	Years in speciality	SP status	Use of prescribing skills in day-to-day job
7	M	Cardiothoracic Unit	18	1	No	
8	F	Critical Care	22	5	No	
9	M	Renal	16	5	No	
10	F	Respiratory Medicine	7	4	Applied for course	Plans to use this to prescribe antimicrobials for cystic fibrosis outpatients
11	F	Endocrinology	11	4	No	
12	F	Antimicrobials	7	1	No	
13	F	Liver transplant/General Surgery	6	1	No	
14	F	Musculoskeletal	24	12	Yes	Yes, but not on a regular basis; sometimes writes up CMPs for individual patients
15	F	Neonatology, Obstetrics and Gynaecology	26	16	On a SP course	Adjusting doses of gentamicin and vancomycin and IV-to-oral switches as part of a prescription amendment policy on the neonatal unit
16	F	Renal vascular	32	7	Yes	Not used; held back due to approval of a divisional policy
17	F	Renal transplant	11	6	Yes	Not used; held back due to approval of a divisional policy
18	F	Acute Medicine	15	7	No	
19	F	Neurosciences	9	1.5	No	
20	F	Colorectal surgery	28	8	No	
21	F	Infectious diseases/HIV	20	12	No	
22	F	Medicine for the Elderly/Acute Medicine	6	3	No	

Participant	Sex	Speciality	Years as pharmacist	Years in speciality	SP status	Use of prescribing skills in day-to-day job
23	F	Palliative care	7	2.5	No	
24	F	Haematology	9	2.5	Applied for course	Plans to use this to prescribe chemotherapy and supportive treatment; does not plan to prescribe antimicrobials
25	F	Respiratory/Cardiac/ Cystic Fibrosis	11	4	On a SP course	Plans to use this to prescribe antimicrobials for cystic fibrosis outpatients and other medicines for other respiratory patients; though does not plan to start off with antimicrobials but with "more simple things"
26	F	Critical Care/Managerial	15	7	No	
27	F	General Surgery/Managerial	15	2	Yes	Not currently making use of prescribing qualification
28	M	General Medicine and Cardiovascular/ Managerial	25	15	On a SP course	
29	M	Gastroenterology/ Liver/Nutrition	12	4.5	Yes	Not currently making use of qualification but planning to use this in nutrition and methotrexate therapy for Crohn's patients
30	F	Managerial/Specialist Services	7	2.5	Yes	Planning to start a Roaccutane clinic in February 2007
31	F	Medical Admissions	2	6 months	No	
32	F	Infectious Diseases/Respiratory	4	8 months	Yes	Not currently making use of prescribing qualification
33	F	Infectious diseases/ HIV/ HCV/ Antimicrobials	20	19	On a SP course	

Participant	Sex	Speciality	Years as pharmacist	Years in speciality	SP status	Use of prescribing skills in day-to-day job
34	F	Academia/ Respiratory/ Infectious Diseases	20	17	No	
35	F	Antimicrobial utilisation	7	3	No	
36	F	Antimicrobial utilisation	21	3	No	
37	F	Acute Medicine/ Respiratory	14	9	Yes	Not currently making use of her prescribing skills

3.3.1.3 Background Survey

This survey was sent out to the participants at the recruitment phase and was aimed at providing information around PP, with two of the questions exploring PP of antimicrobials within the specific location as follows:

<p>a) Are you or any colleagues prescribing antimicrobials?</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>If yes, can you provide more details on what conditions you are prescribing for and what antimicrobials are involved?</p> <hr/> <hr/>
<p>b) Are there any PGDs (eg intravenous to oral route conversion) for antimicrobials in your department?</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>If yes, please list.</p> <hr/> <hr/>

Results to these two questions are summarised in Table 15. None of the pharmacists participating were SP antimicrobials at the time of discussion. Some pharmacists highlighted the availability of PGDs involving antimicrobials; many were aimed at nurse prescribing through the PGDs. Answers also included reference to some other policies and are described in the table below.

Table 15: Results of background survey

	Pharmacist supplementary prescribing of antimicrobials	PGDs available in hospital relating to antimicrobials	Other policies
1	No	<p>Nurse led PGDs:</p> <ul style="list-style-type: none"> • Administration of benzylpenicillin or clindamycin for management of streptococcal infection for women at childbirth • Administration of piperacillin with tazobactam in immunocompromised haematology and oncology adult patients with febrile neutropaenia not allergic to penicillin • Impression that this is underutilised by nurses on wards 	<ul style="list-style-type: none"> • Trust joint formulary policy for IV-to-oral switch
2	No	No	<ul style="list-style-type: none"> • Guidance of IV-to-oral switch set up and running parallel with an educational campaign
3	No	No	<ul style="list-style-type: none"> • Prescription amendment policy allowing pharmacists to change doses of gentamicin and vancomycin as part of TDM and IV-to-oral switches on a neonatal unit
4	No	No	No
5	No	<ul style="list-style-type: none"> • IV-to-oral switch PGD which seemed to be restricted to specialist departments such as ID • Not all pharmacists were aware of this 	No
6	No	<ul style="list-style-type: none"> • Nurse led PGDs involving the administration of ceftriaxone and flucloxacillin in cellulitis patients 	<ul style="list-style-type: none"> • Adjustment of aminoglycosides and dose adjustments of antimicrobials in cystic fibrosis patients on ICU

3.3.2 Pharmacists' perceptions of the barriers and challenges towards pharmacist supplementary and independent prescribing in secondary care

The aim of this phase of the research was to explore the pharmacists' perceptions of PP in secondary care with a focus on antimicrobials. Discussions focused mainly on general PP with antimicrobial examples provided where relevant. This same approach has been taken when describing the results. Therefore a description of findings about general PP is initially presented with specific antimicrobial examples provided where these were discussed.

It is worth noting that, in most focus groups, there was more extensive coverage of challenges and barriers as opposed to feasibility and value. Since these focus groups were conducted between July 2006 and January 2007, all participant prescribers or those in training were supplementary prescribers. Therefore discussions around SP drew mainly on the participants' own experiences. However, independent prescribing had not yet been introduced and discussions focused solely on participants' perceptions rather than their own experiences.

The results here are presented without any comments since these are considered and a discussion provided in Section 3.4. The categories and themes are organised according to Table 16 below. Extracts from the focus group discussions are provided to illustrate these themes.

Table 16: Categories and themes relating to barriers and challenges towards pharmacist supplementary and independent prescribing in secondary care

Category	Themes
Lack of management support	Lack of support to take on prescribing role Lack of planning to implement PP
Current working practices and processes	Lack of provision of a 24-hour service Lack of time spent on the ward Logistical issues
Lack of resource and capacity	Inability to sustain new services Lack of adequately trained pharmacists
Limitations of pharmacist SP	The clinical management plan
Concerns relating to pharmacist IP	Lack of pharmacist training to make a diagnosis
Issues within the pharmacy profession	Lack of pharmacist confidence Lack of evidence of clinical outcome of PP Concerns about increased responsibility and financial remuneration
Concerns relating to other healthcare professionals	Communication difficulties with other team members Deskilling of junior doctors Lack of support and professional rivalry
Concerns about patient safety	Risk if pharmacist prescribes
Concerns about training of pharmacist prescribers	Assessment of competencies and skills to prescribe Competencies of newly qualified pharmacists Experiences on SP training

3.3.2.1 Lack of management support for expanded role

The lack of management support was a major concern and was discussed at length during all focus groups. Two main themes emerged and are:

Lack of encouragement to take on a prescribing role

Pharmacists felt that there was a lack of communication and provision of information about prescribing courses by pharmacy management. There were no reports of discussion between pharmacy managers and practising pharmacists about potential prescribing roles within different specialties.

" ...^x I don't feel there is an awful lot of support for doing the course though, because you do get an email every six months, 'Who wants to go on the prescribing course?', and then about a month later you do get another

^x "... " at the start of a quotation indicates that there are words or dialogue before this excerpt in the original focus group transcript.

email, and it's usually all very short notice as well..."

(Female, non-supplementary prescriber, 20 years in pharmacy, 12 years in infectious diseases/HIV)

Therefore, the individual rather than the management was largely perceived as the main driving force, identifying a potential role for him/herself within the specialty.

" ... I was not particularly encouraged to do this [prescribing course].^{xi} I informed them that I wanted to do this and it was never suggested that I should do this or that it has ever been suggested to the rest of you..."

(Female, on SP course, 7 years in pharmacy, 4 years in respiratory medicine)

A pharmacist who was on the SP course felt that there was a lack of support in terms of study leave and protected time to complete essential elements of the course such as 'reflective essays' and 'the period of learning in practice.' The pharmacist therefore felt that completion of the course depended primarily on the individual's motivation.

" ... but again, in our department you get no time to do any study, no time off, study leave ... everything has to be done in your spare time. So it's not the most encouraging."

(Female, on SP course, 7 years in pharmacy, 4 years in respiratory medicine)

Some pharmacists commented that more resource was required to change working practices enabling pharmacists to take additional roles; management was perceived as not committed to provide this.

" ... because you have to have a commitment from management to allow you to do these things [attend regular ward rounds to prescribe]; and I think that's where we're in this fox [Sic]^{xii} at the minute where we don't know what we want to do or we know what we want to do but we don't know how to go about it."

(Female, non-supplementary prescriber, 15 years in pharmacy, 7 years in critical care/management)

^{xi} [] indicate words that were not actually spoken by the participant but have been added for clarity and to aid contextualizing the quotations.

^{xii} [Sic] this indicates that the preceding word has been written up as believed to be intended by the participant.

"I almost get the feeling that if you were to take on that role, that would be an add-on, you wouldn't get anything taken away from what you're already doing."

(Female, non-supplementary prescriber, 11 years in pharmacy, 4 years in endocrinology)

"Unfortunately, I think the department is quite negative in that you don't want to get people to expand because you know well next week you'll have their wards to cover as people are on holiday. They tend to look at the negative side of things; yes we're going to be stretched at some point so we're not going to offer the chance to do something else, we'll just keep it as is."

(Female, non-supplementary prescriber, 7 years in pharmacy, 1 year as antimicrobial pharmacist)

A pharmacist in a middle management role perceived higher management to have different priorities; pharmacy higher management was perceived as being keener and more motivated to manage risk and make efficiency savings rather than promote the development of the role of a specialist clinical prescribing practitioner. He goes on to comment that the fact that the directors of pharmacy are not themselves prescribers may discourage other pharmacists to take on a prescribing role.

"And there is no way on earth here our Director of Pharmacy or head of department in primary or secondary care will ever think about prescribing themselves, and to me, that is a barrier because it doesn't develop the kind of ethos in the environment and motivation within a group of staff to develop service in that way."

(Male, supplementary prescriber, 18 years in pharmacy, 16 years in medicine/managerial)

Pharmacists in two focus groups commented that the lack of financial rewards for a perceived increase in responsibility was a potential barrier.

"I think to be fair we'd end up becoming the cheap man's prescriber, if we're expected to be prescribing the same as most of the medical staff on

the ward and take the same responsibility ...^{xiii} but the wages might not even increase."

(Male, non-supplementary prescriber, 18 years in pharmacy, 1 year in cardiothoracic unit)

Pharmacists in focus group 6, who were antimicrobial specialist pharmacists, thought that there was no specific drive or incentive to encourage prescribing of antimicrobials unless this was part of a cost cutting exercise. Examples of such cost cutting were given and included, shorter bed stays due to optimisation of treatment, use of cheaper but as effective antibiotics and a better knowledge of interactions and potential adverse effects.

Lack of planning to implement PP

Most pharmacist non-supplementary prescribers expressed reluctance to go on the course unless there was a clear prescribing role identified within their specific area of practice.

" ... I've been asked several times 'Do I want to do it' and I've answered 'Well, not really because I don't know where I am going to use it.'"

(Female, non-supplementary prescriber, 21 years in pharmacy, 3 years in antimicrobial utilisation)

"I'd like to in the future but at the moment, it's hard to see how it would fit in with my current practice."

(Female, non-supplementary prescriber, 28 years in pharmacy, 8 years in colorectal surgery)

Both pharmacist supplementary and non-supplementary prescribers highlighted the fact that a significant number of pharmacists were not making use of their prescribing qualification due to the lack of planning to integrate the pharmacist prescribers within the multidisciplinary team. A pharmacist shared her experience as follows:

"When I did the SP course, my consultant is actually a general medical consultant, so it's actually very difficult to implement it in general medicine

^{xiii} "... " as part of a quotation indicates that in the original focus group transcript, the two extracts divided by the " ..." did not follow on directly but were separated by other words not in this quotation.

... so although I've got the qualification in theory, I've not done anything about it because I'm still waiting to see what role I can have."

(Female, supplementary prescriber, 14 years in pharmacy, 9 years in acute medicine/respiratory)

The pharmacists commented that management needed to have a clearer plan to enable the implementation of PP, prior to allowing pharmacists to enrol and complete any course.

"I think management are quite keen for us to do it, and to get more and more people, but what their final vision is, I have no idea."

(Female, on SP course, 11 years in pharmacy, 4 years in respiratory/cardiac)

" ... there was a big pressure from the centre to produce supplementary pharmacist prescribers, but there was less attention at the time to having a plan as to what they actually do once they became supplementary prescribers ... I suppose that's coming home to roost now and we've got an ever growing number of prescribers and it's not clear how they should practice or in what way they should practice."

(Male, on SP course, 25 years in pharmacy, 15 years in medicine/cardiovascular/management)

"I think people have been encouraged to go on the course with no direction where they're going to use it and maybe that's why people are not using it as soon as they qualify, because there's no direction at the moment."

(Female, supplementary prescriber, 15 years in pharmacy, 2 years in general surgery/management)

A pharmacist expressed her concern that a lack of utilising prescribing skills may lead to the practitioner forgetting what was learnt during the course. During the discussion, pharmacists tried to pinpoint why, in their view, management were keen to have pharmacists with a prescribing qualification despite no clear plan for its implementation. A middle management pharmacist (Participant 28) thought this was "a catch-up type role"; since the newly qualified pharmacists were perceived to now possess a prescribing qualification, pharmacy management were encouraging the more experienced specialist pharmacist to pursue this too. Having this larger number of pharmacist prescribers might then facilitate its

implementation. Another pharmacist perceived potential tensions with the nursing profession:

“I think another fear for management is that if we don’t do it now, then nurses are going to get in there and we are better placed to do it than nurses, so we need to be organized.”

(Female, on SP course, 9 years in pharmacy, 2.5 years in haematology)

3.3.2.2 Current working practices and processes

Lack of provision of a 24-hour service

This was highlighted at all focus groups as a barrier to the successful implementation of PP. Pharmacists thought that standard working hours covering 9am to 5pm only was a major barrier, particularly since there was currently no contingency to provide a PP service outside these hours. Outside a pharmacist’s working hours, prescribing would therefore need to be handed back to other healthcare professionals. As one pharmacist highlighted, providing such a service would need all pharmacists to be experienced prescribers thus able to provide 24-hour cover, which they deemed to be an unlikely scenario.

“ ... you could argue that the on-call service at the weekend would be able to go and prescribe, but at the moment, that would not happen because you would require all the pharmacists to be prescribers. I would imagine that is highly unlikely that everybody would be at the same level.”

(Female, supplementary prescriber, 12 years in pharmacy, 5 years in surgery/anaesthesia)

Participants noted that prescribing services were being built around individual practitioners rather than a team. This may also lead to problems with no one available to cover any absences needing to hand back to other healthcare professionals.

“I think one of the challenges in a small hospital would be, even if I was a supplementary prescriber and could prescribe antimicrobials what would happen when I wasn’t there? It wouldn’t be a team, therefore this

responsibility for prescribing would then have to pass on to another profession..."

(Female, non-supplementary prescriber, 21 years in pharmacy, 3 years in antimicrobial utilisation)

Lack of providing a 24 hour, seven day a week service was perceived as a particular barrier to pharmacists prescribing antimicrobials and was raised as an issue at all groups. Pharmacists distinguished between acute situations, where it was unlikely for a pharmacist to be available to prescribe antimicrobials, and less urgent scenarios, where a PP antimicrobials may be more feasible (see Section 3.3.3.1 for more details). Examples of the former included:

- (a) Emergency admissions requiring an antimicrobial to be started immediately

" ... when they [antibiotics] are getting prescribed, especially if they are IV's, if they [patients] are admitted as an emergency, often we are not always there at the point of admission when the decision [diagnosis] is actually made."

(Female, non-supplementary prescriber, 11 years in pharmacy, 4 years in endocrinology)

" ... often they come in out-of-hours and its sort of emergency, start first line antibiotics straight away ... they need to be started at 3 o'clock in the morning if that's when they're admitted which obviously doesn't suit pharmacy"

(Female, on SP course, 9 years in pharmacy, 2.5 years in haematology)

- (b) Following up recommendations from microbiology

" ... being there at the right time, so if a diagnosis comes through from Micro or from somewhere, they're not going to wait for the pharmacist to come to the ward; they're going to prescribe the antibiotics right there and then."

(Female, non-supplementary prescriber, 20 years in pharmacy, 12 years in infectious diseases/HIV)

(c) Providing a service to specialist areas

"I don't think you can do it [PP] in a specialist area like that [ICU] because they're [medical staff] there seven days a week."

(Female, non-supplementary prescriber, 15 years in pharmacy, 7 years in critical care/management)

Lack of time spent on the ward

Most pharmacists believed that they needed to spend regular and a substantial number of hours on the ward daily with attendance at ward rounds and with a contribution to decision making about prescribing. This would facilitate integration as prescribers within the ward-based clinical team.

"You can't just be popping into the wards; somebody will do the mornings and somebody the afternoons; the sporadic way we sometimes do wards as a pharmacist, you couldn't continue that practice if you are taking on more."

(Female, non-supplementary prescriber, 15 years in pharmacy, 7 years in critical care/management)

" ... [for successful PP] I think being an accepted part of the clinical team and not being perceived as somebody based in pharmacy or outside of the department in which they occasionally appear and more often than not disappear."

(Male, supplementary prescriber, 18 years in pharmacy, 16 years in medicine/manAGERIAL)

Logistical issues

Discussion in most focus groups questioned whether having a PP on a ward was actually necessary. This was suggested as there are often more medical staff than pharmacists on a ward and consequently medical staff were most likely to be on the ward at any one time. Therefore participants argued that, while in theory, a doctor diagnosing and a PP may seem like ideal, this is very difficult to implement logistically.

"It just is the practicalities of it really; if you and the doctor walk round the ward all day together, then that would work, but it doesn't work like that;

until there is one pharmacist per one ward and you're on the ward at every ward round and you're involved in everything."

(Female, on SP course, 7 years in pharmacy, 4 years in respiratory medicine)

A participant also viewed the fact that pharmacists are usually linked to a ward rather than a clinical team as another barrier, since this working practice did not provide an opportunity to follow up a patient on antimicrobials throughout their hospital stay. Another pharmacist mentioned that not all consultants may approve of a PP. Consequently if SP, it may be difficult to filter out which patients to prescribe for. This may be a particular issue for example, if the pharmacist has taken over the prescribing of a specific drug such as vancomycin since they would be able to prescribe for patients under the care of one consultant but not those under the care of another.

3.3.2.3 Lack of resource and capacity

Inability to sustain new services

This theme emerged at all focus group discussions. Most pharmacists thought that there were a relatively small number of pharmacist prescribers when compared to other healthcare professionals. Many were already stretched for time to cope with their current workload so they would need additional support to take on any new roles.

"It would always be the resources of having enough people to take on an extra role over and above what you are already doing."

(Female, on SP course, 11 years in pharmacy, 4 years in respiratory/cardiac)

"... we're so pushed for time probably we would need to have more support ... I mean you wouldn't get your basic work done on a day-to-day basis."

(Female, non-supplementary prescriber, 7 years in pharmacy, 1 year as antimicrobial pharmacist)

A pharmacist commented that finding and recruiting pharmacists to maintain current services was already a struggle so it would be difficult to recruit and retain more pharmacists. Securing funding for new posts was also a major barrier.

This small number of pharmacists, and indeed the lower number in any speciality have shaped the way in which prescribing roles are developing. To enable sustainability of a service with manageable patient numbers, pharmacists reported prescribing in smaller areas of practice or in clinics on a sessional basis. They also reported that this lack of resource makes it unlikely for their role to be covered if away.

" ... possibly the biggest barrier for us at the moment is sustaining service where we developed it around prescribing, so that's why we haven't gone for admissions areas, we've gone for small-scale areas where we know the patients' cases are manageable."

(Male, supplementary prescriber, 18 years in pharmacy, 16 years in medicine/managerial)

Participants feel that this may be even more pronounced with antimicrobials, where it is likely that there will be large numbers of patients prescribed antimicrobials at any one time.

"At any one time how many patients are there likely to be on antimicrobials? That workload could be just overwhelming to the extent that would be what was concentrated on as opposed to some other things."

(Female, supplementary prescriber, 12 years in pharmacy, 5 years in surgery/anaesthesia)

To enable sustainability of a service involving PP of antimicrobials within the current resources, it would be necessary to target patients rather than review all patients.

" ... with the throughput of patients and the number of pharmacists versus the number of patients who are likely to be on antimicrobials, it could make things very difficult unless you have a way of targeting patients who need your more specific help or advice..."

(Female, supplementary prescriber, 12 years in pharmacy, 5 years in surgery/anaesthesia)

For pharmacists to take on prescribing on wards, they highlighted that they would need to closely monitor spending more time on wards. However, this may not be an option with current staffing levels.

" ... we would need to have enough staff so that the pharmacist would be at the ward round and be very closely involved with what's happening to the patient and it would just not be possible with the current resources."

(Female, non-supplementary prescriber, 20 years in pharmacy, 12 years in infectious diseases/HIV)

It was thought that the larger numbers of nurses facilitated more sustainability of services and consequently they have been able to take on areas of care with larger numbers of patients.

" ... one pharmacist, as well as their own jobs, small roles, bite size little pieces; we're not going to capture volumes of patients; we don't have the resource like nursing have where they just see volumes of patients."

(Female, supplementary prescriber, 7 years in pharmacy, 2.5 years in specialist services/management)

Lack of adequately trained pharmacists

This potential barrier was brought up during one discussion, where one pharmacist was concerned that there may not be sufficiently trained pharmacists to deal with the more complex patients requiring antimicrobials.

"Are we able to provide the workforce to fit into those roles, to treat those more complex patients, as rapidly as the legislation is changing to enable to prescribe? So the workforce itself could be perceived to be a barrier, the number of available pharmacists with those skills to treat those complex patients."

(Male, supplementary prescriber, 18 years in pharmacy, 16 years in medicine/managerial)

3.3.2.4 Limitations of pharmacist supplementary prescribing

The Clinical Management Plan

The CMP as a requirement of SP was viewed as a major barrier to the implementation of SP in secondary care and was a theme discussed at every focus group. Pharmacists thought that it would be very time consuming to draw up a CMP for every patient for whom the supplementary prescriber was planning to prescribe. The large patient turnover would imply

having many CMPs which could take up a substantial part of a prescriber's day. Pharmacists believed that this may not be a good use of resource particularly since patients are likely to be in hospital only for a short period of time.

" ... trying to get an individual CMP for every single patient, then if they were almost in for two or three days; that's the biggest hurdle."

(Male, on SP course, 25 years in pharmacy, 15 years in medicine/cardiovascular/management)

" ... but I think that you would spend all day doing paperwork just to prescribe something; whereas you might just discuss it and get somebody else to prescribe it."

(Female, on SP course, 7 years in pharmacy, 4 years in respiratory medicine)

" ... we can't generate CMPs every time patients are admitted because we are not there or simply because the throughput of patients is too high."

(Male, supplementary prescriber, 18 years in pharmacy, 16 years in medicine/managerial)

Agreeing the CMP with the prescriber is another step in the process which extends the time required to complete a CMP. One pharmacist was concerned that this would cause a delay in patients accessing their medicines, when compared to the current prescribing processes.

"Giving patients access to skills and medication as well is another aspect of it; if you're waiting for a CMP, in any area to be agreed with the consultant"

(Male, supplementary prescriber, 18 years in pharmacy, 16 years in medicine/managerial)

"The time involved to sit down and draw up a CMP and agree with the consultant about the patient."

(Female, non-supplementary prescriber, 6 years in pharmacy, 3 years in medicine/geriatrics)

Some pharmacists thought that obtaining patient consent may be a problem in some areas of secondary care which also made using a CMP in an acute setting a challenge.

“If the patient is very ill you don’t want to be putting a form in front of them saying “Sign this”, they don’t know what their treatment is, so it’s difficult in an acute setting...”

(Female, supplementary prescriber, 15 years in pharmacy, 2 years in general surgery/management)

Pharmacists believed that when developing a CMP for an individual patient, it would be difficult to envisage all eventual potential requirements particularly in an acute setting where there may be a rapid change in a patient’s condition. This would require regular review of the CMP.

“It is not hugely practical; it’s not practical in secondary care, I would say, because you can’t envisage every possibility.”

(Female, supplementary prescriber, 14 years in pharmacy, 9 years in acute medicine/respiratory)

This was also deemed to be the case with antimicrobials where patients may be admitted for an acute infective episode. Overall, the CMP was viewed by participants as being more suited for chronic conditions as indicated by the period of review required as part of the plan. Some pharmacists recommended developing generic CMPs for the management of specific conditions to overcome some of these barriers highlighted above. This may lend itself particularly well to an area such as antimicrobials, where the plans may be based on the hospital’s antibiotic policy. However, they believed that whereas this may be an option for standard treatments such as surgical prophylaxis, it may be difficult to implement for more complex conditions and patients.

“The problem is as well, there’s going to be so many individual patients, you’ve got to think about allergies, what they’ve had before they’ve come in with cellulitis; you can’t have a standard cellulitis management plan.”

(Female, supplementary prescriber, 4 years in pharmacy, 8 months in respiratory/infectious diseases)

3.3.2.5 Concerns relating to pharmacist independent prescribing

Lack of pharmacist training to make a diagnosis

Pharmacists, whether supplementary prescribers or not and in all locations felt that they were not adequately trained to make a diagnosis, when

compared to the medical profession. This was despite the additional training as part of the independent prescriber's curriculum.

"It took five years of medical school, there must be some point to that; so how are we suddenly going to be able to diagnose?"

(Female, non-supplementary prescriber, 21 years in pharmacy, 3 years in antimicrobial utilisation)

"They [bodies involved in setting up the IP curriculum] must assume you're a doctor then! You can't just train someone to diagnose and say that's the same as seven years of medical school. Ridiculous."

(Female, non-supplementary prescriber, 15 years in pharmacy, 7 years in acute medicine)

"I think we would have to take extra training, apart from the straight forward things."

(Female, on SP course, 26 years in pharmacy, 16 years in neonatology/obstetrics)

"If you are going to be an independent prescriber, should you just go and train as a doctor to start with which I personally never wanted to do; I did not want to be a diagnostic person; I don't know how others feel about that; so I don't know how much training; but years and years."

(Female, non-supplementary prescriber, 22 years in pharmacy, 5 years in critical care)

Some pharmacists commented that although making a diagnosis in a community pharmacy may be feasible, this would not necessarily translate to the hospital setting.

"Especially [prescribing without a diagnosis] in hospital because they are sicker, not like OTC for community pharmacy, when you can do straight forward simple diagnosis."

(Female, on SP course, 9 years in pharmacy, 2.5 years in haematology)

Some pharmacists thought that further specialist training in making a diagnosis would be required, particularly if prescribing antimicrobials.

“Because infection is a bit more complicated than that; sometimes they wouldn’t have been diagnosed with infection in terms of what they’ve had before ... we’re not trained to [prescribe without a diagnosis].”

(Female, non-supplementary prescriber, 7 years in pharmacy, 3 years in antimicrobial utilisation)

“Are we able to provide the workforce to fit into these [prescribing] roles, to treat those more complex [HIV] patients, as rapidly as the legislation is changing to enable to prescribe?”

(Male, supplementary prescriber, 18 years in pharmacy, 16 years in medicine/managerial)

A lack of skills to assess the severity of the patient’s illness particularly with limited information was perceived by some pharmacists as a further limitation to the pharmacist independently prescribing antimicrobials in hospital.

“I think it would be difficult for us from a point of view of how ill a patient is and what [antimicrobials] they require to be treated with, because that is really the medical staff’s assessment of how unwell a patient is and whether they require intravenous, whether they require a larger dose, whether its just oral, whether its topical.”

(Female, supplementary prescriber, 7 years in pharmacy, 4 years in respiratory medicine)

“ ... but it’s the actual knowing of whether it warrants it or not, say you have no bloods, no sensitivities, nothing and someone just presents at a routine clinic appointment feeling a bit chesty.”

(Female, supplementary prescriber, 7 years in pharmacy, 4 years in respiratory medicine)

3.3.2.6 Issues within the pharmacy profession

Lack of pharmacist confidence

The lack of individual pharmacist’s confidence was viewed as a barrier by both some prescribing and non-prescribing pharmacists.

“I think pharmacists in general are a very cautious breed. I think it might be that we’re not confident [to prescribe]; we’re used to being behind the desk or behind a book or something.”

(Male, non-supplementary prescriber, 18 years in pharmacy, 1 year in cardiothoracic unit)

Specialist antimicrobial pharmacists believed that this lack of confidence may be more pronounced with antimicrobials.

“ ... some pharmacists find antimicrobials quite scary to prescribe and much more difficult than anything else that they would normally do.”

(Female, non-supplementary prescriber, 20 years in pharmacy, 17 years in respiratory/infectious diseases)

“I think general pharmacists wouldn't be keen to prescribe antimicrobials because they wouldn't feel confident doing that”

(Female, non-supplementary prescriber, 21 years in pharmacy, 3 years in antimicrobial utilisation)

This view was reiterated by others who perceived this lack of confidence as a reflection of the novelty of this expanded role and a fear of the perceived increase in responsibility the role may bring with it.

“I don't know, maybe in 10 years' time it might be a quite different conversation. We all seem very nervous, I suppose it's new, maybe that would change with a bit of experience.”

(Female, non-supplementary prescriber, 20 years in pharmacy, 12 years in infectious diseases/HIV)

“ ... that's [prescribing] quite a step to take because we've always got a barrier there; there's a doctor there who signs it although we might take 50% of the responsibility if we give bad advice or we write something wrong or that sort of thing, there's always a nice little buffer zone there.”

(Male, non-supplementary prescriber, 18 years in pharmacy, 1 year in cardiothoracic unit)

Another pharmacist thought this lack of confidence is a reflection of a pharmacist's undergraduate training and lack of experience in prescribing.

“I don't think pharmacists are trained to be confident to deal with that [prescribing]; I think we'd build up confidence when we're working.”

(Male, non-supplementary prescriber, 18 years in pharmacy, 1 year in cardiothoracic unit)

Pharmacists thought this may change due to the changes in pharmacist training which incorporate more prescribing in the undergraduate curriculum.

"I do think that pharmacists who are newly qualified may not think in the same way we feel; they may be more confident because they've done their training stuff at an earlier stage than we would have."

(Female, non-supplementary prescriber, 11 years in pharmacy, 4 years in endocrinology)

"The new generation, prescribing is a big deal to us, but it's not going to be a big deal to them."

(Female, non-supplementary prescriber, 15 years in pharmacy, 7 years in acute medicine)

Some other pharmacists were concerned that some of the newly graduated pharmacists may however be too overconfident and this may result in them not appreciating the extent of training and experience required to prescribe safely.

"... there will always be some who are just a bit too cocky and that's a scary thought. So they're the ones who might go 'Oh yes, that's fine. I'll prescribe everything' without the practical or the clinical experience."

(Female, non-supplementary prescriber, 6 years in pharmacy, 3 years in acute medicine/geriatrics)

"... you could have inappropriate people who are full of confidence thinking that they are great supplementary prescribers and inexperienced as well."

(Female, non-supplementary prescriber, 22 years in pharmacy, 5 years in critical care)

Lack of evidence of clinical outcomes of pharmacist prescribing

This theme emerged at several of the focus group discussions. One pharmacist argued that to be an integral part of the clinical team and take on a prescribing role, the prescribing pharmacist needed to be seen as a resource who would add benefit to patient care. To gather support for the implementation of PP in secondary care, she stated that there was a need to prove that it would add value to patient care.

" ... at the end of the day, people are not going to lay out any money whatsoever if they don't see it [PP] as beneficial to patient care."

(Female, on SP course, 26 years in pharmacy, 16 years in neonatology/obstetrics)

Participants in a focus group felt that the pharmacy profession did not always take the right approach to proving its worth. This highlighted that rather than measuring outcome in terms of improvement in patient care, pharmacists measure outcome in terms of cost reduction or try to demonstrate superiority to other professional rivals. This was perceived to be a barrier to the expansion of PP in secondary care since it had resulted in a lack of evidence of clinical outcomes for PP.

" ... there's always a focus on demonstrating that we're improving things in pharmacy, demonstrating that we're worth investing in ... I don't think we should always necessarily need to demonstrate that we're better than other professional groups ... I don't think you've got to demonstrate that you're better as a pharmacist than a nurse or better as a nurse than a medic."

(Male, supplementary prescriber, 18 years in pharmacy, 16 years in medicine/managerial)

Concerns about increased responsibility and financial remuneration

This theme was discussed mainly in focus group two. Pharmacists here perceived prescribing as implying an increase in responsibility and appeared reluctant to take this on without any financial remuneration.

"We were actually discussing this, and whether it would come down to financial incentives, and also legal, medico-legal insurances to cover if you were an independent prescriber."

(Female, non-supplementary prescriber, 22 years in pharmacy, 5 years in critical care)

3.3.2.7 Concerns relating to other healthcare professionals

Communication difficulties with other team members

Although this issue was not discussed at all focus groups, there were lengthy discussions when the issue was raised, with pharmacists drawing on their current experiences as ward based pharmacists. A lack of documentation by physicians in medical notes was thought to make it

difficult for a pharmacist to monitor the patient's progress, such that prescribing may become an option only if the pharmacist prescriber is an integrated part of the multidisciplinary team.

"That's where all these problems come together, in communication. Doctors are insisting on having communication on their ward round so that way they communicate with each other, whereas the way they communicate with the rest of the hospital is in silence! Half a dozen words in the notes and you're meant to try and interpret, to try and read ... Among all these problems that we're talking about, the common big thing in the middle is poor communication."

(Male, supplementary prescriber, 12 years in pharmacy, 4.5 years in gastroenterology/liver/nutrition)

A pharmacist suggested potentially managing only certain infections which are protocol regulated, such as urinary tract infections. Other pharmacists thought this practice may lead to confusion on the ward since it would be difficult for the pharmacist prescriber to have a defined role and ensure the wider team is aware of this. One pharmacist shared a different experience where lack of communication was due to other members of the team not reading the patient's medical notes on a weekend resulting in the patient receiving inappropriate therapy.

" ... So with the best will in the world, you sit down, go through it, you document it all, and yet still."

(Female, supplementary prescriber, 24 years in pharmacy, 12 years in musculoskeletal)

Some discussions raised the issue of communication difficulties with the microbiology department in relation to decision-making and a potential lack of defined roles and responsibilities within the team. Participant experiences resulted in a mixture of positive and negative descriptions of team-working with the latter being more common. Most felt that microbiologists did not take a holistic approach when giving advice being only concerned with the choice of drug. There was also an inconsistent approach from one individual microbiologist to another. Consequently, it was considered more appropriate for a pharmacist to take recommendations from microbiology. A

prescribing pharmacist was thought to be better placed to prescribe than more junior doctors who were unlikely to challenge any recommendations made.

“The advantage of a pharmacist taking advice from Micro is that I think, sometimes if you’ve got junior doctors they tend to take ‘Oh, microbiology said prescribe vancomycin 1g twice a day.’ ‘Yes but the patient’s 40kg and a renal function of ... just change the dose!’ If they just choose the drug without being so specific and then as pharmacists ‘Yes OK, I’d take the drug on board and I’ll think about the dose myself.’ ”

(Female, non-supplementary prescriber, 6 years in pharmacy, 3 years in medicine/geriatrics)

“They don’t ask basic questions; that’s what concerns me; because I had a call from one of the SHOs nervous about dosage, fluconazole 12mg/kg and the microbiologist hadn’t asked the liver function.”

(Female, non-supplementary prescriber, 15 years in pharmacy, 7 years in acute medicine)

Deskilling of junior doctors

Pharmacists in some of the focus group discussions expressed their concern that should they take on prescribing roles, medical staff might miss the opportunity to learn safe and effective prescribing. This knowledge would be required at least out of hours and on weekends where it was thought unlikely for a prescribing pharmacist to be available.

“There’s a risk of them being deskilled as well, they just think, ‘Oh I don’t need to know about antibiotics, the pharmacist will think about it.’ So they are then in a situation where they do have to think about it and they don’t know what they should be prescribing.”

(Female, non-supplementary prescriber, 21 years in pharmacy, 3 years in antimicrobial utilisation)

“Changing doses could be certainly [a role for the pharmacist prescriber] but as we keep saying, the whole education thing would be an issue, but that would be possible, and it is the sort of thing we would do just now though we go to the doctor and say “This dose is wrong, can you sign this please?”

(Female, on SP course, 9 years in pharmacy, 2.5 years in haematology)

"It needs to be us on a daily basis actually making them [educating doctors]; perhaps that will be worst if we become independent prescribers because if you're an independent prescriber, and they've made a balls of the Kardex; ... you would change it so you wouldn't actually get them to correct their own mistake."

(Female, supplementary prescriber, 32 years in pharmacy, 7 years in renal vascular)

Lack of support and professional rivalry

Some pharmacists felt there was a lack of support and acceptance of their expanded role from doctors and professional rivalry, mainly from nurses.

"So I think some areas there will be the confidence issue, with the medics thinking, 'Does the pharmacist know about the individual patient to be able to take on this role?'"

(Female, non-supplementary prescriber, 15 years in pharmacy, 7 years in critical care/management)

The pharmacist further highlighted that doctors may perceive nursing staff better placed to take on a prescribing role due to there being traditionally more contact between a patient and a nurse. This was notwithstanding the fact that pharmacists may be more knowledgeable from a pharmacology perspective compared to nurses. One pharmacist thought that any pharmacist prescriber would be more closely monitored.

" ... there would be a lot of scrutiny as to your prescribing habits and if mistakes were made, I think you would come under more criticism than if a doctor."

(Female, non-supplementary prescriber, 9 years in pharmacy, 1.5 years in neurosciences)

A pharmacist in another discussion was in disagreement and perceived doctors as likely to support pharmacists rather than nurses to take on a prescribing role.

"I've spoken to some medics and I've read things in some papers and journals ... I do get a gist where if you've got to toss up between a nurse

and a pharmacist doing some prescribing, the medical establishment are far happier or are not too bothered for a pharmacist but are a bit concerned if nurses have to do it."

(Male, non-supplementary prescriber, 18 years in pharmacy, 1 year in cardiothoracic unit)

A specialist antimicrobial pharmacist also believed that this would apply if pharmacists were to prescribe antimicrobials.

" ... the Scottish Microbiology Forum, they actually put in a complaint in that they didn't want nurses doing SP because they didn't want another group [prescribing antimicrobials], they said they were OK with pharmacists SP, but they didn't want nurses to be SP antibiotics, because they reckon there would be a massive over-prescribing of antibiotics."

(Female, on SP course, 20 years in pharmacy, 19 years in infectious diseases)

A perception that professional rivalry may be an issue was brought up by some pharmacists who viewed nurses as direct competitors who could take on PP jobs. Nurses and their management were perceived as more pro-active than their pharmacy counterparts and had already identified areas of care with a potential for a non-medical prescribing role.

"So the nursing profession I think are jumping ahead to do this [prescribe]. But again, I think they have a head start because they are more in your face, they are more high profile and they would do these things because there are many of them."

(Male, non-supplementary prescriber, 18 years in pharmacy, 1 year in cardiothoracic unit)

Some pharmacists thought that doctors may be a barrier, since having a pharmacist prescribe may be perceived as an encroachment on a doctor's traditional role, particularly if independently prescribing.

"I wonder if it would be a challenge with doctors accepting PP if they've always done it."

(Female, non-supplementary prescriber, 20 years in pharmacy, 12 years in infectious diseases/HIV)

“I think it would be more acceptable to the medical staff, they would accept us more, maybe they would have more confidence if they had diagnosed, and we would just take it on from there, than have the pharmacist out there to diagnose.”

(Female, supplementary prescriber, 14 years in pharmacy, 9 years in acute medicine/respiratory)

3.3.2.8 Concerns about patient safety

Risk if pharmacist prescribes

Pharmacists viewed themselves as currently having a major role in ensuring patient safety through clinically checking medication prescribed for inpatients at ward level. If a pharmacist prescribed for an inpatient, though the chart would be reviewed by many other members of the team, no-one would carry out a clinical check in the same manner as the pharmacist would. This, in the view of the participants, might be an additional risk and compromise patient safety.

“One of my concerns, both supplementary or independent, at the moment when a junior doctor prescribes, or any other doctor prescribes, we are clinically checking, so we’re checking that the dose is appropriate. Nobody is checking us. You’ve not got a double check. OK, you might be competent, but everybody can make a mistake but nobody is checking that. There’s nothing in place for that.”

(Female, supplementary prescriber, 15 years in pharmacy, 2 years in general surgery/management)

“I mean one of our major roles in this hospital is to reduce clinical risk and that is checking prescribing, and if we’re expected to do a lot of the prescribing, its not controlled ... who is going to check that person, and that’s my concern.”

(Female, non-supplementary prescriber, 15 years in pharmacy, 7 years in acute medicine)

Where a pharmacist was prescribing, organizational systems seem to be in place to ensure that discharge prescriptions were checked by a second pharmacist and consequently, pharmacists were not so concerned about patient safety. One pharmacist, however, raised the issue that safety may

be compromised if the checking pharmacist does not specialise in the same area of practice as the prescribing pharmacist.

“Because we have that scenario down in oncology at the moment, I mean I don’t feel competent in oncology at all, and I’m doing the professional check that the prescription is appropriate ... but you’re checking a pharmacist who works in that area ... so that has taken us back one step safety wise I think, by having the PP, if we don’t then think how we are able to then have a double check on their work.”

(Female, non-supplementary prescriber, 15 years in pharmacy, 7 years in critical care/management)

3.3.2.9 Concerns about training of pharmacist prescribers

Assessment of competencies and skills to prescribe

Discussions in some groups focused around the areas of competence that a pharmacist prescriber would need to have to ensure safe prescribing.

“So you can’t let loose anybody in that kind of environment without the appropriate training or peer review before they are enabled to do that. So demonstrating competency, I think is really essential in our hospital environment with acute, severely ill patients if we are going to be independent prescribers.”

(Male, supplementary prescriber, 18 years in pharmacy, 16 years in medicine/administration)

However, pharmacists perceived that it may be a challenge to demonstrate such competencies, since these are based on self-assessment and on recognition of gaps in knowledge by the prescribing pharmacist.

“It’s one of those things, a gap in your knowledge, how do you know that you’ve got a gap?”

(Female, non-supplementary prescriber, 15 years in pharmacy, 7 years in critical care/management)

“How are you going to prove competencies; it’s not part of knowledge service framework, it’s not part of agenda for change so if you’re doing performance appraisals in line with knowledge service framework, then prescribing is not in there. Then how do you prove competencies?”

(Female, supplementary prescriber, 11 years in pharmacy, 6 years in renal transplant)

This led on to discussions about professional obligation where the pharmacist must recognise their own competencies and their own limitations.

“You would be able to demonstrate that you have a professional competence in the area in which you worked; so ... if a pharmacy manager says ‘I want you now to go in dermatology and be a supplementary prescriber,’ then you have a professional obligation to say to them, ‘Well, I can’t do that because I don’t have the necessary skills or knowledge or the competency to do that.’ ”

(Male, on SP course, 25 years in pharmacy, 15 years in medicine/cardiovascular/management)

Being based on self-assessment, pharmacists expressed their concerns about the risks of over-confidence, which may lead to a few pharmacists prescribing outwith their skills and competencies.

“My understanding of it is you yourself judge whether you are competent and you know, some people are very critical, some people think they’re wonderful.”

(Female, non-supplementary prescriber, 15 years in pharmacy, 7 years in acute medicine)

“I think there will be a few of us who will be taking care; a few of us would want to go into a territory where we don’t feel comfortable.”

(Female, supplementary prescriber, 26 years in pharmacy, 16 years in neonatology/obstetrics and gynaecology)

Competencies of newly qualified pharmacists

Some pharmacists expressed their concern about newly qualified pharmacists taking on prescribing roles. Despite the fact that they were perceived as having a prescribing qualification, this would not necessarily indicate that they were sufficiently specialised to take over these roles. This might be more of an issue with the introduction of IP.

“I think they [newly qualified] have to acknowledge that they have to get plenty of practice based experience behind them and that they really only have got the qualification on paper at the moment.”

(Female, applied for SP training, 9 years in pharmacy, 2.5 years in haematology)

Numerous issues were raised which might need to be considered and resolved; for example, the grade and years of experience when a pharmacist may take on prescribing roles.

“But with the newly qualified pharmacists coming out with a prescribing qualification ... What training and what has to be in place before they can actually take these roles on?”

(Female, supplementary prescriber, 7 years in pharmacy, 2.5 years in specialist services)

Experiences on supplementary prescribing training

Issues around experiences related to SP training were raised at one focus group although there was very little discussion. One pharmacist commented that the “theoretical” assessments as part of the course were not in any way related to her area of practise and expertise:

“The problem when I did the course was I picked medical because there really wasn’t an area where I would be prescribing on the course, so it wasn’t relevant to the area.”

(Female, supplementary prescriber, 15 years in pharmacy, 2 years in surgery/managerial)

3.3.3 Pharmacists’ perceptions of the feasibility of pharmacist supplementary and independent prescribing in secondary care

This section describes pharmacists’ perceptions of the feasibility of pharmacist supplementary and independent prescribing in secondary care. As in section 3.3.2, discussions around SP drew mainly on the participants’ own experiences. However, at the time of this study, IP had not yet been introduced and discussions focused solely on participants’ perceptions rather than their own experiences. Again as in section 3.3.2, a description

of findings about general PP is initially presented with specific antimicrobial examples provided where these were discussed.

The results here are presented without any comments since these are considered and a discussion provided in section 3.4. The categories and themes are organised according to Table 17 below. Extracts from the focus group discussions are provided to illustrate these themes.

Table 17: Categories and themes relating to feasibility of pharmacist supplementary and independent prescribing in secondary care

Category	Themes
Feasibility dependent on environment of practice in secondary care	Feasibility dependent on patient's clinical condition Feasibility dependent on areas of clinical care
Pharmacists' perceptions of the advantages of PP	Perceived advantages of PP of antimicrobials Perceived advantages of pharmacist SP Perceived advantages of pharmacist independent prescribing
Issues within pharmacy profession	Pharmacy management support to take on prescribing role
Issues around other healthcare professionals	Acceptance of the pharmacist prescriber by the medical profession A need to work within a multidisciplinary team

3.3.3.1 Feasibility dependent on environment of practice within secondary care

The feasibility and potential for PP was largely attributed by the participants to the clinical environment of practice with discussions around this arising during all focus groups.

Feasibility dependent on patient's clinical condition

Pharmacists, irrespective of whether supplementary or non-prescribers, felt that there was a greater challenge when implementing non-medical prescribing in acute care, where the patient's condition is rapidly changing. Pharmacists therefore perceived that prescribing for patients with chronic conditions in secondary care may be more feasible.

“I don’t think it’s [PP] really been designed for inpatients; I think [prescribing is feasible] in the outpatient setting, where they are not acutely unwell, [or] chronic conditions where they will be reviewed”

(Female, non-supplementary prescriber, 11 years in pharmacy, 4 years in endocrine)

Since in-patients requiring antimicrobials were usually very sick and required immediate intervention, participants thought that this may be more pronounced due to the nature of antimicrobial treatment

“A lot of [antimicrobial] prescribing there [secondary care] is probably acute, initially when they have their diagnosis, so I don’t know you would necessarily see much of a role there.”

(Female, non-supplementary prescriber, 11 years in pharmacy, 4 years in endocrinology)

Chronic conditions were linked to more stable patients, mainly in outpatient settings and it was here that participants believed pharmacist prescribers could play a role in managing antimicrobial treatment.

“ ... in-patients, it’s usually an emergency, during the night you’re going to get prescribed antibiotics, and we’re not here, whereas out-patients is planned work.”

(Female, non-supplementary prescriber, 7 years in pharmacy, 3 years in antimicrobial utilisation)

Numerous clinical examples of specific chronic conditions where pharmacist antimicrobial prescribing may be feasible were given throughout the discussions. Often, no distinction was made between pharmacist supplementary or independent prescribing. These are summarised in Table 18.

Table 18: Clinical examples of chronic conditions where pharmacist antimicrobial prescribing may be feasible

Condition	Illustrative quote
HIV patients	<p>“So I do think more stable [HIV] patients could be managed by a pharmacist, and again in an out-patient setting ... that’s an area where I think a pharmacist supplementary prescriber could make a contribution.” (Female, non-supplementary prescriber, 21 years in pharmacy, 3 years in antimicrobial utilisation)</p>
Bronchiectasis patients	<p>“XXX doing her bronchiectasis clinic, that’s a completely different situation altogether [compared to in-patients] ... she’ll need to run the prescribing of the appropriate antibiotics and other treatment.” (Female, supplementary prescriber, 11 years in pharmacy, 6 years in renal transplant)</p>
Cystic fibrosis patients	<p>“It would probably work for the kind of [cystic fibrosis] out-patients we have, they come and they know what’s wrong with them, we know what’s wrong with them, so they get antibiotics every 3-4 months, so it would probably work for that situation if I was around.” (Female, on SP course, 11 years in pharmacy, 4 years in respiratory/cardiac)</p> <p>“I think we have a role in chronic patients ... because we deal with patients that have repeat courses of IV antibiotics on a regular basis ... it’s just that the patients do need their antibiotics particularly cystic fibrosis [patients] and I don’t see any reason why we can’t [prescribe] in these cases.” (Female, supplementary prescriber, 7 years in pharmacy, 4 years in respiratory medicine)</p>
Out-patient antibiotic clinics	<p>“I work in an antibiotic clinic ... these [patients] are prescribed antibiotics and we’re changing them from what they are in hospital to what they would be on as an outpatient, and there’s a potential role there.” (Female, non-supplementary prescriber, 7 years in pharmacy, 3 years in antimicrobial utilisation)</p>
Antibiotic prophylaxis	<p>“You could certainly have a role in prescribing prophylactic antibiotics if you have a set policy with different surgical procedures and just making sure that they are only prescribed for a number of doses rather than continued for 48 hours or 96 hours or whatever.” (Female, non-supplementary prescriber, 7 years in pharmacy, 1 year in antimicrobials)</p> <p>“I think possibly in my area [haematology], the prophylaxis could be omitted, or extra antimicrobials are prescribed when they’re not actually required, so you could possibly do it [prescribe] there, but for treatment I think, it would be a lot more difficult.” (Female, on SP course, 9 years in pharmacy, 2.5 years in haematology)</p> <p>“Probably there’s quite a role in prophylactic surgery, ensuring that it was actually prophylactic and stopped.” (Female, non-supplementary prescriber, 20 years in pharmacy, 17 years in respiratory/infectious diseases)</p>

Feasibility dependent on areas of clinical care

(a) Ward type

Pharmacists thought that the practice setting where PP was to be implemented could influence whether this was feasible. A distinction emerged between general medical wards and high dependency units such as the intensive care unit (ICU) and the coronary care unit (CCU). Pharmacists perceived that there may be less scope for PP in the latter practice setting due to the constant presence of more senior and more specialised medical staff. With prescribing on general wards being the remit of the more junior doctors, the potential need for input from pharmacist prescribers might be greater.

“I wouldn't see myself doing much prescribing in the CCU because a senior doctor's there all the time; it's a different setting but up on the general wards it's a bit free for all; there's much less senior input; in fact there's a serious lack of it so there's a much bigger potential in that sort of area as opposed to a high dependency, heavily staffed [units].”

(Male, on SP course, 25 years in pharmacy, 15 years in medicine/cardiovascular/management)

Another pharmacist, drawing on her experiences, perceived implementation of PP within outpatient clinics or in specialities as the more feasible practice settings when compared to general ward areas.

“When I did the supplementary prescribing course, my consultant is actually a general medical consultant, so it's actually very difficult to implement it in general medicine; it's more appropriate within a speciality or within a clinic session.”

(Female, supplementary prescriber, 14 years in pharmacy, 9 years in acute medicine/respiratory)

Examples of potential pharmacist-led outpatient clinics were given by the other participants and included reviewing of hypertension medication or primary prophylaxis of myocardial infarction and stroke within a diabetes clinic.

“Within the diabetes clinic, then there is scope for reviewing their hypertension medication, or their renal and cholesterol monitoring or effective at prevention of MI/stroke; that sort of area in a clinic setting.”

(Female, non-supplementary prescriber, 11 years in pharmacy, 4 years in endocrine)

(b) Areas where providing considerable advice

Pharmacists perceived a good starting point for their prescribing as including areas of care where they were already providing considerable advice and input. Here they would often be recommending changes to the prescribed medication which had to be endorsed by very junior staff.

“I think where the supplementary prescribing fits at the moment is in a situation where without supplementary prescribing, we go and chase a house officer to change something for us whereas supplementary prescribing allows us to change that for ourselves; it allows us to take responsibility for making that decision, not going to find that poor little 21 year old house officer who knows nothing to change it for you.”

(Male, supplementary prescriber, 12 years in pharmacy, 4.5 years in gastroenterology)

Such current practices cited included warfarin dosing, total parenteral nutrition, adjustment of doses in organ dysfunction and therapeutic drug monitoring (TDM).

“ ... TDM vancomycin, warfarin dosing, nutrition, you know, that’s where we really are advising at the moment and those are probably easier things for us to take on.”

(Female, non-supplementary prescriber, 15 years in pharmacy, 7 years in critical care/management)

“I think that’s even a role for a supplementary prescriber, that’s one of the things you get involved with a lot on the wards, adjusting doses, augmentin, aciclovir...because of renal impairment.”

(Female, on SP course, 20 years in pharmacy, 19 years in infectious diseases)

“There is specific things like vancomycin and gentamicin where the doctors don’t know what they are doing. So you’re the one who works out what the dose is based on the pharmacokinetics, so the doctors can’t really do that

and don't have access to the information and just now, they are relying on us to tell them exactly what to do, whereas you know, if there's pharmacist supplementary prescribers doing that, then it's easier, but then you have to make sure that you communicate to the doctors more."

(Female, on SP course, 20 years in pharmacy, 19 years in infectious diseases)

(c) Clinical areas where protocols and guidelines are available

The availability of protocols and guidelines was perceived as facilitating implementation of PP and consequently as another potential area for introducing PP. The guidelines and protocols could be utilised to build a CMP if SP, and similarly applied to IP but without the need for a patient specific CMP.

"For most patients that we see, or for the common things that we see within our own specialties, there are agreed protocols and pathways that are normally followed. And that's what you would do anyway in a CMP if you were going to be a supplementary prescriber ... and independent prescribing removes that hurdle [CMP], but it doesn't change the medicines not the circumstances if you would prescribe them, I would think."

(Male, on SP course, 25 years in pharmacy, 15 years in medicine/cardiovascular/management)

Examples were provided of current practices where guidelines were being applied to facilitate pharmacist SP.

"At the moment, we are just prescribing any anti-hypertensive according to the British Hypertension guidelines 2004."

(Male, supplementary prescriber, 18 years in pharmacy, 16 years in medicine/managerial)

Another pharmacist described the development of protocols to facilitate the implementation of SP.

"I've done my course but in the renal unit, we're still trying to develop protocols; first of all we think of doing it in renal bone disease ... and we are in the process of coming up with the anaemia protocols that would enable

to supplementary prescribe for the community patients and possibly the haemodialysis patients.”

(Female, supplementary prescriber, 5 years in pharmacy, 2 years in renal)

Following guidelines was viewed by the participants as an inherent part to antimicrobial prescribing.

“That is what we currently do when we recommend things [antimicrobials], follow guidelines.”

(Female, supplementary prescriber, 14 years in pharmacy, 9 years in acute medicine/respiratory)

Where protocols could be followed was perceived as a potential opportunity for introducing PP of antimicrobials. This was especially because this was unlikely to require any specialist training to implement. Examples given included IV-to-oral switch and management of TPN line-infections.

“Certain groups of patients are targeted at the point of admission to apply the formulary processes [through PP] perhaps around IV-to-oral switch.”

(Male, supplementary prescriber, 18 years in pharmacy, 16 years in medicine/managerial)

“Certainly IVSWOT which is IV-to-oral switch therapy ... there are specific criteria for using oral therapy as opposed to IV therapy, so that’s another potential role [for SP] as well.”

(Female, supplementary prescriber, 14 years in pharmacy, 9 years in acute medicine/respiratory)

“I think that something all pharmacists could probably do would be IV-to-oral switching of antibiotics ... changing someone from IV-to-oral therapy, I think that can be done at many levels in pharmacy.”

(Male, supplementary prescriber, 12 years in pharmacy, 4.5 years in gastroenterology/liver/nutrition)

“I was thinking about TPN patients who end up with line infections; treatments for them are standard until you get something identified which can take up to 48-72 hours.”

(Male, supplementary prescriber, 12 years in pharmacy, 4.5 years in gastroenterology/liver/nutrition)

Pharmacists were more comfortable with adjusting existing treatment rather than initiating treatment. This would also fit in with their current work practices.

“Pharmacists aren’t often around at the time of prescribing of antimicrobials. So it’s about changing of regimens.”

(Female, non-supplementary prescriber, 20 years in pharmacy, 17 years in respiratory/infectious diseases)

“If I was prescribing, I would probably be parenteral first, then analgesia, and then probably antimicrobials but generally changing IVs to orals and stopping as opposed to initiation.”

(Female, non-supplementary prescriber, 28 years in pharmacy, 8 years in colorectal surgery)

“I think it’s just looking at the dose they want and making sure it is appropriate for that individual, so I suppose I look at it more for somebody to make the decision to initiate the treatment and I want to make sure it’s the appropriate thing for the patient, based on what else they are on.”

(Female, non-supplementary prescriber, 15 years in pharmacy, 7 years in critical care/management)

“You would also do it [prescribe] if positive results come back with cultures and sensitivities and you can be narrowing down and utilise your skills.”

(Female, supplementary prescriber, 12 years in pharmacy, 5 years in surgery/anaesthesia)

(d) Areas of care where shortage of doctors

Reference was made to clinical areas of practice where there may be a shortage of doctors as another feasible starting point for a pharmacist prescriber.

“I think the numbers [of HIV patients] are increasing and they are very short of medical staff.”

(Female, non-supplementary prescriber, 21 years in pharmacy, 3 years in antimicrobial utilisation)

(e) Management of minor ailments and symptom relief

Pharmacists also perceived a potential role in the management of minor ailments and prescribing for symptom relief in secondary care, such as

thrush, constipation and dry skin. This was compared to the community pharmacist's response to patients presenting with minor ailments^{xiv}.

"You can see a role in community and minor ailments and stuff like that, and there may be a role for it in basic stuff like in A & E like 'I'm from Spain and I forgot my tablets' ... a pharmacist can deal with that."

(Female, non-supplementary prescriber, 15 years in pharmacy, 7 years in acute medicine)

"I think it's probably more symptomatic, the treatment that you'd be talking about, because there's not many patients in hospital who don't have a diagnosis already or a working diagnosis that's brought them into hospital but then they acquire a lot of things like UTIs or they get dry skin, you know, there's loads of other minor things that you don't maybe need specialist knowledge to do"

(Male, on SP course, 25 years in pharmacy, 15 years in medicine/cardiovascular/management)

"Another thing we could do is minor ailments, say for example you would be seeing an HIV patient on regular HIV medication and they come with something that sounded like oral thrush."

(Female, non-supplementary prescriber, 7 years in pharmacy, 3 years in antimicrobial utilisation)

3.3.3.2 Pharmacists' perceptions of advantages of pharmacist prescribing

Perceived advantages of pharmacist prescribing of antimicrobials

This theme emerged at several of the focus group discussions. Participants were of the opinion that a PP antimicrobials was more likely to implement recommendations within the hospital formulary and adhere to local policies. This application of evidence, particularly when choosing empirical therapy, might result in a reduced risk of developing resistance, particularly in areas of high risk as in high dependency units.

"We could have a lot of benefit in controlling not only the appropriate choice of empiric treatment particularly in situations like ICU or other high dependency areas where patients are severely ill and exposed to resistant

^{xiv} Prescribing here would be different to the community pharmacy "minor ailments" scheme, where pharmacists can "prescribe" pharmacy or general sales list medicines in response to patients presenting with minor ailments, if they are usually exempt from NHS charges.

organisms; the risks around developing resistance are reduced as well as improved potential outcome because we are applying evidence from the formulary.”

(Female, supplementary prescriber, 12 years in pharmacy, 5 years in surgery/anaesthesia)

“Well. I think also choice of antibiotic because sometimes we have certain ones that are restricted and a lot of junior doctors might prescribe those and they might have not checked the set criteria, so you would give advice at the moment on ‘Why are you prescribing this. Could you not use as alternative?’ So certainly maybe on choice once it’s been agreed that they need to treat, we would probably be prescribing.”

(Female, supplementary prescriber, 15 years in pharmacy, 2 years in general surgery/management)

Optimisation of antimicrobial use through PP of antimicrobials was also perceived as indirectly leading to a reduction in overall costs through shorter bed stays, using cheaper but same spectrum antimicrobials, ensuring appropriate duration and switching to oral use when feasible.

“If you’re choosing more appropriate antibiotics, in theory, you should have shorter bed stays. Again that’s all coming down to costs but yeah optimisation of treatment. And they [pharmacist prescribers] may be initially using as effective but cheaper antibiotic rather than going in straight with the big guns.”

(Female, supplementary prescriber, 14 years in pharmacy, 9 years in acute medicine/respiratory)

“ ... so you know apart from the dosage side, we need to use it for minimal times, for the duration as well, which is another which comes into my area, and also from an obviously economic and possibly from a patient compliance, ease of administration, is it IV or change over as well.”

(Female, on SP course, 26 years in pharmacy, 16 years in neonatology/obstetrics and gynaecology)

“I think another thing is that we all know that in surgery in particular, you get prophylactic doses that go on and on and on; so that’s one area you can come in and go ‘There’s no need for that. You really need to get it stopped.’ If we were prescribing in the first place, then you would stop it.”

(Female, supplementary prescriber, 11 years in pharmacy, 6 years in renal transplant)

Participants in different groups were also of the opinion that pharmacists would be more likely to take into consideration allergies and drug interactions when prescribing antimicrobials.

“Allergies as well, when taking drug histories, quite often allergies to antibiotics are not reported; so we’re more aware of that; making sure the patients aren’t prescribed, or the allergies are true allergies; it’s not just stomach upset.”

(Female, supplementary prescriber, 32 years in pharmacy, 7 years in renal vascular)

Perceived advantages of pharmacist supplementary prescribing
Despite the pharmacists identifying numerous restrictions that SP may impose in a secondary care environment, some pharmacists also identified some advantages of current implementation of SP. SP was perceived as a route for a pharmacist to build up confidence and utilise and maintain their prescribing skills, consequently acting as a “stepping stone” towards IP.

“Starting off as a supplementary prescriber, and then moving on to be an independent prescriber, then it’s quite a good progression really to build up your confidence and skills and working relationships you know; doctors being confident that you’re prescribing well.”

(Female, non-supplementary prescriber, 20 years in pharmacy, 12 years in infectious diseases/HIV)

“It is very useful for us to be utilising our prescribing skills, because you know, if you don’t use it you’re going to lose it. And we’re looking forward to developing independent prescribing roles in the not too distant future; hopefully within the next year to eighteen months. So our skills that we’ve developed to date are going to be more appropriately used in an acute hospital environment in independent prescribing roles.”

(Male, supplementary prescriber, 18 years in pharmacy, 16 years in medicine/administration)

One pharmacist believed that documenting treatment options within the CMP may help to keep the SP prescriber “in check” especially when less experienced pharmacists are involved in prescribing. This setting of

boundaries within which to prescribe may be especially important in cases of legal and professional aspects since it helps to lay down clear lines of accountability for the prescribing pharmacist.

"You are on your own as a prescriber and it's clear that when you are supplementary prescribing you are actually on your own legally but at least you can say I've got a CMP and this is the limit to what they agreed for me to do."

(Male, supplementary prescriber, 18 years in pharmacy, 16 years in medicine/administration)

Perceived advantages of pharmacist independent prescribing

Most pharmacists perceived IP to be more feasible to implement in an acute sector because this would allow prescribing pharmacists to prescribe for a diagnosed condition without the restrictions imposed by a CMP.

"Although we might qualify as independent prescribers, in the hospital sector, we are not going to use it in the sense of what it's meant; it's going to free us up from having clinical management plans for patients and that's where it will be used; but you'd still be doing it as what a supplementary prescriber would be doing. You're not going to actually change the types of prescribing you're doing, it's just taking you a step away from documentation."

(Female, supplementary prescriber, 11 years in pharmacy, 6 years in renal vascular)

"If you were going to be a supplementary prescriber, if you were going to work the letter of the law, you would have to get an independent prescriber to sign them off for each individual patient. So it's not that you would be doing anything different, in terms of what you might actually be prescribing but it takes a step out of the process which is actually quite prohibitive in an acute setting ... that's the hurdle and independent prescribing removes that hurdle."

(Male, on SP course, 25 years in pharmacy, 15 years in medicine/cardiovascular/management)

“It really is another form of supplementary but without the management plan.”

(Female, on SP course, 26 years in pharmacy, 16 years in neonatology/obstetrics and gynaecology)

3.3.3.3 Issues with the pharmacy profession

Pharmacy management support to take on prescribing role

This theme emerged during some of the focus group discussions. Overall there were lengthier discussions about the lack of management support for pharmacists to take on a prescribing role (see section 3.3.2.1). Some pharmacists thought that despite pharmacy management potentially supporting staff to train as supplementary prescribers, there was a lack of vision as to where this would be implemented.

“ So I think they [pharmacy management] are supportive, yeah, but I think maybe people doing the course ought to have a clearer idea of what they want to do, to get the most out of it.”

(Female, non-supplementary prescriber, 21 years in pharmacy, 3 years in antimicrobial utilisation)

“I think management are quite keen for us to do it, and to get more and more people but what their final vision is, I have no idea.”

(Female, supplementary prescriber, 11 years in pharmacy, 4 years in respiratory/cardiac)

“The individuals, it’s the top of the tree, would like all pharmacists to be trained as supplementary prescribers at least because that is a priority for the profession; but I would say with regard to changing our roles to allow us to do it, that’s not quite happened yet.”

(Female, non-supplementary prescriber, 15 years in pharmacy, 7 years in critical care/management)

Participants also believed that support for prescribing might be a financially driven incentive, for example stopping antibiotics by a pharmacist prescriber might result in a cost saving.

“I think the aim of folk would be to save money”

(Female, on SP course, 20 years in pharmacy, 19 years in infectious diseases)

“It may be stopping rather than starting antimicrobials...yeah, financially driven.”

(Female, non-supplementary prescriber, 20 years in pharmacy, 17 years in respiratory/infectious diseases)

“Personally, [management will support] only if it brings money back into the department at the moment is my personal view.”

(Female, supplementary prescriber, 7 years in pharmacy, 4 years in respiratory medicine)

3.3.3.4 Issues with other healthcare professionals

Acceptance of the pharmacist prescriber by the medical profession
This theme emerged at some of the focus group discussions. Some pharmacists had already discussed the role of a pharmacist prescriber with doctors and this was viewed as feasible in areas such as HIV, oncology and haematology, and antimicrobials as part of CF patient management.

“I discussed HIV prescribing of antiretrovirals, and the doctors involved were very keen.”

(Female, on SP course, 20 years in pharmacy, 19 years in infectious diseases)

“The consultants within oncology and haematology are quite keen to do as well, and are very keen to get it [PP] established as soon as possible.”

(Female, on SP course, 9 years in pharmacy, 2.5 years in haematology)

“But they’re all for it [PP of antimicrobials in CF] so I’m sure if it would fit in other areas, other consultants would be all for it as well. There was no discussion; they just said ‘Great, give me the form to sign.’ That’s all I can say.”

(Female, on SP course, 7 years in pharmacy, 4 years in respiratory medicine)

Other pharmacists thought that doctors might support the role of a pharmacist prescriber in areas such as post-transplant patients and where pharmacists were already providing considerable advice and input.

“I think transplant they would be quite keen because they are very aware of the interactions between various antimicrobials and immunosuppressants.”

(Female, supplementary prescriber, 32 years in pharmacy, 7 years in renal vascular)

“Vanc [vancomycin] and gent [gentamicin] you know; they are very confident of the pharmacist’s ability so that’s probably one area where they would be accepted.”

(Female, supplementary prescriber, 14 years in pharmacy, 9 years in acute medicine/respiratory)

“It would be relatively easy to extend that to other antimicrobials; it’s often just letting the toe in the door and just letting medics know what we can do and letting them become confident with what we can do.”

(Female, non-supplementary prescriber, 20 years in pharmacy, 17 years in respiratory/infectious diseases)

“And I think if we were able to [prescribe] as we all become supplementary and independent prescribers we would find support from the medical and surgical consultants to switch IV-to-oral.”

(Female, non-supplementary prescriber, 15 years in pharmacy, 7 years in acute medicine)

“I think traditionally, ITU being such a high priority, high risk area we always gave a very good service there; the pharmacist is already accepted as a member of the team, so I don’t think that would be a huge jump to get them to accept your prescribing.”

(Female, supplementary prescriber, 14 years in pharmacy, 9 years in acute medicine/respiratory)

One pharmacist commented that consultants in her area of practice were willing to support PP, provided the pharmacist would regularly attend ward rounds.

“They [consultants] said I wouldn’t be prescribing on the ward until I was an active part of the ward round five days a week ... they didn’t see it as an obstacle, they didn’t want to say no to it, but they definitely didn’t want the role to develop if that person wasn’t going to commit to being around at the time when decisions were being made about prescribing which is at the ward round.”

(Female, non-supplementary prescriber, 15 years in pharmacy, 7 years in critical care/managerial)

Another pharmacist perceived doctors supporting and having confidence in a pharmacist who they had worked with for a prolonged period of time.

“And probably doctors are confident in pharmacists in that they know they’ve been working with for years. Whether you would have the same confidence in somebody new that they didn’t know, you know somebody new in the post.”

(Female, non-supplementary prescriber, 28 years in pharmacy, 8 years in colorectal surgery)

A need to work within a multidisciplinary team

Pharmacists in some groups believed that if they were taking on prescribing roles, it would be more feasible and probably safer practice to work within a multidisciplinary team, even more so, since currently, decision making related to prescribing tended to be more within a team rather than on an individual basis. This might involve changes in current roles, where pharmacists tended to work more as individuals rather than as part of a team.

“There are very few things that are actually done, individuals making a decision; it’s all discussed, and then the decision made of what to prescribe so I think, we have to change our way of working which enables us to take on these [prescribing] roles.”

(Female, non-supplementary prescriber, 15 years in pharmacy, 7 years in critical care/management)

The lack of skills of a pharmacist to make a differential diagnosis would also make it necessary for pharmacists to work within a multidisciplinary team, where the knowledge of different healthcare professionals would complement each other.

“There is quite a lot of scope within the ICU to be involved as part of the multidisciplinary team, bearing in mind that you will not be taking full responsibility for the prescribing of antimicrobials for that patient. But because of our knowledge of differential diagnosis, we have to be part of the team; we do not have those [diagnostic] skills.”

(Female, supplementary prescriber, 12 years in pharmacy, 5 years in surgery/anaesthesia)

To make full use of the skills of different members of the multidisciplinary team and to integrate the newer roles of the prescribing pharmacist, a participant recommended the introduction of an antimicrobial team, possibly made up of an infectious diseases physician, a microbiologist and a pharmacist. She goes on to comment that such teams have already been set up in England and could be a way of integrating the pharmacist involved in prescribing antimicrobials.

“What they have down in England is to have an antimicrobial team, and they get referred patients by pharmacists, and this team goes round [to review patients], and [is made up of] a microbiologist, an infectious diseases physician and a pharmacist ... a lot of what they do is stop antibiotics but that’s a potential role for a supplementary prescriber; because actually one of the teams involves a microbiologist who’s not a consultant microbiologist, he’s not a doctor microbiologist, he is a scientist microbiologist, and he actually doesn’t have the power to stop prescribing and it’s the pharmacist who’s involved in stopping the prescribing, so that’s a potential role.”

(Female, on SP course, 20 years in pharmacy, 19 years in infectious diseases)

Throughout, emphasis has been placed on developing collaboration with microbiologists, who are most likely to have access to vital information about sensitivities required for the effective and optimal prescribing of antimicrobials.

“If you collaborate with them [microbiology]; for example with me, my first port of call would be, if I take on supplementary prescribing [of antimicrobials], to discuss the whole matter with them [microbiology].”

(Female, on SP course, 26 years in pharmacy, 16 years in neonatology/obstetrics and gynaecology)

One specialist orthopaedic pharmacist had already developed this working relationship with microbiology:

“I work with microbiology quite closely, so I do have access to sensitivities, the data”

(Female, supplementary prescriber, 24 years in pharmacy, 12 years in musculoskeletal)

She went on to give examples from her current practice of the importance of collaborative work between pharmacy, the microbiologist and the orthopaedic surgeon caring for the patient, to ensure optimal and appropriate choice of antimicrobial for the individual patient.

“ I think it does have to be a collaborative approach, so between surgical and microbiology; my interest is treatment of prosthetic joint infection and sometimes you don't get growth florets from the cultures ... but you know there's an infection there; you have to go back to the surgeon, because a joint can appear to be clinically infected and you can have no more growth on culture; so you couldn't prescribe on the evidence [from microbiology]; so microbiology would have to get the surgical opinion as well.”

(Female, supplementary prescriber, 24 years in pharmacy, 12 years in musculoskeletal)

3.4 Discussion

3.4.1 Key findings

This phase of the research set out to explore:

- The extent to which pharmacists were using their prescribing privileges
- Pharmacists' perceptions of the usefulness of PP in secondary care with a focus on antimicrobials
- Pharmacists' perceptions of potential barriers towards PP in secondary care with a focus on antimicrobials.

Out of all 19 participants who indicated they were supplementary prescribers or in training:

- Four were using their prescribing skills, three regularly and one occasionally writing up a CMP
- Eight were not using their prescribing privileges
- Seven were in training

None were prescribing antimicrobials; two in training indicated that they planned to prescribe antimicrobials for cystic fibrosis patients following qualification. To the knowledge of the participating pharmacists, no other pharmacists within the hospital were prescribing antimicrobials. One pharmacist was involved in changing doses as part of TDM of vancomycin and gentamicin and in IV-to-oral switching, in line with a hospital prescription amendment policy. Hospital wide PGDs involving antibiotics were mainly reported to be nurse-led.

Overall, there were more in-depth discussions on barriers to PP compared to usefulness. When discussing SP, pharmacists drew on actual experiences; however since independent prescribing had not yet been introduced, perceptions of the future were discussed. Pharmacists in all focus groups perceived that the usefulness of PP was determined by the clinical environment, which included the patient's clinical condition and the areas of clinical care. Numerous examples were provided relating specifically to antimicrobials. Pharmacists perceived the main barriers towards PP in secondary care to be: the lack of management support for expanded roles, the current working processes and practices (such as a lack of provision of 24 hour service), a lack of resource and capacity (such as an inability to sustain new services), and the CMP as a requirement of SP. Drawing up the CMP and lack of provision of a 24-hour service were perceived as being a major barrier towards PP of antimicrobials since it was likely that patients prescribed antimicrobials were admitted with an acute episode that was rapidly changing.

3.4.2 Strengths and limitations

To the author's knowledge, this is the first research that has focused on PP of a specific drug or drug groups in secondary care. The roles of the pharmacist in the optimisation of antimicrobials as part of a multidisciplinary team have been well established.(195) The author supports the opinion of Weller et al that it is likely that the introduction of PP will be adopted as a new way of practice in the future as part of strategies aimed at optimising antimicrobial use.(47) The focus on

antimicrobials may help policy makers who are looking for novel ways of integrating the pharmacist prescriber as part of this antimicrobial multidisciplinary team. Despite the fact that the focus is mainly on SP, (since IP was not yet introduced at the time of the discussions) the study may help inform the successful implementation of IP since problems and barriers highlighted may be similar. The author believes that the choice of focus groups as a method offered more in-depth information than if a questionnaire was used particularly since this was exploratory research looking into pharmacists' perceptions.

The study has numerous strengths with respect to the sampling strategy. The focus group participants purposely did not include pharmacists who were in higher management. The author felt that including members of higher management and in positions of power might lead to suppression of other pharmacists leading to them not airing their opinions especially when discussing topics which were directly related to management views and support of PP within the institution. Both supplementary prescribers and non-prescribers were included and the groups were therefore heterogeneous with respect to prescribing experience. This is unlike most of the published literature which focuses mainly on pharmacists who are supplementary prescribers or in training. (123,130-132,196,197) Heterogeneous groups were employed to help stimulate discussion among participants. The sampling strategy also ensured that the pharmacists were experienced and "hands on" in a mix of specialties. A maximum of six to eight participants was aimed for per group to allow for participants to have sufficient opportunity to express themselves which may not have occurred if larger groups were used. (186,189)

Throughout the research, approaches were incorporated (when data gathering and during the analysis process) to minimise the author's and supervisory team's bias and to enhance validity. These included ensuring appropriate training of the author, having a systematic approach when conducting the focus groups, transcribing all discussions "ad verbatim" to allow for more rigorous analysis and having more than one researcher reviewing transcripts for emerging themes. These aspects are described in

detail at section 3.2.4. Data saturation was achieved when no more new themes emerged at focus group six.

The study is limited by geographical location within Scotland. There was much debate about this issue between the author and the supervisory team; however the devolution of healthcare in the UK has resulted in non-uniform health policy and practice, hence basing the final study in Scotland. The views of the participants cannot be considered representative of all hospital pharmacists and, as in all focus group discussions, participants may have felt under pressure to agree with dominant views.(189)

3.4.3 Discussion of findings and comparison with the literature

Published evidence indicates that the devolution of the UK^{xv} healthcare system may have resulted in different priorities for PP in Scotland, Northern Ireland, England and Wales. Thus, pioneering literature based exclusively in Northern Ireland (129,130) shows that the greater majority of pharmacists who trained as supplementary prescribers work in a hospital setting while literature based exclusively in Scotland (131) indicates that most were based in a primary care setting. Another questionnaire based study of pharmacist SP in England reports that 47% of respondents were using their training but no information is provided on healthcare setting.(196)

Literature which explores GB^{xvi} wide PP indicates that most trained supplementary prescribers were based in hospital (119,120) whilst the fewest were based in community pharmacies.(198)

Few of the published studies provide details on the extent to which the trained prescribers were making use of their prescribing privileges. Where available, this seems to reinforce that two groups of prescribers have been successful at implementing SP; hospital pharmacists have been most successful at implementing pharmacist SP in Northern Ireland (130) and primary care pharmacists in Scotland.(131) Reports of a GB wide study exploring early experiences of supplementary prescribers shows pharmacists in primary care settings were most likely to prescribe despite

^{xv} UK – United Kingdom which includes England, Scotland, Wales and Northern Ireland

^{xvi} GB – Great Britain which includes England, Scotland and Wales

the fact that hospital pharmacists were more likely to be trained as SP; 42% of trained hospital pharmacists were not prescribing. (119) A survey of pharmacists overseeing the implementation of pharmacist SP in England showed similar percentages were planning to implement SP in both secondary and primary care settings (57% and 56% respectively). (121)

Results from our study show that few of the supplementary prescribers were actually making use of their skills and none were prescribing antimicrobials. Most of the pharmacists who were on a course had identified where to start prescribing once qualified, with two pharmacists planning to prescribe antimicrobials. This is in line with reports from the literature which show that the focus of both training and implementation of pharmacist SP in Scotland in the initial phases appeared to be in the primary care setting. This potentially indicates that primary care was a priority for the implementation of pharmacist SP for Scottish health boards resulting in a lack of implementation in secondary care in Scotland. However, the author believes that the implementation of pharmacist SP is a very complex issue influenced by numerous potential factors. This is shown by the fact that despite reports that most GB pharmacists training as supplementary prescribers worked in hospital, yet most pharmacists implementing SP were in primary care. It is also worth highlighting that the different methodologies of the published studies and the varying timescales over which they were published make it difficult to draw any definite conclusions.

Pharmacy management was perceived by most participants to be one of the main barriers, not supporting the training required to take on a prescribing role and lacking a plan to facilitate the implementation of pharmacist SP following qualification. This was also true for antimicrobial prescribing where there was no specific drive or incentive to encourage PP unless as part of a cost-cutting exercise. This may potentially reflect the fact that implementation of PP is not an organisational priority as evidenced by the lack of organisational recognition as reported elsewhere in the literature. (120,130) A lack of support of directors of pharmacy for this expanded role of the pharmacist also comes across by the fact that most or none are themselves prescribers. The apparent lack of a plan to implement

PP was causing frustration among pharmacists who had qualified as supplementary prescribers and were not making use of training, and also causing reluctance to train among those who were still to embark on the training. The author thinks that further research is required involving pharmacy management to investigate potential reasons for this apparent lack of support and implementation plan. This is crucial to facilitate service development involving PP and to ensure there is no loss of motivation among staff or loss of trained personnel due to changing of jobs.

This perceived lack of organisational support indicates that in our study, the individual pharmacists emerged as the driving force initiating the process necessary for training and completing the course, often within their own time. Following training, they were utilising their own initiative to identify prescribing roles within their specialties and often appeared to be taking on a higher workload to implement an expanded role. It is likely that these pharmacists are innovators, a social category first defined by Ryan et al and later further characterised by Rogers, as individuals having an ability to understand and apply complex technical knowledge, being venturesome and coping with a degree of uncertainty about an innovation.(199) Other reports in the earlier literature researching PP also characterise individuals who were amongst the first to train as prescribers as innovators.(123,131) Other social categories identified by Ryan et al are early adapters, early majority, late majority and laggards.(199) Interestingly, a survey of pharmacists who were not prescribing or in training classified themselves as innovators or early adapters, though they were still reluctant to take on prescribing, with many feeling they did not have sufficient support to take on expanded roles.(198) This is in conflict with evidence derived from a survey of pharmacists who were overseeing the implementation of PP in different healthcare settings and who believed that most pharmacists would want to take on prescribing.(63) In view of this, the author believes that investigating further the behaviour of social categories other than innovators as defined by Ryan et al may help inform wide-scale service developments, and especially help inform the successful implementation of pharmacist IP in secondary care.

There is considerable literature discussing the potential lack of support of the medical profession to pharmacist supplementary and IP due to a fear of encroachment on the doctor's role.(124,129,130) It is difficult to determine why there is such a perception but the initial opposition of medical associations to the introduction of non-medical prescribing may be a reason and has been described in detail in Chapter 1. Interestingly, though there was some discussion about this in some focus groups, the participating pharmacists did not perceive this potential lack of support as of major concern. This probably reflects that more experienced ward based pharmacists were included in this study, and were already well established members of the multidisciplinary team such that there was no professional rivalry between the professions. Indeed, some pharmacists who had already discussed the potential of implementing pharmacist SP in their specialty were met with encouragement and specific potential roles identified. Gaining and ensuring the support of the medical profession may be a way of ensuring the successful implementation of PP. Interestingly, some professional rivalry with the nursing profession emerges, with participants commenting that they are being trained as prescribers to make sure there are enough numbers as there are nurse prescribers. This has been reported elsewhere in the literature where nurses believe that they are better placed to prescribe than pharmacists.(200) Some go further to comment that PP is an encroachment of nursing territory.(130)

The pharmacists were concerned that current working practice encouraged pharmacists to work more on an individual basis rather than as part of a multidisciplinary team. They felt that this practice would need to change allowing pharmacists to become more integrated within the multidisciplinary team to ensure safe implementation of PP. This may be even more important if the pharmacist is independently prescribing and is required to ensure effective communication and an appropriate skill mix within the teams especially since pharmacists perceived themselves as having a lack of diagnostic skills. This may be especially so with antimicrobials where pharmacists thought they would need further specialist diagnostic training together with training on assessing the severity of the patient's condition due to the potential complexity of the patients. Working as part of the

multidisciplinary team would also help overcome the likely lack of enthusiasm by doctors for pharmacists to become independent prescribers.(129,131) The multidisciplinary team with pharmacy involvement has been very well developed in the area of infection and antimicrobial teams promoting optimal use of antimicrobials are now well established in most UK hospitals.(195) There may therefore be further scope for the development of a prescribing role for a specialist antimicrobial pharmacist working within such teams, although the need for clarification and defined responsibilities of all the members of the team would be necessary.

Despite the numerous perceived barriers and challenges to implementing PP in secondary care, the introduction of PP in this healthcare setting has often been reported in the literature as a natural extension of the pharmacist's role. The practice of ward-based hospital pharmacists lends itself well to PP, with access to patient clinical records and pharmacists already reviewing charts and making recommendations on a daily basis, with junior doctors only signing off prescriptions, very often not really understanding what they were signing.(201,202) Pharmacists who were SP in a hospital setting commented that SP "streamlined and legalised practice." (130) Interestingly, doctors who were mentors to pharmacist prescribers were also of this opinion.(129) In previous research, pharmacists report "informal" prescribing, though there was a wide variation in this from making verbal recommendations with no documentation, to actually writing up prescriptions due to a shortage of medical staff.(123) Pharmacists in our study also thought that there were areas where they were already making considerable input, such as in TDM and in dosing for organ dysfunction, that may be particularly suited for initiating PP. Some clinical applications of PP of antimicrobials have been reported in the literature though no reports were found on outcomes. These included repeat prescribing of antiretrovirals in HIV positive out-patients and dose adjustments of antibiotics in an intensive care unit.(203,204) A study by Hobson et al looked at the views of pharmacists who were overseeing implementation of PP.(121) Roles were identified in areas where the pharmacist input was already well established and included HIV care, following protocols for

antibiotic prophylaxis in surgical-orthopaedic preadmissions clinics and cystic fibrosis patients. Anecdotal evidence through discussions as part of a UKCPA special interest group have indicated pharmacists starting and stopping antibiotics as part of surgical prophylaxis and dose adjustment of gentamicin and pharmacists planning to implement prescribing by adjusting antibiotic regimen and doses depending on sensitivity results, interactions and renal and hepatic function. These reported activities were similar to potential roles identified by pharmacists in this study, though a broader range of activities were identified here. Pharmacists in this study felt that they had sufficient pharmacological knowledge to take on antimicrobial prescribing, especially when compared to the more junior doctors. Other stakeholders have also perceived pharmacists to be competent in pharmacology and pharmacotherapy, though lacking in counselling and diagnostic skills. (197) This is similar to views of the pharmacists in this study who though knowledgeable to prescribe, would rather do so for a diagnosed rather than undiagnosed condition.

Pharmacists in our study appeared keen to progress from supplementary to IP, the latter seen as a more feasible option in secondary care offering more flexibility since no CMP is required. The participants perceived the CMP as a major barrier to implementation of PP particularly in secondary care and perceived it to be especially unsuitable for the management of patients with infection who were likely to be complex and whose condition was rapidly changing. They thought it would only be suited for use in patients with chronic conditions or an option in areas of care where patients were likely to receive standard treatment, such as surgical antibiotic prophylaxis. The CMP has also been reported as a major barrier to implementation of PP in other research (123,130,131,197) with IP offering “more autonomy and clinical responsibility.” (205) One study involving pharmacists who were SP revealed that some were actually reverting to the previous way of getting doctors to sign their prescription or prescribing without using a CMP. (123) As indicated by some participants in our study, SP may become a transitional model, and may be the initial form of prescribing undertaken by the pharmacist till enough confidence has been gained to prescribe independently.

Pharmacists in this study put forward a model of PP that would be both feasible and ensure patient safety in secondary care. This would involve a doctor making a diagnosis and starting new treatment and an independent pharmacist prescriber adjusting and monitoring treatment without the need for the CMP. This model would enable some barriers to PP in secondary care discussed above to be overcome and would ensure that both doctors and pharmacists are confident with the process involved in that all professions were working within their own competence. Similar models have been reported elsewhere as the way forward for PP in secondary care. (129,130) Weiss et al report a slightly different model where the nurse conducts clinical examinations, the doctor diagnoses and the pharmacist monitors and adjusts drug treatment. (124) Whichever model, the author believes that the potential fragmentation of the prescribing process makes it imperative to have robust communication and very clearly defined roles and responsibilities within the multidisciplinary team to ensure patient safety.

3.4.4. Conclusion

The study shows that despite pharmacists being trained as prescribers in secondary care, there is a lack of implementation which emerges across most health boards where the focus groups were conducted. This has led to a lack of motivation and frustration among pharmacists, especially since numerous potential areas where PP is feasible have been identified by the participants. It is not possible to pin-point one reason for this lack of implementation through this phase of the research though numerous interplaying factors emerge such as a lack of management support, some current working practices and difficulties with implementing SP in an acute healthcare setting. It is also difficult to establish whether this is a Scotland-wide issue and further background research needs to be conducted to try and clarify this.

Chapter 4

Background Scoping Exercise

4.1 Introduction

The analysis of the focus group discussions was followed up 12 months later by a background scoping exercise conducted between February and May 2008. This informed how PP in secondary care, particularly the prescribing of antimicrobials, had developed since the initial focus group research. In turn, this would potentially allow a more reasoned discussion of the subsequent stages of the research as the original research questions seemed no longer appropriate. Figure 5 summarises the approach taken.

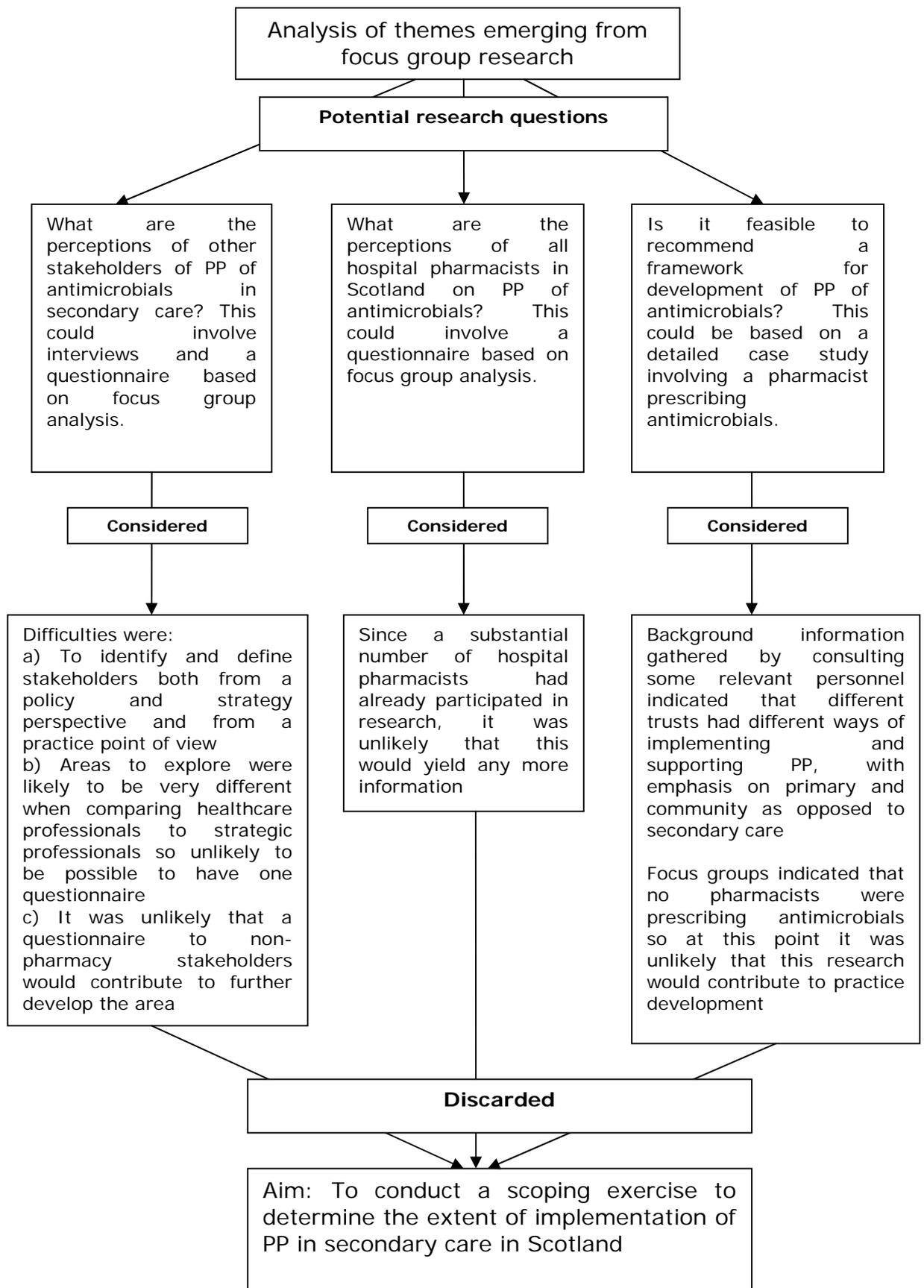


Figure 5: Schematic representation of evolution of the research following focus group analysis

The aim of this part of the research is highlighted in Figure 5. A number of objectives were linked to this aim:

- To update information on the extent to which pharmacists who participated in the focus group discussions were using their prescribing privileges and to determine whether any were prescribing antimicrobials and to obtain more detail on the prescribing role of any PP antimicrobials
- To investigate the existence of a national Scottish framework or guidance for PP
- To investigate what documents were available at a local level to guide PP and whether any focused specifically on secondary care and to determine what healthcare professionals were involved in the developing and authoring of frameworks [definitions and further details are provided at Section 4.4].

The method and results will be presented separately for each objective. This fact-finding exercise was carried out between February and May 2008.

4.2 Objective 1

Objective

To update information on the extent to which pharmacists who participated in the focus group discussions were using their prescribing privileges, to determine whether any were prescribing antimicrobials and to obtain more detail on the prescribing role of any PP antimicrobials.

4.2.1 Follow up of focus group participants

Method

An email was sent in February 2008 to all 19 pharmacists who were either prescribers or on the prescribing course and had previously participated in the focus group discussions. Email addresses were available through previous research. They were asked to provide information as follows:

“I am now planning Phase 2 of my research which is likely to evolve from results in Phase 1 and I am following up participants from Phase 1 who

were supplementary prescribers or on the course. I was just wondering whether there have been any changes to your circumstances and whether you are making use of your prescribing skills. If yes in what area and does this involve antimicrobials at all?"

A reminder email was sent out to non-respondents and a letter was sent by post in March 2008 to remaining non-respondents.

Results

A response was obtained from 17 participants and is summarised as follows:

- (a) Four participants had moved to other health boards and no contact details were available
- (b) One participant was on maternity leave
- (c) Three participants had not yet completed their course, mainly due to other work commitments
- (d) Six participants were not making use of their prescribing qualification
- (e) Three participants had converted/were converting to IP and were using their prescribing skills in their area of practice. One was prescribing antimicrobials.

Further details are at Table 19.

Table 19: Prescribing status of focus group participants at follow up

Participant number	Prescribers or on course at focus groups	Follow up prescribing status
1	SP	Left post – no contact details
2	SP	Converting to IP; currently prescribing antihypertensives in a diabetes clinic
3	On SP training course	Not yet completed course
5	SP	Changed specialty; not prescribing since now in a post with no direct patient contact
6	SP	Left post – no contact details
10	On SP training course	Completed SP training; converted to IP; currently prescribing antimicrobials to cystic fibrosis patients
15	On SP training course	Completed SP training; not prescribing; planning to convert to IP which is perceived to be more appropriate for the relevant patient groups
16	SP	Not prescribing
17	SP	Left post – no contact details
25	On SP training course	Left post – no contact details
27	SP	Changed specialty; not prescribing since currently not working on wards
28	On SP training course	Not yet completed course
29	SP	Converting to IP; currently prescribing nutrition; not planning to prescribe antimicrobials
30	SP	On maternity leave
32	SP	Not prescribing
33	On SP training course	Not yet completed course
37	SP	Not prescribing

4.2.2 Further follow up of participant 10

Participant 10 was the only pharmacist who was prescribing antimicrobials at the follow up stage. To obtain a more complete picture of the current status of PP among focus group participants, interviews were conducted with the pharmacist and the medical consultant with whom she worked. The latter was also the independent prescriber she worked with as a supplementary prescriber. Though an interview with a patient for whom the pharmacist had prescribed was considered, it was unlikely that the information that a patient would provide could contribute much to the research.

Method

The North of Scotland Research Ethics Committee was contacted to provide advice on the need for an NHS Ethics application. The committee advised that an application was not required, classifying this as a minor amendment to the previous application. NHS R and D were also informed (Appendix 4.1).

Both the pharmacist and the consultant were initially approached by e-mail to determine whether they would be willing to participate in an individual one-to-one interview. The e-mail address for the pharmacist was available from the previous focus group discussions, while that for the consultant was available through the hospital website. Following positive responses, a recruitment pack was sent to each with a participant information sheet and a consent form indicating that the interview would be audio-recorded (see Appendix 4.2). A short interview schedule evolved through discussions within the supervisory team.

Follow up interview with prescribing pharmacist

1. I wonder whether it would be possible to review the way in which you were practising prior to the prescribing course? You had just registered on the SP course at the focus group.
2. Can you describe the way in which you are practising following the prescribing course? What are the drug groups and who are the patient groups you are prescribing for?
3. How was this role identified? How did this come about and who drove it?
4. Has this been as expected? Have there been any specific challenges and barriers to overcome? Is there potential to expand this role further?
5. Do you expect any changes once you qualify as an independent prescriber?
6. What has been the feedback from colleagues, medics, nurses and patients?

Follow up interview with consultant

1. I wonder whether it would be possible to review the way in which patients' antimicrobial treatment was managed prior to the pharmacist's involvement as a supplementary prescriber?
2. How would you describe your experience as a mentor during the pharmacist's supplementary prescribing course?
3. Can you describe the way in which the management of patient's drug treatment has changed following the pharmacist's prescribing course? What are the drug groups and who are the patient groups involved?
4. How was this role identified? How did this come about and who drove it?
5. Has this been as expected? Have there been any specific challenges and barriers to overcome? Is there potential to expand this role further?
6. What are your views on pharmacist independent prescribing? Do you expect any changes once the pharmacist qualifies as an independent prescriber?
7. What has been the feedback from other medics, nurses and patients?

Interviews were carried out in September 2009. The interviews lasted between 20 and 30 minutes. These were held with a specialist respiratory pharmacist who was prescribing independently and with a consultant respiratory physician. Recordings were transferred onto a password protected computer and will be destroyed once the research has been completed. Since the aim of these interviews was to gain more detail of the pharmacist's prescribing role, a descriptive account of the interview was generated rather than an ad verbatim transcription for analysis. Once completed, the descriptions were sent to each participant for participant verification with no changes made by the participants. Key points were identified relating to the success of PP and the prescribing partnership.

Results

Interview with pharmacist

The following are key issues emerging from this interview:

- The transition from supplementary to independent prescribing enabled the pharmacist to work outwith CMPs. However, she felt these were still useful as a guide to the drug management of specific disease states.

- The pharmacist was involved in prescribing antimicrobials to cystic fibrosis in- and out-patients. This involved both empirical prescribing, and prescribing following the availability of culture and sensitivity results. The pharmacist reviewed all patients prior to bronchoscopy in a pharmacist and nurse led clinic thus ensuring that all appropriate medication had been prescribed prior to the intervention. She also prescribed in response to symptoms, such as laxatives, titration of analgesia and antacids, and believed that this area of prescribing was a potential starting point for a pharmacist working in any speciality.
- The pharmacist's perceptions were that feedback about this expanded role was positive, at medical, nursing and dispensary levels. This led to pharmacy management encouraging other pharmacists to identify potential areas for prescribing within their areas of expertise.
- The pharmacist attributed the success to the fact that she knew the cystic fibrosis patients very well and had worked closely with the consultant involved prior to her training to prescribe.
- The pharmacist described what she perceived as some disadvantages that were a consequence of her prescribing independently. These were deskilling of junior doctors and a missed second check on prescriptions written up by the pharmacist. The department was putting a number of safety procedures in place to tackle the latter.

Interview with consultant

The following are key issues emerging from the interview:

- The consultant highlighted prescribing of antimicrobials for cystic fibrosis patients as the main service provided by the prescribing pharmacist. Other areas she was involved in included assessing appropriateness of inhaler device for the individual patients, prescribing palliative care for lung cancer patients and ensuring that treatment charts were written up accurately and making any necessary changes.
- Advantages of having a pharmacist prescriber included the fact that she knew the patients very well, unlike junior medical staff who

tended to rotate frequently, safer prescribing with less errors and more rational prescribing with an opportunity for a reduction in costs.

- The consultant highlighted the potential of conflict between a doctor and pharmacist due to a difference in opinion as a potential challenge.
- He felt that the mentoring process during the pharmacist's prescribing training was a positive experience which did not involve any additional work. He thought this was mainly due to the fact that the two were already working closely beforehand and expressed his concern that this might be very different if it was another pharmacist whom he did not know very well.
- He believed that PP was a very positive experience and should be expanded to other specialities.

4.3 Objective 2

Objective

To investigate the existence of a national Scottish framework or guidance for PP

Method

(a) To obtain information on a national level, an e-mail was sent out in February 2008 to the Chief Pharmacist of the Scottish Government for further information as follows:

"I am a PhD student at The Robert Gordon University currently researching around PP in secondary care. The first part of this project has involved focus groups in five health boards in Scotland exploring pharmacists' views and perceptions. I am now into the planning part for Phase 2 which is being informed by Phase 1 of the project. It appears that this second phase will evolve mainly around policy making associated with PP.

I am trying to determine whether or not a national framework for PP has been formulated in Scotland. I am aware that

a non-medical prescribing framework^{xvii} is available and has been published by NHS Scotland but this seems to cover nursing prescribing only.

Consequently, I was wondering whether it would be at all possible to provide any further information or key contact persons around this."

(b) Similar correspondence was sent to a generic email address at NHS Quality Improvement Scotland, to determine whether any guidelines or standards were available or under development and relating to both PP and NMP.

Results

(a) The response from the Scottish Government indicated that the draft national framework document available entitled "A Safe Prescription"^{xviii} (206) did not specifically mention PP due to a number of concerns of the Government policy makers:

- Administrative issues relating to the new community pharmacy contract and how pharmacist IP would evolve in the future
- Governance issues relating to the fact that pharmacist independent prescribers may also be dispensers

Consequently, separate broad guidance for NHS Health Boards was issued by the Scottish Government in December 2007 to support PP focusing mainly on PP in primary care services.(207)

(b) Information provided indicated that no national guidance or standards had been published or were being developed in relation to PP or NMP.

^{xvii} This refers to the NHS Scotland document entitled "Non-Medical Prescribing in Scotland" and published in September 2006. This provides guidance for the implementation of non-medical prescribing by nurses in Scotland but makes no reference to PP.

^{xviii} This document was later published in September 2009 and updated in August 2010 as "A safe prescription. Developing nurse, midwife and allied health profession prescribing in NHS Scotland."

4.4 Objective 3

To investigate what documents were available at a local level to guide PP and whether any focused specifically on secondary care, and to determine what healthcare professionals were involved in the developing and authoring of frameworks.^{xix}

Method

(a) The Scotland Directors of Pharmacy Group was contacted to obtain a list of Directors of Pharmacy for all 14 health boards in Scotland. In February 2008, a letter (at Appendix 4.3) was sent to all directors of pharmacy [n = 13; one director covered two health boards] providing them with the aim of this scoping exercise and a background survey they were asked to complete and return in the self-addressed envelope provided. The following background survey was developed through discussion with the supervisory team.

^{xix} The term “framework” is used here. It was however evident that there was no standard terminology or approach across the 14 health boards as presented in further detail in Table 20 below.

Background fieldwork into frameworks, strategies and models of PP

Please tick as appropriate.

1a. Has a framework been drawn up to provide a broad outline for pharmacist prescribing within the health board?

Yes
No

1b. If yes, would it be possible to provide a copy of this framework?

2a. Has a strategy been drawn up for PP within the acute sector?

Yes
No

2b. If yes, would it be possible to provide a copy of this?

3a. Are there any models of PP within the acute trust?

Yes
No

3b. Are there any written standards to aid pharmacist prescribers?

Yes
No

3c. Are any pharmacists prescribing or planning to develop prescribing within the area of antimicrobials?

Yes
No

4. Approximately how many pharmacists are involved in PP in the acute sector – both in developing policies and in using their prescribing skills?

5. Please feel free to add on any comments you would like to make.

(b) The NMP lead in Grampian, who was also the lead for PP, agreed to provide further information about implementation of NMP in Grampian. To obtain further information about the implementation of NMP including PP in other Scottish health boards she sent out an email to all NMP leads as follows:

Dear All

We have a pharmacy PhD student in Grampian who is carrying out a study on non-medical prescribing. She would like contacts in other health board areas. Would you mind if I gave her your contacts?

The contacts who provided their email addresses and were willing to be involved in the research were asked to provide information as follows:

“Thank you for accepting to help me with my research. My research is around PP of antimicrobials in secondary care and I am at this point planning Phase 2 of my project. At this point I am trying to build up a database of contacts, mainly involving professionals who are involved in NMP within their health board particularly if they have been involved in drawing up a framework for NMP within the health board. I wondered whether you could indicate whether a) there is a NMP framework in your health board and whether this includes pharmacy b) your position with respect to NMP within the health board.”

Further contacts were obtained through the leads where relevant. The work place email addresses of these contacts were stored on a password protected file for potential future use in further research.

Results

(a) Eleven [out of thirteen] completed background surveys on PP were returned by the Directors of Pharmacy.

(b) NMP leads in all health boards in Scotland were willing to provide information about NMP including PP within their health board. They provided seven documents^{xx} relating to NMP. A summary of information obtained through (a) and (b) above is in Table 20.

^{xx} The general term “documents” is being used here since health boards used different terminology including framework, policy, strategy and Standard Operating Procedure.

Table 20: A snapshot of pharmacist prescribing in Scotland – May 2008

HB	NMP framework in place	Aim of document	Pharmacy involved in authoring NMP	Framework for PP	Strategy for PP in acute sector	Models of PP in the acute sector	Written standards for PP	PP or planning to prescribe antimicrobials	Other information provided
1	Yes – (undated) Termed “Non-medical prescribing policy”	“To provide a governance framework related to NMP”	Yes - but nurse led development	No	No	No	Yes	Yes - planning	No active pharmacist prescribers at present
2	Yes – April 2008. Termed “Non-medical prescribing policy”	“Code of practice”	Yes – NMP group chaired by Director of Pharmacy	No	No	No	No	No	15 out of 35 qualified PP actively prescribing in primary care
3	No – currently under development	“Comprehensive strategy and operational policy”	Yes - but nurse led development	No	No	No	No	No	
4	No – currently under development		Yes - Director of Pharmacy involved						Very small number (not provided) of prescribers in acute sector
5	Yes – currently being reviewed due to the introduction of IP								
6	Yes – May 2007. Termed “Policy and Framework for Non-Medical Prescribing including Independent Contractors”	“Sets the guidance for non-medical prescribers in NHS Grampian to promote safe and effective prescribing”	Yes – policy developed by Non-Medical Prescribing Group of which pharmacist members	Yes – this is part of the NMP policy and framework	No		Yes – this is part of the NMP policy and framework	Yes	2 pharmacists involved in developing policies and prescribers in the acute sector

7	Yes – October 2006. Termed “Standard Operating Procedure for Nurse/Pharmacist Supplementary and Nurse Independent Prescribing”	“Sets out the process and steps required from enrolment to practice as non-medical supplementary and independent prescribers”	Yes, lead pharmacist for prescribing leads central prescribing team	Yes	Yes	Yes	Yes – RPSGB standards for pharmacist prescribers	Yes - planning	15 registered pharmacists of whom 1/6 th are actively prescribing. A NMP group dealing with mental health issues is being established and likely to cover primary and secondary care
8	No – currently under development		Yes – but nurse led development	No	No	No	No	Yes - planning	1 PP in acute sector
9	Yes – October 2006. Currently under review. Termed “Framework for non-medical prescribing”	“Seeks to provide that [a governance framework in relation to non-medical prescribing] framework in relation to non-medical prescribing”	Yes – both in original development and in updating	Yes – this is part of the general framework for non-medical prescribing	No	Yes	No	Yes	12 pharmacists involved in developing policies and prescribers in the acute sector
10	No – currently under development		No	No	No	No	No	No	4 pharmacists involved in developing policies and prescribers in acute sector
11	Yes – October 2007. Termed “Non-Medical Prescribing Policy”	“Set out the systems and procedures that must be adhered to, to	Yes	Yes – as part of general non-medical prescribing policy	Yes	Yes	Yes	Yes – planning	15 pharmacists involved in developing policies and prescribers in the

		assure safe and effective non-medical prescribing.”							acute sector
12	Yes – January 2008. Termed “Non-Medical Prescribing Policy.” An adjunct document “Policy and procedure for Non-Medical Prescribing” in draft form	“To support best practice for the delivery of patient care.”	Yes	No – in development as part of “Policy and procedure for Non-Medical Prescribing”	No	No	No	No	4 pharmacists involved in developing policies and prescribers in the acute sector
13	No – currently under development		Yes						No pharmacist prescribers within this health board
14	No – currently under development		Yes	No	No	No	No	Yes – planning	No pharmacist prescribers within this health board

HB – Health Board; NMP – Non-Medical Prescribing.

4.5 Discussion

4.5.1 Key findings

This phase of the research was conducted between February and May 2008 and set out to inform how PP in secondary care, and particularly the prescribing of antimicrobials, had evolved since the initial focus group research. This was carried out utilising different sources of information including: a longitudinal follow up of the focus group participants; investigating the existence of a national Scottish framework by obtaining information through the Scottish Government; and exploring any local health board level guidance to facilitate PP.

It was evident from the 12-18 month follow up of focus group participants that there had been little evolution regarding the implementation of PP in the secondary care health boards studied. This lack of progress was despite the fact that non-medical prescribing legislation had advanced now permitting pharmacists to train and register as independent prescribers.(96) The interview with one pharmacist independent prescriber and one medical consultant within the same multidisciplinary team described successful implementation of both PP of antimicrobials and PP in response to minor ailments. Both interviewees reported a positive response from other stakeholders but none were formally interviewed.

Response from different Scottish Government bodies indicated that no national frameworks or standards had been published or were being developed in relation to PP, despite a national framework guiding nurse, midwife and allied health professional IP.(206) This was mainly due to the Scottish Government policy maker's concerns relating mainly to the implementation of pharmacist IP in a community pharmacy setting [personal communication]. A broad administrative guidance for NHS Health Boards was issued in 2007 by the Scottish Government with a main focus on implementation of pharmacist IP in

primary care entitled “Pharmacist Independent Prescribing – Guidance for NHS Health Boards.” (207)

Eleven out of 13 Directors of Pharmacy and NMP in all health boards provided information on the availability of documentation to guide PP at a local level together with information on the development and authoring of NMP frameworks where these were available. Eight NMP frameworks were in place, with different nomenclature reported; most were termed “policies”, one was a “standard operating procedure” and two included the word “framework.” [Further details of the terminology used are found at Section 4.4]. Six were reported to be under development. Pharmacy had been involved to a varying extent in authoring most NMP frameworks; some reported nurse led development, some reported pharmacists chairing working groups and one reported a pharmacist leading the development. Most health boards did not have a specific framework for PP; where this was available, it was a part of the NMP framework. Few had a strategy in place for PP in the acute sector. Two health boards reported having PP antimicrobials and four health boards reported having pharmacists planning to prescribe antimicrobials.

4.5.2 Strengths and limitations

This phase of the study provides information on the evolution of the implementation of PP in secondary care within the health boards studied. A review of the literature revealed no published studies which used a longitudinal approach to explore the evolution of PP by following up a group of pharmacist prescribers. This would be important since PP is still in early stages of its development, and consequently it is probable that practices would change over time. Similarly, no information was available to provide a snapshot of documentation available relating to PP within all Scottish health boards. This enables any differences in implementation of PP in the different health boards to be determined.

To enhance reliability, when conducting the interviews, both interviewees were provided with their own descriptive summary of the interviews.

Limitations were mainly related to difficulties encountered in obtaining the relevant information. For example, when following up focus group participants, it was not possible to follow them all for different reasons including changing jobs and maternity leave. It was also a very lengthy process to obtain contact details of all NMP leads in Scotland since no readily available database was identified which had this information. It was therefore a very lengthy and labour intensive process involving much correspondence to collate such a database and meeting all data protection requirements.

Though three pharmacists were identified as independent prescribers or converting to IP, only one was prescribing antimicrobials. Consequently only one pharmacist and the medical consultant on the team, who was also her mentor during her training, were interviewed to further inform this background scoping exercise. The author believes that the conclusions that may be drawn from these interviews are therefore limited, though helping to provide more descriptive information on the implementation of PP.

4.5.3 Discussion

Follow up of the focus group participants indicated that there was little evolution in implementation of PP in secondary care within the sampled health boards, despite the legislative change which allowed IP.⁽⁹⁶⁾ This lack of progression to and uptake of IP is a sharp contrast to participants' views expressed during the focus group discussions. At that time, they perceived IP as the more feasible model in secondary care since there were no restrictions imposed by the CMP and also more easily allowing for prescribing in an environment where there were potential rapid changes in a patient's condition. They also thought it was especially relevant if prescribing antimicrobials. Many had also indicated that they would rather train as independent prescribers than supplementary prescribers. The three pharmacists who had still not completed

training cited other work commitments as the reason for this; the author believes that this reinforces focus group participants' perceptions that there were other priorities within the hospital pharmacy departments, and hospital pharmacy managers still did not have a clear implementation plan in place to facilitate PP.

The interview with the pharmacist independent prescriber described successful implementation within the multidisciplinary team of both PP of antimicrobials and prescribing in other areas mainly in response to minor ailments. The pharmacist described a model involving running out-patient clinics in collaboration with nursing staff. Though this model has been described in the literature it is different to the model proposed by pharmacists during the focus group discussions.(124) Further research may be carried out to determine other successful models where PP has been implemented in secondary care and to identify the key factors associated with success by conducting an in-depth case study. The pharmacist commented that pharmacy management were now more aware of the potential of PP and were consequently encouraging other pharmacists to train as prescribers. However, no defined strategy for the expansion and implementation of PP within this health board was apparent from the interview. Deskilling of junior doctors and missing the second check were the pharmacist's main concerns. These were similar to concerns that have been raised both during the focus group discussions and in the literature.(129)

The interview with the consultant was the first involvement in this research of other potential stakeholders. It was evident that this consultant considered the pharmacist a trusted skilled member of the multidisciplinary team who was well qualified to prescribe making a significant contribution to patient care. He attributed this good working model and team integration to prior working relationships. This is similar to reports in the literature where a previous working relationship between a consultant and pharmacist were important for future successful implementation of PP in secondary care.(129)

The information obtained from Scottish Government bodies reinforced that the focus of the Scottish Government, at least during the initial phases of PP, was mainly primary care.(207) This supports the findings of early published research reporting that the training and implementation of PP in Scotland was successful mainly in primary care (Section 3.4.3).(131) However, despite the focus of the Scottish Government not changing, information obtained through the interview with the pharmacist independent prescriber together with anecdotal evidence from specialist discussion forums indicates that more pharmacists are now training and successfully implementing PP in secondary care. The author believes that due to the complex and numerous factors that influence the implementation of PP, it is not possible to determine at this stage to what extent the Scottish Government policies are actually influencing where PP is predominantly implemented successfully.

Information obtained at local health board level reinforced that there were no standard frameworks available to aid in the planning and implementation of PP, even as part of general NMP frameworks. Where documents were available, they had heterogeneous nomenclature, aims and content. Different health boards were also at very different stages of implementation of NMP including PP. Though no conclusions may be drawn on what drives successful implementation of PP, the information available seems to indicate that there is an association between availability of a framework for NMP, including PP, and the number of pharmacists actively prescribing. Health boards where the NMP framework was being reviewed and updated reported having more pharmacist prescribers than those where the framework was still at the development stage. Interestingly, NMP including PP in one health board was evolving to develop a framework within a specialty area (mental health). Similarly, health boards having a framework for PP in the acute sector were those where pharmacists were likely to be prescribing.

4.5.4 Conclusion

This scoping exercise has identified a lack of evolution of PP in secondary care within the health boards sampled, despite a change in legislation allowing for non-medical IP. The Scottish Government focus, at least in the initial phases of PP, appears to have been primary care, with no framework available for implementation of PP in secondary care. Likewise, few of the Scottish health boards reported having a framework in place to facilitate implementation of PP, including secondary care. However, availability of a framework seemed to be linked with a larger number of actively prescribing pharmacists and consequently potentially more successful implementation of PP.

Chapter 5

Development of consensus guidance to facilitate a service redesign to involve pharmacist prescribing in secondary care

5.1 Introduction

As discussed in Chapter 4, the scoping exercise highlighted a potential “gap” between training of pharmacists as prescribers and implementation of pharmacist prescribing in secondary care. To aid implementation, this phase of the research aimed to develop consensus guidance to facilitate service redesign to involve PP in secondary care [a discussion on choice of method is in Section 5.3.1 below]. This guidance was based on evidence gathered from the focus group discussions and the scoping exercise.

5.2 A brief overview of consensus methods

The aim of formal consensus methods is to define the extent to which participants agree with a given issue; “agreement” refers to both the extent of agreement with the issue being proposed and the extent to which participants agree with one another. There is no agreement in the literature as to what consensus is; Jackie et al refer to this as “one of the most contentious components of the method.” (208) There are three main methods described in the literature that may be applied to seek formal consensus: the Nominal Group Technique (NGT), the Delphi Technique (Delphi) and the Consensus Development Conference. All methods attempt to systematically gather expert opinion usually in areas where there is a lack of or incomplete evidence. These methods are not intended to generate “right” answers, but what experts in the field think is important in relation to the topic at the point in time.(209) There are few studies comparing the different methods, and there appears to be no evidence that any one method is superior to another.(210) As comprehensively summarised by Campbell et al, these methods are useful for the following reasons:(211)

“Enhance decision-making, develop policies and estimate unknown parameters
Facilitate the development of quality indicators or review criteria
Support quality assessment and thus quality improvement as well as clinical
governance
Synthesize accumulated expert opinion/professional norms
Identify, quantify and subsequently measure areas where there is uncertainty,
controversy or incomplete evidence”

Consensus methods have been criticised for a lack of credibility, validity and reliability including questionnaire design, methods of defining and selecting experts and a lack of definition of consensus levels.(212) However, these issues may be overcome by ensuring a rigorous method and having a clear “decision trail” (as described in greater detail later in the context of this research).(211,213) Other critics have questioned whether the consensus reached is a true or an apparent consensus where participants conform to a central response due to peer pressure rather than their own acceptance of the position adopted by the group. This may be more pronounced in face-to-face discussions.(214) There may also be subject bias since it is likely that those most interested in the subject will respond or participate.(209)

The following is a brief description and critique of each method.

5.2.1 The Nominal Group Technique

NGT is a technique developed in the United States in the 1960s and is in the form of a highly structured facilitated meeting bringing together experts in the field, though there appears to be no published guidance on definition of ‘expert’. The following are key elements of NGT with some modifications also reported in the literature: (211,212,215)

- Experts are identified, assembled and asked to individually list issues related to the topic under discussion independently and privately.

- During the meeting, each individual, in turn ['round-robin feedback'], presents the most important idea to the group and the facilitator [who is an expert on the topic or a non-expert who has credibility with the participants] records this on a flip-chart, such that all members of the group may view the list under development. The process is repeated until no new ideas are generated.
- A highly structured discussion follows where all ideas are discussed and clarifications made. Similar suggestions are grouped together. Usually 15 minutes are allocated to discuss each item.
- Participants then privately and in writing rank each idea as part of the process at the meeting.
- The ranking is presented to the whole group for discussion. If agreement is reached, then consensus is established. If not, the item is deferred for later discussion.
- The overall ranking is re-ranked in light of the discussion.
- The final rankings are presented to the group.

Discussions can be audio-recorded to allow qualitative analysis particularly if there are any divergences. Supporters of this technique claim that the structured approach to the discussion both ensures that there is a discussion of all ideas generated rather than just one or two ideas and gives the opportunity for all to express their opinions. (210) Disadvantages include cost and the fact that an expert facilitator may bias outcomes by expressing his/her opinion or by having done so in the past [e.g. through publication]. (212)

5.2.2 The Delphi Technique

Delphi may be considered to be a mixture of quantitative and qualitative methods. Delphi originated in the 1950s and was developed by the RAND Air Force Corporation in America as a forecasting tool to estimate key nuclear targets in America from a Soviet point of view. (211) It has been modified for use in a number of applications within the healthcare area.

Delphi proceeds in a series of rounds as follows: (211,212,215)

- The initial stage involves development of a questionnaire on a specific topic using open-ended questions which is sent to experts in the area of research who are invited to provide opinions and views about the topic. The questionnaires are usually self-administered and completed by mail or electronically.
- The responses are analysed qualitatively and the questionnaire is reformulated by drafting statements that are suitable for ranking.
- This is resent to the panel and each individual is asked to rank the level of agreement or disagreement with each statement provided.
- The results are re-analysed quantitatively and the panel members are provided with the responses of other panellists and given the opportunity to reconsider their responses and re-rank statements.
- The cycle is repeated until group convergence of consensus is obtained and the final results are fed back to the participants.

A “Delphi approach” has been described where the initial questionnaire consists of structured or semi-structured questions that are derived using alternative sources such as the literature or surveys. (213)

The Delphi technique offers the following advantages:

- This process gathers the opinions of experts without needing to meet. (209,213) and lends itself to be conducted electronically hence performed more economically, conveniently and in the timescale required.
- Since opinions are expressed anonymously, it helps overcome the disadvantage of dominating individuals within group discussions. In open group discussions, individuals may feel a pressure to conform to the main ideas generated by the group. (215,216) In addition, individuals are given time to consider the topic rather than being pressurised to make a decision at the meeting.

- Controlled feedback with the responses of the rest of the group provided anonymously. Participants consequently have the opportunity to re-consider issues that they may have thought unimportant or missed.(209,214)
- Statistical aggregation of the group response ensures that the views of all members of the group are considered and all views are given equal weighting.(214)

Disadvantages include:

- Extensive time commitment from the participants (213)
- Anonymity may lead to lack of accountability if participants have hastily completed the questionnaire (213)
- Lack of face-to-face interaction may diminish the potentially positive aspects of discussion of any disagreement.(210)

5.2.3 Consensus Development Conference

This technique was developed by the US National Institute of Health. The aims of this method are to co-ordinate consensus development and provide methods of applying these.(212) Though it has been applied in countries outside the US, this method requires resources that are not usually readily available to most researchers.(215) The process takes the following format:

- An open meeting which may last a few days is convened with selected participants.
- During this chaired meeting, evidence is presented about the topic by experts and other groups or individuals who are not part of the decision-making group.
- The decision-making group then privately discusses the evidence presented and attempts to reach a consensus. This is also a chaired meeting.

Since it is expensive and difficult to organise, this method has only been used by large-scale health organisations.

5.3 Study design

5.3.1 Aim and objectives

The aim of this phase of the research was to develop consensus guidance to facilitate service redesign to involve PP in secondary care.

The objectives were:

- To use evidence generated through the focus groups to formulate statements about service development involving PP in secondary care
- To develop a questionnaire incorporating these statements for ranking using a Delphi technique
- To identify key stakeholders likely to be involved in a service redesign involving PP in secondary care to form the expert panel for the Delphi study
- To confirm or otherwise the evidence obtained through the focus groups by seeking the opinion of an expert panel
- To formulate the consensus guidance to facilitate service redesign based on the Delphi results

A consensus method was chosen in this context since the implementation of PP in secondary care is an area of pharmacy practice where there is still little evidence (see Chapter 1). This phase of the research also provided triangulation as a quality assessment step where the evidence obtained from the focus groups in the previous research was confirmed. Consensus methods are useful where there is a lack of evidence-base and to support quality assessment.⁽²¹¹⁾ A Delphi method was chosen due to the advantages described above mainly that it can be conducted electronically and within the timescale provided without a need for the expert panel to meet.

5.3.2 Questionnaire development

This is summarised at Figure 6 below.

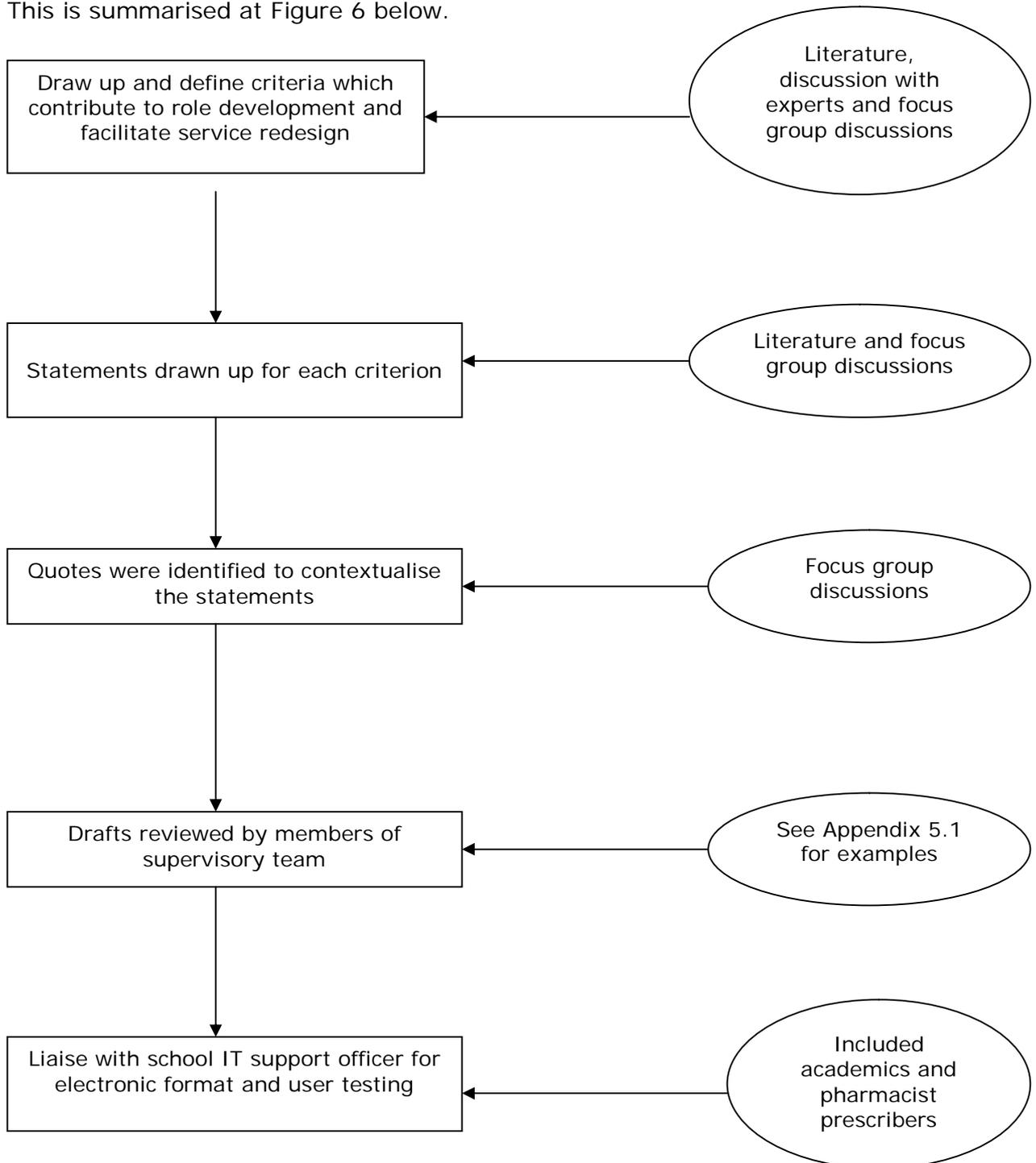


Figure 6: Development of questionnaire

No published literature was identified on key factors and guidance facilitating a service redesign^{xxi} when a preliminary search was conducted in the pharmacy database International Pharmacy Abstracts (IPA). However, relevant literature was identified relating to nursing and midwifery professions. Discussions were consequently held with local and national experts as follows: a consultant in public health, the director of pharmaceutical care model schemes, the non-medical prescribing lead in Grampian and a senior lecturer with extensive expertise in nursing development. They highlighted key documents that were subsequently adopted for use in this research. Through this literature, criteria which may facilitate a service redesign were identified.(217) These fell into two categories: **service management** which includes criteria aiming to encourage the efficient provision of the health service being provided, and **role specific** aiming to provide details of the educational and training support which needs to be provided to promote role expansion, the work expected to be undertaken, and the expected future orientation of the service. Each of the categories was sub-divided into criteria derived mainly from the literature and summarised in Table 21 below.(217) Other role development criteria were identified in the literature such as those relating to involvement in research activity and leadership qualities. However, evidence from the focus group discussions indicated that the role of the pharmacist prescriber was still developing and consequently these criteria were not relevant at present.

^{xxi} This has been defined by NHS Scotland as “an approach to improve outcome and efficiency in health” and is available at : <http://www.clinicalgovernance.scot.nhs.uk/section2/redesign.asp>

Table 21: Criteria that may facilitate a service redesign involving pharmacist prescribing in secondary care

Service Management	Role Development
1. Succession Planning	1. Education
2. Inter-professional Working	2. Future orientation of service
3. Quality Evaluation	
4. Practice Development	
5. Outcome measures	

To ensure consistency in understanding throughout this research, a definition of each criterion derived mainly from the literature and a rationale for each criterion derived mainly from the focus group results were drawn up. These are as follows:

A. Service Management

1. Succession Planning

Definition: This means that there are managerial processes in place within a health board to ensure that the role is not reliant on one person alone and that a system of staff development, supervision and support is in operation to enable others to take on the role.(217)

Rationale: Statements within this section aim to assist successful planning, strategy development for pharmacist prescribing and implementation of pharmacist prescribing making best use of the resource available. They aim to highlight the importance of the planning phase of the service redesign consequently making it possible to identify areas where pharmacists may improve the quality of patient care by utilising their prescribing skills following qualification.

2. Inter-professional Working

Definition: This means that the pharmacy role is part of a system of integrated professional working which is inclusive in nature.(217)

Rationale: Statements within this section aim to act as a trigger to ensure that other members of the multidisciplinary team likely to be stakeholders in the process, are involved at each stage of the service redesign. This is likely to assist the acceptance and uptake of pharmacist prescribing both within the institution, and within a specific area of care. This would also encourage the building of efficient multidisciplinary teams.

3. Quality Evaluation

Definition: This refers to the issues including quality assurance and audit processes, risk management and clinical governance which are used to evaluate the pharmacist prescribing service and ensure a safe and effective running of the service.(217)

Rationale: Statements within this section aim to highlight the need to analyse the implementation of a pharmacist prescribing service to ensure that its introduction does not compromise patient safety and quality of care. Any service redesign would need to take into account guidance issued by the Royal Pharmaceutical Society of Great Britain relating to this matter.(218,219)

4. Practice Development

Definition: This refers to the overall change in practice within secondary care which may be expected to accompany a service redesign which involves the establishment of pharmacist prescribing. (217)

Rationale: Statements within this section aim to act as a trigger to consider how the development of the pharmacist prescribing role will fit into current pharmacy service provision in secondary care. It may be necessary to analyse, review and change some current practices to ensure that these will not jeopardise the sustainability of a pharmacist prescribing service.

5. Outcome Measures

Definition: This refers to the evidence of both positive and negative consequences which are available to enable the professional merit of the role to be assessed at two levels: direct patient care and effect on other health professionals.(217)

Rationale: Statements within this section aim to act as a trigger to consider what outcomes may be indicative of the consequences of pharmacist prescribing. Outcomes must be valid, reliable and easily measurable and need to relate to both the clinical effects and the actual processes and procedures adapted. These may be of particular importance since there is little evidence available describing the outcomes of pharmacist prescribing.

B. Role Development

1. Education

Definition: This refers to the individual continuing professional development and the opportunities for continuing education provided for prescribing trainees and following qualification as a pharmacist prescriber. (217)

Rationale: Statements within this section aim to highlight the importance of considering areas such as competencies and continuing professional development for pharmacists who are prescribers. These may be of particular importance with the advent of independent prescribing, where a pharmacist may prescribe any licensed medication (other than controlled drugs) for any undiagnosed condition. With prescribing being a relatively newer task for pharmacists in secondary care, it may be necessary to provide support both for prescribing trainees and prescribing pharmacists, to ensure they are comfortable within this expanded role. (220)

2. Future orientation of the service

Definition: This refers to the advisory or supportive role of the pharmacist prescriber towards other healthcare professionals and patients. It also includes the level of practice that might be regularly expected from a specialist pharmacist prescriber and may include expanding the boundaries of pharmacy practice, demonstrating independent clinical decision making, carrying out systematic assessment and intervention and portraying a sophisticated use of clinical knowledge. (217)

Rationale: Statements within this section aim to project the likely future development of the role of the pharmacist prescriber, possibly moving from a "generalist" practitioner to a "specialist" practitioner.

Statements relevant to service redesign were constructed from thematic analysis of the focus group discussions. The statements were then grouped under the seven criteria above based on relevance. It was evident that some areas were discussed during the focus groups in much greater detail than other topics and consequently some sections are longer than others. To contextualize statements, to provide evidence that the statements were derived from the discussions and to offer a link between the statement and practice, an illustrative quote was provided for each statement. More than one quote was

initially identified for each statement and the quote in the final version of the questionnaire was selected based on which was the most appropriate to reflect the statement. Numerous drafts were produced and were reviewed by members of the supervisory team. Drafts illustrating the development of the questionnaire are available at Appendix 5.1. Members of the research team reviewed drafts mainly in terms of:

- Clarity of definition and rationale for each criterion
- Appropriateness and clarity of statements ensuring that there were no double-barrelled statements
- Relevance of statements to the specific criterion
- Appropriateness and choice of illustrative quotes provided
- Ease of use and comprehension for respondents.

A self-completed, electronic method of survey administration was chosen. Very little literature was identified critically describing the strengths and weaknesses of these methods of administration relating specifically to Delphi. The discussion below therefore refers to administration of survey questionnaires.

Self-completed postal survey questionnaires offer a number of advantages over face-to-face or telephone interviews: (221)

- Can cover a large geographical area – this was especially relevant here since the expert panel was likely to cover the whole of Scotland (a detailed description of selection of participants is provided later)
- Data may be collected from all respondents simultaneously. This allows for same “context” and “history” since all questionnaires are received at the same time
- Avoids interviewer bias

There are also a number of disadvantages of self-completed postal questionnaires: (221)

- Low response rates – these may be even more of an issue in this study due to busy schedules of respondents. A discussion on methods adopted to enhance response rates is found below in Section 5.3.5.
- Non-response bias where the characteristics of non-respondents may be different to those of respondents. However, no information is available on how non-response may bias results in a Delphi study. (211)
- May be an “inflexible” method since one cannot probe further as in an interview. To try and overcome this, participants were provided with a “comments” section to provide any additional statements or other relevant issues they thought were omitted.
- No control over who completes the questionnaire.

Advantages of self-completed web based delivery compared to a postal delivery include:

- Time and cost-savings with quicker response speeds reported (222,223)
- Allows more precise tracking (e.g. undeliverable email) (223)
- Convenient since it is completed at the participant's leisure (222)
- Better response quality (e.g. longer answers to open-ended questions) (223)
- Some evidence that a wider range of rating scales is used compared to paper-and-pencil methods. (221)

Disadvantages include:

- Limited to respondents with web access which may bias towards areas and individuals with higher income resulting in racial and ethnic groups not represented.(222) This makes it difficult to obtain a sampling frame that is truly representative of all the population.(223) This is unlikely to be an issue in this study since all participants have e-mail and web access through their place of work.

- Security and data integrity – there may be concerns about confidentiality that discourages participants.(222) Further details on precautions adopted in this study are in Section 5.3.3 below.
- Technical troubles may produce different looking surveys from one participant to another or prevent access to surveys altogether.(222) Efforts were made to overcome these difficulties through prior user-testing of questionnaires.
- Variation in user-capability though again this was not likely to be an issue here.(223)
- Respondents submitting multiple questionnaires.(221) Liaison with the school IT facilitator indicated that there was no way of ensuring that participants submit the completed questionnaire no more than once. It was not possible to determine whether this did occur in this research since all questionnaires were completely anonymous.

The questionnaire was developed to enable electronic delivery following close liaison with the School E-learning support officer. Participants were asked to rank each statement provided on a five point scale: Strongly Agree, Agree, Undecided, Disagree and Strongly Disagree. The literature recommends using no more than five points when adopting rating scales.(221) There has also been some debate as to whether a “don’t know” category should be included as a response option; some respondents may select this option without thinking about other options but respondents may omit or guess questions if this option is not available. McColl et al consequently recommend including this.(221)

The questionnaire was then user-tested and sent to individuals who were not likely to be part of the final cohort as follows: one academic with experience in questionnaire development and use of Delphi, one academic also closely involved in policy, one independent pharmacist prescriber and one pharmacist prescriber also involved in medicines management. They were all sent the following email:

Dear all,

I am wondering whether it would be at all possible to help me out with user testing of my questionnaire. This may be accessed using the link provided below. This is intended to be a Delphi study where participants will be asked to indicate agreement or disagreement with given statements which I have derived from previous focus group discussions. I would be interested in knowing how long it takes to fill in and ease of use. I have tried to select people who are involved in prescribing/teaching, involved in strategy development or who have previously conducted Delphi studies.

All agreed to review the questionnaire. They reported taking 10-20 minutes to complete and submit the questionnaire. A recurring comment was that the participants felt that they should agree with all statements, increasing the probability of acquiescence response bias. As a result of this comment, the statements were reviewed and some statements rewritten to have more of a negative meaning to them. [Appendix 5.1 - Questionnaire after user-testing, (changes and comments are in blue)] However, on further discussion and analysis, the original statements were retained, mainly since the revised ones were not derived from the focus group discussions and consequently, did not appear to be grounded in the data. Besides, McColl et al (2021) conclude that there is conflicting evidence as to what influence positively or negatively worded questions have on response bias. They therefore recommend caution if adding negatively phrased attitudinal items. Other recommended changes were minor. These included changes to some statements and instructions and giving the participants an option at the end to add on any statements if necessary. The final questionnaire for round 1 is available at Appendix 5.2. The following is an example of screen-shots from the final electronic questionnaire.

I. Service Management – this section aims to encourage the efficient provision of the health service being delivered. The service being considered here is pharmacist prescribing in secondary care.

1. Succession planning:

Definition: This means that there are managerial processes in place within a health board to ensure that the role is not reliant on one person alone and that a system of staff development, supervision and support is in operation to enable others to take on the role.¹

Rationale: Statements within this section aim to assist successful implementation of pharmacist prescribing making best use of the resource available. They aim to highlight the importance of the planning phase of the service redesign consequently making it possible to identify areas where pharmacists may improve the quality of patient care by utilising their prescribing skills following qualification.

In view of the above information, for each of the following statements, please indicate how strongly you agree or disagree that this is important to ensure effective succession planning, when developing service redesign to involve pharmacist prescribing. Please provide any comments that you have about the criteria in the space provided.

A. It is important to undertake a systematic and objective assessment of pharmaceutical needs in order to identify gaps in the current service delivery and patient care and outline ways in which pharmacist prescribing may improve patient care or encourage better utilisation of staff skills and resources.

RGU: AT Questionnaire - Windows Internet Explorer

http://iws.rgu.ac.uk/pharmacy/practice/page.cfm?pge=47988

File Edit View Favorites Tools Help

RGU: AT Questionnaire

II. Role Specific – this section aims to provide a detail of the work expected to be undertaken by a pharmacist prescriber, the support which needs to be provided to promote role expansion, and the expected future orientation of the service.

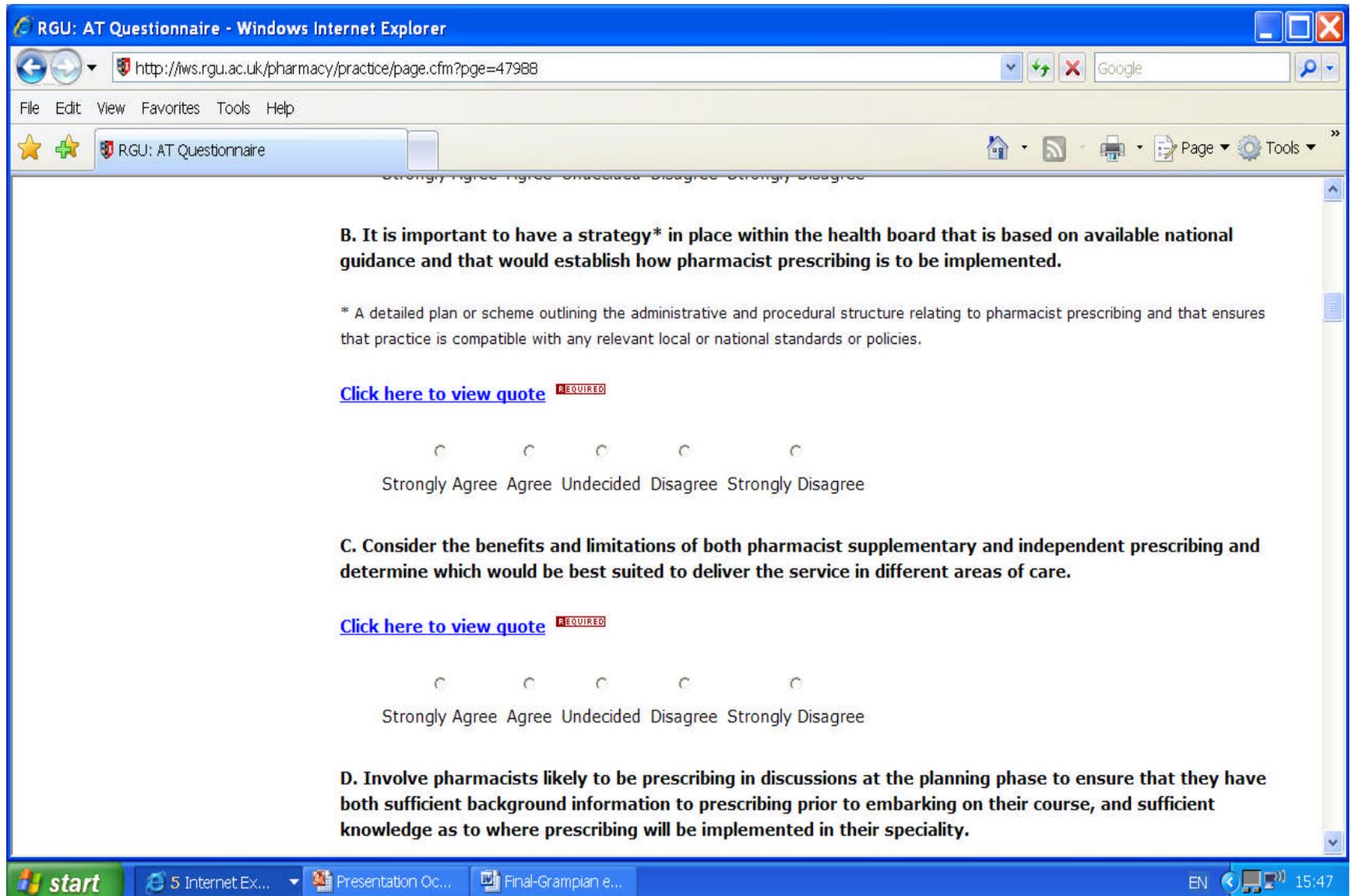
1. Education:

Definition: This refers to the individual continuing professional development and the opportunities for continuing education provided for prescribing trainees and following qualification as a pharmacist prescriber.¹

Rationale: Statements within this section aim to highlight the importance of considering areas such as competencies and continuing professional development for pharmacists who are prescribers. These may be of particular importance with the advent of independent prescribing, where a pharmacist may prescribe any licensed medication (other than controlled drugs) for any undiagnosed condition. With prescribing being a relatively newer task for pharmacists in secondary care, it may be necessary to provide support both for prescribing trainees and prescribing pharmacists, to ensure they are comfortable within this expanded role.

In view of the above information, for each of the following statements, please indicate how strongly you agree or disagree that this is important to ensure appropriate education for pharmacists who will be/are prescribing, when developing service redesign to involve pharmacist prescribing. Please provide any comments that you have about the criteria in the space provided.

A. Provide the necessary support for pharmacists during training or who are planning to train to be prescribers.



RGU: AT (I) 1C Succession Planning - Windows Internet Explorer

http://iws.rgu.ac.uk/pharmacy/practice/page.cfm?pge=47969

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Succession Planning

"....it [independent prescribing] takes a step out of the process, which that step is actually quite prohibitive in an acute setting, trying to get an individual clinical management plan for every single patient, if they were almost in for two or three days; that's the biggest hurdle and independent prescribing removes that hurdle, but it doesn't change the medicines nor the circumstances if you would prescribe them."

Male, On supplementary prescribing course, 25 years in pharmacy, 15 years in medicine/cardiovascular/management

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5.3.3 Research Governance

The research proposal and the final questionnaire were reviewed by the School of Pharmacy and Life Sciences, Robert Gordon University ethics committee in July 2008. Following this, the proposal was submitted for review to the North East of Scotland Research Ethics Committee in September 2008 with all documentation submitted at Appendix 5.3. Approval was granted in October 2008, following a number of minor amendments (all correspondence and reviewed documents at Appendix 5.4). The initial proposal indicated conducting interviews with members of the Scottish Government aiming to determine whether the consensus guidance produced by this research was in line with the Scottish Government policy. However, as the research progressed, it was evident that the research had moved beyond this, and therefore the interviews were unlikely to add any further new information.

Since NHS staff were involved in completing the questionnaires, it was also necessary to obtain Research and Development approval from all 14 NHS health boards. Approvals were granted between December 2008 and January 2009 for 12 health boards, and these were included in this study. Approval for the remaining two health boards was granted in March 2009 (the study was in progress then) and June 2009 (the study was completed) and these were therefore not included.

To protect the participants' anonymity and to ensure that participants were unaware of who else was invited to complete the questionnaire, the invitation to participate was sent through the "Blind Carbon Copy" (bcc) facility in e-mail. The same process was used in all further correspondence such as when sending out the questionnaire web-link and reminders. All signed consent forms were stored in a password protected laptop and no hard copies were made. Throughout the process, respondent anonymity has been maintained such that it was not possible to trace back questionnaire responses to any of the respondents. All e-mail correspondence was done through the university e-

mail account to ensure protection by the university firewall. E-mail addresses of all respondents were destroyed upon completion of the research.

5.3.4 Process used to achieve consensus

Choice of expert panel

Selection of the expert panel forms an integral part of a sound methodology involving Delphi.(215) There is agreement in the literature that the input of a number of experts will enable more in-depth information to be provided than that obtained from one individual.(208) However, there is a paucity of guidance defining the criteria to be fulfilled by an “expert”, identification and the likely number required. Fink et al provide some guidance on choosing an expert panel as follows:

“Consensus participants should qualify for selection because they are representative of their profession, have power to implement the findings, or because they are not likely to be challenged as experts in their field.” (212)

There have been wide variations in panels reported in the literature with the number of participants ranging from 4 to 3000.(211) It has been suggested that the larger the sample, the greater the reliability of the research, but there is no evidence that a larger sample will have any effect on reliability and validity.(213) Hasson et al comment that participants who are knowledgeable and interested in the topic are likely to increase content validity.(209) In their discussion on “Consensus methods in prescribing research,” Campbell et al recommend that an appropriate consensus method should include an expert panel that reflects the stakeholders it is trying to represent and importantly takes into account the research objectives of the study.(211) In view of this recommendation by Campbell et al, key stakeholders likely to be involved in a service redesign involving PP in secondary care were invited to form the final expert panel. The choice was informed by evidence from the focus group discussions (Chapter 3), the scoping exercise (Chapter 4) and discussion within

the research team. Both strategic and practising professionals formed part of the final expert panel.

The key stakeholders in Scotland and potential participants as an expert panel in this research were identified as follows:

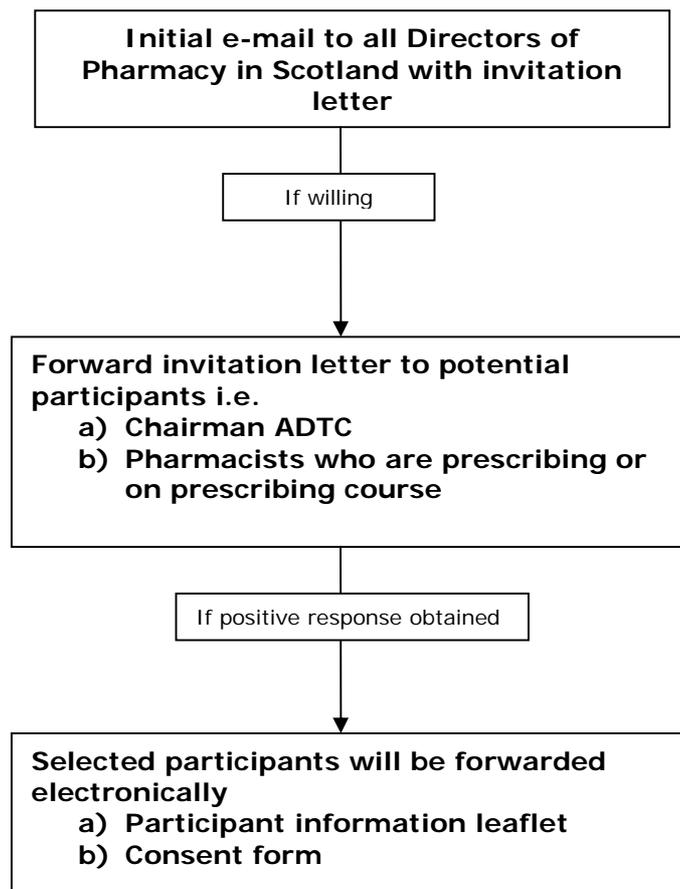
- a) Scottish Directors of Pharmacy were included since the background scoping exercise indicated that it was likely they would be closely involved in a service redesign from a strategic point of view.
- b) Acute health board pharmacy directors [this post was not available for all Scottish Health Boards] included as above. They were likely to be more knowledgeable on secondary care issues, the area that the research was focusing on.
- c) Pharmacists who were authors of Scottish prescribing frameworks due to their potential strategic role in local developments.
- d) Secondary care practising pharmacists prescribing or on a prescribing course – two pharmacists from each health board were included if available and agreed to participate; pharmacists who had participated in the initial focus group discussions were not included since their opinion had already been considered to draw up this document.
- e) Non-medical prescribing leads who were not pharmacists but direct authors of frameworks and policies. These were included since it was evident from the background scoping exercise that in most health boards, the approach taken was to have a general non-medical prescribing policy drawn up by pharmacy and nursing.
- f) Chairmen of Area Drugs and Therapeutic Committees (ADTC). These were included since non-medical prescribing policies are reviewed by ADTC.

The following were excluded:

- i) Pharmacists who were non-medical prescribing leads in their health boards since all those identified were primary care rather than secondary care practitioners which is the focus of this research.

- ii) Independent prescribers who had mentored pharmacists as designated medical practitioners during their prescribing course. The research team felt that the study was unlikely to be of direct relevance to them and they were unlikely to be aware of the practitioner's perspective of the topic under investigation.
- iii) Clinical pharmacy managers since following user-testing it became apparent that it would be difficult to define and validate this role. Consequently it was likely that the role would vary across health boards.

Stakeholders in groups a, c and e above had already been identified in the background scoping exercise and their e-mail addresses were available in the public domain. Contact details for other stakeholders were identified using the following procedure: an e-mail was sent out to all Directors of Pharmacy in Scotland. If willing, they were asked to forward an invitation letter attached to the e-mail to their respective health board chairmen ADTC, and pharmacists who are prescribing or on a prescribing course. Those willing to be potentially selected for participation to form part of a purposive sample (of strategic or practicing professionals with involvement in pharmacist or non-medical prescribing) made direct contact with the researcher. This ensured that contact details were available only for those willing to participate. The recruitment process is summarised as follows:



Data collection and analysis

During February 2009, an e-mail was sent out to all individuals who had indicated that they were willing to be contacted to take part in the Delphi study (n=76). This e-mail included an invitation to participate, an information sheet together with a consent form (Appendix 5.4). Participants consenting were asked to return this form by e-mail.

In late February 2009, round 1 of the study was initiated when a web-link to the questionnaire was sent out to all consenting (n=40). Participants were encouraged to contact the research team if there were any technical difficulties with accessing and completing the questionnaire. Should they prefer, participants were given the option to ask for a paper copy of the questionnaire

(in actual fact, none of the participants opted for this). To enhance response rates, a reminder was sent out after seven days. Since the questionnaire was completed anonymously, the reminder was sent to all individuals who were sent out the initial e-mail. No literature was identified on enhancing response rates to Delphi questionnaires, though a maximum of three rounds is recommended since it is likely that response rates will start to fall due to participant fatigue.(213) Participant follow up has been reported to produce an increase in response rate to e-mail surveys though it is not clear how many follow ups produce the optimal response rate.(223) No evidence on increasing response rate specifically in Delphi questionnaires was identified in the literature.

Following completion of round one, data was analysed for achievement of consensus. Consensus was defined as 70% agreement (ranked strongly agree or agree on Likert scale provided) with each statement. Since there was no literature identified on the topic, a consensus value of 70% agreement was thought to be a realistic target. Based on results of round one, a revised questionnaire (see Appendix 5.5) was sent to the participants for ranking of six statements – four statements were from the previous questionnaire and where no consensus had been achieved, two statements were new and based on comments made by the participants. Participants were also provided with the group response for the original statements together with comments provided for each. This was in line with the iterative process which is part of the Delphi method.(211) The same process of dissemination of the questionnaire used in round 1 was used in round 2 and this was completed in April 2009.

5.3.5 Characteristics of a good Delphi and application to this research

There has been much debate in the literature about the reliability and validity of Delphi, with some recommendations that criteria for qualitative methods may be more suited than those for quantitative methods.(209,211) There is agreement that a sound methodology with a robust “decision trail” enhances

the credibility, reliability and validity of Delphi research, with characteristics of good Delphi methods identified.(213) This section will aim to describe these and their application to this research.

- **Selection of experts**

A detailed description of this can be found at section 5.3.4 highlighting the appropriateness of each participant.

- **Consensus**

There is no agreement in the literature as to what consensus is and Crisp et al comment that this is “one of the most contentious components of the method.” (208) To enhance validity and reliability, a definition of consensus must be provided prior to starting the study; for example “statement is supported by at least X% of participants for consensus to be achieved.” (211,212) This will ensure that results are not open to an uninformed and random judgement.(213) For the purpose of this research, consensus was defined as at least 70% agreement with each statement and was established at the protocol phase of the study.

- **Feedback**

When providing feedback as part of the iterative process, ratings of the individual group members should be kept anonymous and democratic in that ratings from all members of the group must carry equal weighting. It is also recommended that where possible feedback should include both quantitative statistics and qualitative comments if any have been made.(211) Both these were provided anonymously and democratically as part of round 2 (see Appendix 5.5). Campbell et al suggest that there may be differences in results if providing “collective” (feedback from the entire expert panel) or “selective” feedback (feedback from only the relevant professional group).(211) There is not much evidence in the literature on how this may affect selection bias of the same statement; in view of this, collective feedback was provided in this research.

- **Response rates**

Reminders and relevance of the topics to the panellists is likely to increase response rates. However, nothing is known about how rates will bias results in Delphi.(211) A response rate of 70% has been suggested for each round to maintain the rigour of the method.(209)

- **Specificity**

As recommended by Fink et al every effort was made to ensure that statements provided for ranking were clear and specific.(212)

- **Iteration**

The number of rounds that will be conducted should be specified beforehand.(211) Two or three rounds are usually recommended, with successive rounds helping to increase concurrent validity.(209) It was originally planned to have a maximum of three rounds in this study; however it was apparent that consensus was achieved after two rounds and the study was consequently stopped.

5.4 Results

5.4.1 Round 1

The number of participants consenting to participate and to whom a questionnaire was forwarded was 40 (a total of 76 were invited to participate). Thirty-five questionnaires were completed giving a response rate of 87.5%. The participants indicated the following roles within their health boards, with some participants having multiple roles.

Director of Pharmacy	4
Acute health board director	3
Chairman ADTC	4
Non-pharmacist author of non-medical prescribing policies	5
Pharmacist author of non-medical prescribing policies	10
Pharmacist prescriber	15

As previously indicated, consensus was set at 70% and therefore 25 participants were required to strongly agree or agree with a statement for consensus to be reached with that statement. The number of statements where consensus was reached was 27 out of 30 (level of agreement 70%-100%) while the number of statements where there was disagreement was 3 out of 30 (level of agreement 17% - 66%). A detailed breakdown of the results obtained together with any comments given for each statement is provided below.

A. Service Management

1. Succession Planning

A. It is important to undertake a systematic and objective assessment of pharmaceutical needs in order to identify gaps in the current service delivery and patient care.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree
17	17	1	0	0

Consensus reached (97% of 35)

B. It is important to outline ways in which pharmacist prescribing may improve patient care or encourage better utilisation of staff skills and resources.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree
16	19	0	0	0

Consensus reached (100%)

C. It is important to have a strategy^{xxii} in place within the health board that is based on available national guidance and that would establish how pharmacist prescribing is to be implemented.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree
16	17	2	0	0

Consensus reached (94%)

Comments

Use of the word strategy requires to be defined as appears to have been applied at a lower level than would normally be the case. (Director of Pharmacy)

D. Ensure that any strategy in place may be applicable across different practice settings and areas of care. This implies that the service is generic and transferable.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree
7	20	3	5	0

Consensus reached (77%)

^{xxii} A detailed plan or scheme outlining the administrative and procedural structure relating to pharmacist prescribing and that ensures that practice is compatible with any relevant local or national standards or policies.

Comments

The service is not generic and transferable – it is different in different clinical areas, particularly paediatrics/neonates. (Pharmacist prescriber)

E. Consider the benefits and limitations of both pharmacist supplementary and independent prescribing and determine which would be best suited to deliver the service in different areas of care.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree
11	19	2	3	0

Consensus reached (86%)

F. Involve pharmacists likely to be prescribing in discussions at the planning phase to ensure that they have both sufficient background information to prescribing prior to embarking on their course, and sufficient knowledge as to where prescribing will be implemented in their speciality.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree
13	19	2	1	0

Consensus reached (91%)

Comment

Comprises two questions which have different answers. Pharmacists who line manage potential prescribers need to be involved at the planning stage. These managers need to ensure that all potential prescribers have an understanding of the plans. (Director of Pharmacy)

G. Consider in which practice settings it may be more feasible to introduce, implement and monitor pharmacist prescribing.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree
15	19	1	0	0

Consensus reached (97%)

H. Consider procedures that would allow the smooth and safe transition of patients from secondary to primary care if pharmacists are an additional prescriber.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree
13	19	2	1	0

Consensus reached (91%)

Comment

Should not make any difference. [Non prescribing] pharmacist should be seeing these patients anyway and should ensure smooth transition. In practice that non prescriber becomes the prescriber so there is no change in this part of the care process. (Pharmacist prescriber)

Other general comments provided for Section 1

The practicalities of service provision in different practice settings can be pronounced. Hence clinical governance strategy must be tailored to particular settings. (Pharmacist author of non-medical prescribing policy)

Must consider the governance aspects too of the prescriber potentially being the only pharmacist. So who clinically checks their prescription? (Pharmacist author of non-medical prescribing policy)

Essential to determine service need and strategy to address service need. Consider redesign where pharmacist prescribing might replace other disciplines prescribing practice in order to improve access to therapy, or improve quality of prescribing. Also need to consider resource issues and make sure that the prescribing pharmacist is free from other duties which might compete for the time available to prescribe. (Acute health board director)

Specialist services in which prescribing is suitable in secondary care may not be a viable option to transfer to primary care. (Pharmacist prescriber)

There are no questions which focus on identifying how many staff should be competent to prescribe within a particular setting. This is a vital consideration for sustainability. (Acute health board director)

2. Inter-professional working

A. Involve all key members of the multidisciplinary team who are stakeholders when planning the strategy for pharmacist prescribing.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree
19	15	1	0	0

Consensus reached (97%)

B. Determine how likely it is for other key members of the team to accept pharmacists as prescribers.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree
10	21	1	3	0

Consensus reached (89%)

Comments

Agree, to smooth the implementation by identifying areas of concern of the multidisciplinary team. However the standpoint must be thrust forward that this is national policy and that it is going to happen no matter whether individuals agree or not. Pharmacy has to take this forward with confidence. (Pharmacist prescriber)

As well as the prescribing team, we should consider if this will be acceptable for patients- especially if clinical examination skills are required. (Non-pharmacist author of non-medical prescribing policies)

C. Promote a good understanding of the pharmacist prescriber’s role with other members of the multidisciplinary team.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree
24	11	0	0	0

Consensus reached (100%)

D. Promote clearly defined roles relating to pharmacist prescribing within the multidisciplinary team.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree
20	13	1	1	0

Consensus reached (94%)

E. Promote clearly defined lines of communication relating to pharmacist prescribing within the multidisciplinary team.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree
17	17	1	0	0

Consensus reached (97%)

F. Encourage the development of non-medical prescribing multidisciplinary teams.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree
6	17	6	4	2

Consensus not reached (66% agree)

Comments

Suggest that question is wrongly worded – should say “Encourage participation of Non Medical Prescribers within multidisciplinary teams” – would then strongly agree. (Director of Pharmacy)

A multidisciplinary team is just that – multi disciplinary. There is no point creating a separate non-medical prescribing multidisciplinary team because it should be routine, not something outside the norm. (Pharmacist prescriber)

Non-medical prescribing should be based around a central multidisciplinary team, each member contributing. Extra teams would dilute, diffuse and potentially confuse lines of communication and I consider them unnecessary. (Pharmacist prescriber)

Not sure that the question is clear. Would there not be medical prescribers involved in the team too? (Pharmacist prescriber)

I agree with developing multidisciplinary teams of prescribers of all disciplines but I do not agree that we should exclude medical prescribers from these teams. (Acute health board director)

F would be dangerous as it appears to promote establishing a team to rival medical prescribers. We must work with medics and develop consistent approaches and standards. (Acute health board director)

I am not sure if question f reflects the quote. I think that pharmacist meant all prescribers in multidisciplinary teams not just non medical prescribers. (Pharmacist prescriber)

Felt that ALL prescribing should be integrated within one team for the appropriate area and distinguishing between non medical and medical does not help. (Pharmacist author of non-medical prescribing policy)

Other general comments provided for Section 2
This should be for local strategy, but not the multidisciplinary strategy for implementation of pharmacy and non medical prescribing in general. (Non-pharmacist author of non-medical prescribing policy)

As prescribing in this context is novel it is not helpful to put too rigid a framework on it as this may stifle innovation. (Pharmacist prescriber)

Yes do all this but be prepared to be flexible in the light of experience. (Pharmacist author of non-medical prescribing policy)

A to E seem self evident and I cannot understand why anyone would not agree strongly. (Acute health board director)

This may come later but it is my impression that there is a significant capacity issue in pharmacy for prescribing roles. That is why clinical nurse specialists in my hospital have been able to apply the non-medical prescribing model much more effectively than pharmacy. (Pharmacist prescriber)

3. Quality Evaluation

A. Establish that systems are in place (and are defined, documented and regularly reviewed) to promote patient safety and encourage quality patient care when pharmacists are prescribing, which have taken into account the “Clinical Governance Framework for Pharmacist Prescribers and Organisations Commissioning or Participating in Pharmacist Prescribing” and any other local governance structures or strategies. (218)

Strongly agree	Agree	Undecided	Disagree	Strongly disagree
22	12	1	0	0

Consensus reached (97%)

B. Ensure that legal responsibilities and accountabilities are defined and documented within the strategy and have taken into account the “Professional Standards and Guidance for Pharmacist Prescribers” which are part of the Pharmacist Code of Ethics.(219)

Consensus reached (91%)

Strongly agree	Agree	Undecided	Disagree	Strongly disagree
23	9	2	0	1

Comments

At my independent prescribing course I was quite alarmed by the (over) confidence that some colleagues showed towards initiating prescribing in areas where they had no competence eg respiratory pharmacist in GP practice considering prescribing antidepressants! (Pharmacist prescriber)

Current methods for prescribing for in-patients in secondary care (non electronic) mean that it is difficult to identify and quantify non medical prescribing input. This should be given consideration, with recommendations until electronic prescribing (HEPMA) is common place. (Non-pharmacist author of non-medical prescribing policy)

4. Practice Development

A. Consider any changes in current pharmacy service provision in secondary care that may be needed to support the development of a pharmacist prescribing service.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree
14	20	0	0	1

Consensus reached (97%)

Comment

The initial evaluation must take into account the effectiveness of existing services as a pharmacist prescribing service may have to be introduced on a cost neutral basis and

may be in competition with these existing services. Obviously resource may be sourced from the discipline to which the prescribing benefits. (Pharmacist prescriber)

B. Consider any additional resource/s that may be needed to ensure provision and sustainability of a pharmacist prescribing service.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree
19	15	1	0	0

Consensus reached (97%)

Comment

It may not be about additional resource but reconfiguration of existing resource. (Director of Pharmacy, Chairman ADTC, Pharmacist author of non-medical prescribing policy)

Review of skill mix within departments and on wards will be vital. (Pharmacist author non-medical prescribing policy)

General comments for Section 4

Consider pharmacist prescribing only if warranted by a service – add value. (Pharmacist author non-medical prescribing policy)

Pharmacist prescribing on wards should be as part of a multidisciplinary team of prescribers doctors, nurses and pharmacists working within a care pathway any of whom can assume the responsibility for prescribing for the patient at that point in the pathway assuming they are competent to do so in that particular patients' circumstances. (Acute health board director)

Half a service is worse than no service. With no service other healthcare professionals make no assumptions of what might have been done. (Pharmacist prescriber)

Opportunities for pharmacist prescribing exist for out-patients and managing case loads of patients in that setting. For example Pharmacist led pain clinics, cardiovascular risk clinics, chemotherapy capecitabine clinics etc. (Acute health board director)

5. Outcome measures

A. The strategy should include ways of assessing outcomes to measure any positive or negative impact of the role on direct patient care.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree
17	17	0	1	0

Consensus reached (97%)

B. The strategy should include ways of assessing outcomes to measure any positive or negative impact of the role on other healthcare professionals.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree
12	16	5	2	0

Consensus reached (80%)

Comments:

Outcome measures need to be broad ranging. (Acute health board director)

This is something we did – presenting practice audit results at a national conference and during workshops. Not everyone needs to do it though – it just needs sufficient data available to show it is of benefit and others can use this to help develop similar services. (Pharmacist prescriber)

The implementation of the service should be evaluated with reference to the impact on both the patient and the service. (Pharmacist prescriber)

It is every professional's responsibility to assess the outcomes of their practice on their patients. If the objective of the pharmacist prescribing service was to free other disciplines time for example then this should be assessed but not routinely or on an ongoing basis. (Acute health board director)

Possibility of deskilling other prescribers, such as junior medics, should be considered. (Pharmacist prescriber)

Perhaps this work needs to be done before a strategy is put in place? A clear improvement in service to patients is essential. (Pharmacist prescriber)

To work well as a team we don't want to de-motivate other team members if they feel threatened by new roles so will need careful handling, but prime consideration must be to enhance patient care through improved access to required medicines –otherwise not meeting the objective of original 'Crown' report. (Pharmacist author non-medical prescribing policy)

As per comments above. The most tangible impact may be in relation to patient discharge scripts. (Non-pharmacist author non-medical prescribing policy)

B. Role Development

1. Education

A. Provide support for pharmacists during training or pharmacists who are planning to train to be prescribers.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree
20	13	2	0	0

Consensus reached (94%)

Comments

As an independent prescriber, I have had many visits from other non-medical prescribers to see the clinic I work at in practice. (I have had a visit from a podiatrist not just pharmacists which helps with the multidisciplinary element to the clinic). I think this should be an essential part of the "time in practice" element of the course. I would be more than willing to mentor pharmacists with their learning. (Pharmacist prescriber)

There are good existing models for support, developed by Nursing and Midwifery colleagues for mentor and CPD support, currently used in relation to NMP. Within NHS Fife this is open to Pharmacist and AHP colleagues. (Non-pharmacist author non-medical prescribing policy)

B. Provide clearly defined pharmacist competencies to help pharmacists achieve and maintain competency when prescribing ("Maintaining Competency in Prescribing" produced by the National Prescribing Centre may be a good resource). (220)

Strongly agree	Agree	Undecided	Disagree	Strongly disagree
15	17	3	0	0

Consensus reached (91%)

Comment

How do you write competencies for all the individual nuances of levels of practice & expertise? Impossible. (Pharmacist prescriber)

C. Clearly define the level and type of experience required to prescribe in different specialties.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree
14	14	4	3	0

Consensus reached (80%)

Comment

QC - competence should be the measure rather than experience. (Director of Pharmacy)

D. Provide the necessary opportunities for education and training following qualification as a prescriber.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree
18	16	1	0	0

Consensus reached (97%)

Comment

Whilst the employer has some responsibility to provide support for an individual's PDP the individual prescriber is primarily responsible for their own CPD. (Pharmacist author non-medical prescribing policy)

E. Ensure that pharmacists are able to demonstrate competence on an on-going basis to prescribe in their area of practice.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree
18	15	2	0	0

Consensus reached (94%)

Comment

While providing education and training after qualifying, there should be a level of competence in management of conditions prior to undertaking the course, so that once qualified they are competent to prescribe and manage their patients. (Non-pharmacist author non-medical prescribing policy)

F. Ensure that the preparation for the role has taken into consideration the pharmacists' individual views and attitudes.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree
11	14	9	1	0

Consensus reached (70%)

Comments

Only so far as to help filter the most appropriate individuals for the role and not to influence the specification and nature of the role itself. (Pharmacist prescriber).

QF - require to be committed and competent. (Director of Pharmacy).

G. Provide the necessary mentoring scheme to pharmacists who are prescribing.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree
16	18	0	1	0

Consensus reached (97%)

Comments

Lack of pharmacists currently prescribing may mean mentor has to be from another profession. (Pharmacist prescriber)

Clinical supervision would be essential to support pharmacists particularly in the early days of establishing this new role. (Pharmacist prescriber)

General comments

There is a bit of an "art" to prescribing which requires the prescriber to bring together their knowledge and experience to make a professional prescribing judgement. I am not convinced that we can define a set of competencies which can fully describe what goes in to making that professional judgement. I don't think we have enough evidence or experience of pharmacist prescribing to be able to define the level and type of experiences required before authorising prescribing. The prescribing pharmacist needs to make a judgment whether they are competent to undertake the prescribing decision for their patient. In this kind of scenario a multidisciplinary peer group and a mentor is essential. (Acute health board director)

May be difficult to be totally prescriptive here and do we do this for medical prescribers so again need care in what we aim to achieve. (Pharmacist author of non-medical prescribing policy)

2. Future orientation of service

A. Encourage all hospital pharmacists to prescribe in any specialty.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree
2	4	14	12	3

Consensus not reached (17% agree; 43% disagree)

Comments

My indecision over ALL hospital pharmacists prescribing is due to (a) new entrants to hospital pharmacy from other sectors and (b) newly qualified pharmacists who will need mentoring before taking on this role. (Acute health board director, Pharmacist prescriber, Pharmacist author non-medical prescribing policy)

QA. Would require to be implemented in a planned and phased basis. (Director of Pharmacy)

QA. This is the final step in a process that pharmacists already initiate or participate in. Inherent in becoming and maintaining prescriber status is considerable CPD. Becoming a prescriber is a major pathway or opportunity in linking pharmacy even further with the patient journey, becoming a more useful valued member of the multidisciplinary team which improves the skill mix which in turn promotes appropriate use of staff resource. (Pharmacist prescriber)

QA. Pharmacist training should allow them to prescribe. Given that the value of a professional in the NHS is valued by their knowledge skills and experience by and large I think pharmacists at a senior level are adequately remunerated to prescribe. (Acute health board director)

Pharmacist prescribing is not suitable for all areas of patient care. There are areas that are ideal, e.g. intensive care and clinics. In other words specialist areas. (Pharmacist prescriber)

I do not think it is something we should force upon pharmacists. Prescribers should want to prescribe, but I feel it opens up many doors and enhances their role within the multidisciplinary teams. It is part of my practice that I enjoy and get a great deal of job satisfaction with. (Pharmacist prescriber)

Clinical pharmacy involves giving prescribing advice to prescribers (doctors). I consider pharmacist prescribing to be only a small step further since already the responsibility has been there but not 'signed for' directly. (Pharmacist prescriber)

In my view pharmacists should only prescribe when a suitable service model exists and they have sufficient post registration training. A lot of our prescribing problems arise because most junior doctors learn prescribing on the job. (Pharmacist prescriber, Pharmacist author non-medical prescribing policy)

Prescribing is the future for all hospital pharmacist practitioners. There will be a period pre and post registration where prescribing should be strictly supervised but following a foundation training period all hospital pharmacists who have direct to patient pharmaceutical care responsibilities should prescribe. (Acute health board director)

Prescribing should be limited to defined specialties with the appropriate pharmacists in post as your previous questions have indicated. It is not appropriate for all hospital pharmacists as a specialist knowledge within a specific area must be achieved before prescribing can be undertaken. The pharmacist must also have the confidence of and support from the multidisciplinary team they work with. (Pharmacist prescriber)

By saying all hosp pharmacists should prescribe this moves away from assessment of need-it really does often depend on local circumstances .(Pharmacist author non-medical prescribing policy)

B. Encourage the development of prescribing specialist roles.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree
9	19	4	3	0

Consensus reached (80%)

C. Ensure that pharmacist prescribers are financially compensated in line with their added responsibilities.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree
9	12	10	4	0

Consensus not reached (60% agree; 11% disagree)

Comments

It is not legal or ethical to pay someone to prescribe. Pharmacists should see it as part of their expanded patient care role. (Pharmacist prescriber)

QC. Agenda for Change (AFC) should allow for this but in reality may actually not as AFC tends to reward managerial aspects (of which prescribers have some) and not clinical expertise aspects of job roles. In addition, the organisation should pay for the cost of the extra indemnity insurance that is required by pharmacist prescribers. (Pharmacist prescriber)

In terms of financial remuneration - absolutely agree as at this level you are a clinician who happens to be a pharmacist rather than a pharmacist who prescribes. (Pharmacist prescriber)

At least enough to compensate for the extra costs of registering as a prescriber and the indemnity insurance. (Pharmacist prescriber)

I have stated undecided for question c as I think we may not yet be at this stage. (Director of Pharmacy, Pharmacist prescriber, Chairman ADTC)

Generally true that AFC band should be based on an up-to-date job description defining responsibilities. Nothing special here about prescribing. It covers all areas. (Pharmacist author non-medical prescribing policy)

Other Non-Medical prescribers, in particular nurses, are not financially compensated for this responsibility. Prescribing should be based on patient need not rewards. (Non-pharmacist author non-medical prescribing policy)

Question C is a loaded question. Of course pharmacists should be appropriately remunerated but it does not necessarily follow that taking on prescribing roles increases the overall responsibility of the post or that if they are additional responsibilities they are higher level responsibilities to existing roles. Potentially a change in role could reduce grading weight. (Acute health board director)

Financial reward and banding should not be based on any single role component. This should be debated in a wider arena as this has not been the case for NMAHP colleagues. (Non-pharmacist author non-medical prescribing policy)

Once prescribing the responsibilities need to be written into the prescribers job description and adequate weight given to this in AFC bandings. (Pharmacist author non-medical prescribing policy)

As long as this doesn't attract onto course purely for financial reasons. Would need parity across professions to avoid conflict of some receiving pay and others not. (Pharmacist author non-medical prescribing policy)

5.4.2 Round 2

The development of the questionnaire for round 2 of the Delphi has been described previously in the method section. Twenty-nine questionnaires were completed giving a response rate of 72.5%. The participants indicated the following roles within their health boards, with some participants having multiple roles.

Director of Pharmacy	3
Acute health board director	2
Chairman ADTC	2
Non-pharmacist author of non-medical prescribing policies	5
Pharmacist author of non-medical prescribing policies	9
Pharmacist prescriber	11

As previously indicated, consensus was set at 70% and therefore 20 participants were required to strongly agree or agree with a statement for consensus to be reached with that statement. The number of statements where consensus was reached was 3 out of 6 (level of agreement 76 - 90%) while the number of statements where there was disagreement was 3 out of 6 (level of agreement 21 – 55%). A detailed breakdown of the results obtained together with any comments given for each statement is provided below.

1a. Encourage the development of non-medical prescribing multidisciplinary teams.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree
1	14	6	4	4

Consensus not reached (52% in agreement)

Comments

Question should read - encourage non medical prescribing within multiprofessional teams (as opposed to multidisciplinary - discipline could be geriatrics, anaesthetics etc). Because question requires to be reworded I have ticked undecided. (Director of pharmacy)

I thought that the statement was concerning one MDT including NMP and medical prescribers. Would not support a separate team of non-medical prescribers. (Pharmacist prescriber, Non-pharmacy author non-medical prescribing policy)

Agree with some of the previous comments that the question is ambiguous and the important ingredients are a multidisciplinary team and appropriate prescriber - either medical or non-medical. (Pharmacist prescriber)

Would agree with the comment that non medical prescribers should be encouraged to participate in existing multidisciplinary teams not to try and establish new teams. (Pharmacist author non-medical prescribing policy)

I agree with the broad statement to encourage the development of non-medical prescribing multidisciplinary teams, but only where there is a clinical need and only where there is access to a shared medical record. All practitioners, involved in patient care, do not need to have the ability to prescribe for their patient. (Non-pharmacist author non-medical prescribing policy)

There is still some ambiguity to the question as the previous statements have shown, however I take the question to mean; should non medical prescribing be developed within multidisciplinary teams, as opposed to specific non medical MDTs being developed that would work independently of the medical profession. As long as it is the first of these two interpretations I agree, however if it is the second interpretation I feel that the purpose of the team and it's responsibilities would have to undergo careful consideration before being developed. (Non-pharmacist author non-medical prescribing policy)

Although this should not be done in "competition" with medical prescribing multidisciplinary teams. (Pharmacist prescriber)

I agree with comments that we should not be creating a barrier by excluding medical prescribers. (Non-pharmacist author non-medical prescribing policy)

1b. Statement developed from first round:

Encourage participation of pharmacist prescribers within multidisciplinary prescribing teams.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree
16	10	2	0	1

Consensus has been reached (90%)

Comments

We have to be careful to ensure the role of the Pharmacist remains distinct and does not creep into a role where we take over work from other disciplines because of convenience. We must look to where we can add value. (Pharmacist non-medical prescribing policy)

I agree, but feel where I am based that we already have multidisciplinary prescribing teams and CPD, but do feel that everyone has a role within the team, not just pharmacists and therefore all prescribers should be encouraged to participate. (Non-pharmacist non-medical prescribing policy)

2. Encourage all hospital pharmacists to prescribe in any specialty.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree
1	5	6	15	2

Consensus not reached (21% agree)

Comments

With the current number of posts and graduates in Scotland there are a finite number of services where pharmacists can provide a sustainable stand alone service. It is more likely prescribing roles will only be limited to certain specialties. We must look for sustainable developments and cherry pick where we can make a difference. (Pharmacist author non-medical prescribing policy)

There are areas of hospital pharmacy where pharmacists may be working and prescribing may not be an essential part of his/her job. Similarly there may be some specialties where prescribing may not be suited to non-medical practitioners. (Pharmacist prescriber)

Agree with statements regarding newly qualified pharmacists, therefore needs to be time given for pharmacists to gain sufficient experience and confidence before prescribing. NMP's should be limited to prescribing within their area of expertise or retraining applied when changing specialty. (Pharmacist author non-medical prescribing policy)

I disagree, all hospital pharmacists do not need to prescribe in any specialty, prescribing must be based only where there is a clinical need. All pharmacists, involved in patient care, do not need to have the ability to prescribe for their patient. (Non-pharmacist author non-medical prescribing policy)

I think this could be the case but way in the future. (Pharmacist prescriber)

Pharmacy is made up of a lot of specialties e.g aseptic, QA etc. Every bit as valid as clinical and prescribing services. Horses for courses. (Pharmacist author non-medical prescribing policy)

I have to continue to strongly disagree with this statement as the inclusion of 'any specialty' does not take account of each individual prescribers area of competence and confidence and would lead to undue pressures on pharmacists to prescribe within specialities that they may not be comfortable with. (Non-pharmacist author non-medical prescribing policy)

I agree with above statements that workforce planning and post requirements should be considered pre accessing and attaining prescribing qualification, it may not be necessary to have a qualification and there is no point in taking on this role if it is not going to be utilised. (Non-pharmacist author non-medical prescribing policy)

3. Ensure that pharmacist prescribers are financially compensated in line with their added responsibilities.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree
2	14	2	10	0

Consensus not reached (55% agree)

Comments

There is an assumption here that carrying out a prescribing role increases responsibility but this may not necessarily always be the case. The post has to be considered as a whole. (Pharmacist author non-medical prescribing policy)

AFC banding should reflect this additional responsibility, but should be assigned to posts if appropriate for improving patient care, and not to enhance the pharmacist's banding. (Pharmacist prescriber)

Probably agree with some of statements above that we shouldn't be making it cost anyone to take on the prescribing role as it will be beneficial to service. Therefore the costs of additional indemnity and registration should be met by the service. This doesn't necessarily mean an increase in pay but job descriptions should be amended to take into account this responsibility and assessed by AFC panels for regrading if appropriate. (Pharmacist author non-medical prescribing policy)

In so far as costs for registering and indemnity insurance. (Pharmacist prescriber)

Again I agree that the cost of added insurance and registering should be covered. (Pharmacist prescriber)

Generally true that AFC band should be based on an up-to-date job description defining responsibilities. Nothing special here about prescribing. It covers all areas. (Pharmacist author non-medical prescribing policy)

The current reality with regards to remuneration is that pay is decided under Afc conditions, under these rules prescribing is a skill which will only effect a change in banding if there are other changes to a role which increase the responsibilities of that individual. It is not a clear cut question, and has been the subject of much debate at NMP conferences since independent/supplementary prescribing began. (Non-pharmacist author non-medical prescribing policy)

It is a shame this question was not reworded as it is ambiguous. This is actually a no-brainer. Of course pharmacists should be paid appropriately for what they do but you cannot assume that prescribing responsibilities should be remunerated more than others. I have interpreted this as agreeing with the statement but it could equally be undecided or disagree. The question is flawed because it presumes that prescribing responsibilities are both additional and of higher banding weight than other responsibilities. (Acute health board director)

Agenda for Change should allow an increased remuneration for prescribers over non-prescribers. (Pharmacist prescriber)

Other Non-Medical Prescribers are not financially compensated for this responsibility. Prescribing should be based on patient need not rewards. Pay should be based on up to date job descriptions. (Pharmacist author non-medical prescribing policy)

I agree that all prescribers should be fairly remunerated for role. (Non-pharmacist author non-medical prescribing policy)

4a. Ensure that the preparation for the role has taken into consideration the pharmacist’s individual views and attitudes.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree
3	19	6	1	0

Consensus reached (76% agree)

Comments

On reflection, the pharmacist's individual views and attitudes should influence whether (s)he is suited to taking on the role and to then undertake the required preparation. (Pharmacist prescriber)

Since the development of NMP training one of the barriers to developing effective NMP roles has been inappropriate selection of candidates. Individuals’ views and attitudes and motivation are central to the development of such roles and services. (Non-pharmacist author non-medical prescribing policy)

Agree with first comment but generally unsure precisely what the question means. (Acute health board director)

Should be about competencies and when NMP fully established will be linked to a post and therefore determined and aligned to job specifications. (Pharmacist author non-medical prescribing policy)

4b. Statement developed from first round:

Ensure that appropriate pharmacists are selected for the prescribing role by taking into consideration their individual views and attitudes towards pharmacist prescribing.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree
7	19	2	0	1

Consensus reached (90% agree)

Comments

It would seem unlikely that someone would be forced to take on a prescribing role. (Pharmacist author non-medical prescribing policy)

I would have preferred this statement to reflect the pharmacist making the decision about whether to apply for a post or develop his/her practice rather than being 'selected'. (Pharmacist prescriber)

Early implementer pharmacists must be interested and motivated for the role to work. (Pharmacist author non-medical prescribing policy, Pharmacist prescriber)

This is a better question. However, in the future we may expect all pharmacists to prescribe and so it will not be a question of selecting pharmacists for roles but simply ensuring staff are appropriately prepared for roles. Their views and attitudes will be largely irrelevant to this. (Acute health board director)

I agree if cognisance is given to needs of the service rather than desire of the pharmacist. (Non-pharmacist author non-medical prescribing policy)

Should be about post requirements, skills and knowledge. (Pharmacist author non-medical prescribing policy)

5.5 Discussion

5.5.1 Key findings

This phase of the research set out to develop consensus guidance to facilitate service redesign to involve PP in secondary care. This involved using and confirming evidence obtained from the focus group discussions described in Chapter 3. A Delphi approach was used to validate the evidence from the focus groups by seeking the opinion of an expert panel, made up of strategic and practising professionals likely to be involved in a service redesign involving PP in secondary care.

Two rounds of Delphi were conducted with a response rate of 87.5% in round one and 72.5% in round two. In round one, agreement was reached with 27 statements derived from the focus group discussions, providing triangulation and validation of the focus group evidence. Agreement of over 90% was reached with 20 of these statements (consensus was set at 70%). In round two, six statements were included for ranking as follows:

- Four were statements as in round one; three where no agreement had been reached (17% - 66% agreement in round one), and one statement where a consensus of 70% was obtained. These statements were provided for re-ranking to further validate the result obtained in round one. Following re-ranking, no agreement was again reached with three statements, and a 76% agreement with the fourth.
- Two were new statements derived from comments in round one. Agreement was reached with both of these statements in round 2.

The statements where agreement was reached were included in the final guidance aimed to facilitate a service redesign involving PP in secondary care and are found in Section 5.4.

5.5.2 Strengths and Limitations

This research has numerous strengths. To the author's knowledge, this is the first study to address a pharmacy strategic development involving PP using a consensus development method. Though developments involving PP and other areas may have used this approach, these have not been published and could not be identified by the author. A search in the pharmacy database IPA using the key words 'Delphi' and 'pharmacist prescribing' undertaken in June 2010 did not provide any hits; consequently no information could be identified on how strategic developments involving PP in the UK have been undertaken. A second search was conducted in June 2010 using the key words 'Delphi' and 'pharmacy' and no useful hits about processes used in strategic developments were obtained. (Some other applications of the Delphi method in other areas of pharmacy were identified and are described in Section 5.5.3.) Similarly, no information on the process of strategic development or areas of service redesign in pharmacy in Scotland was provided on NHS Scotland or the Scottish Government website. Since nurse supplementary and independent prescribing were introduced at the same time as PP, a search was conducted in June 2010 using the database CINAHL using the terms 'Delphi' and 'nursing prescribing' but again no hits were obtained.

It is clear from the results obtained through rounds one and two of the Delphi that there was a high level of agreement with the evidence from the focus group results. The objectives of the study to use and validate the information obtained through the focus groups by seeking the opinion of an expert panel were therefore met. The high response rate [87.5% in round 1 and 72.5% in round 2] was above the 70% recommended by Hasson to maintain the rigour of the method and to produce meaningful results (209) and was a further strength of the research. This enabled compiling of the guidance to facilitate a service redesign involving PP in secondary care. The usefulness and applicability of these guidelines in practice would need to be evaluated through further research.

The composition of the expert panel was carefully considered to ensure that the opinions of strategic and practising professionals likely to be involved in PP were included. The author was satisfied that the participants provided a mix of professionals with suitable expert knowledge in the subject area. This allowed the input of strategic professionals as well as non-pharmacists with experience in non-medical prescribing, who were not involved in the focus group discussions.

The research focuses only on secondary care in Scotland and the guidance provided is unlikely to be generalisable to other healthcare settings and other geographical areas. The author believes that this may also be a strength since issues affecting PP in secondary care are likely to be different from those in primary care. The guidelines are consequently likely to be more detailed and exhaustive than if all healthcare settings were considered. Likewise, the guidance is only applicable to Scotland; again this may also be a strength since the devolution of the healthcare system may have resulted in the healthcare system in the different UK countries evolving in a different way. The guidance may therefore be more complete than if guidelines considering the needs of all the UK were drawn up.

There are limitations inherent with using a Delphi method, such as use of an expert panel, and measures taken to maintain the credibility of the research have been described in detail at Section 5.3.5. The questionnaire had 30 statements to ensure that all the evidence from the focus groups was included. This exceeded the recommended 25 items; through user-testing it was confirmed to be easy and quick to complete and studies in the literature in other areas of pharmacy practice have successfully used more than 25 items.(224-6) The high level of agreement with the statements may indicate an element of acquiescence response bias and a potential lack of specificity of the statements provided. Measures taken to minimise this have already been discussed in Section 5.3.2. The author is of the opinion that the statements

reflect as closely as possible the evidence obtained from the focus group research.

5.5.3 Comparison with the literature

As described above, this is the first study that uses Delphi relating to the pharmacy prescribing area of practice. The literature reports a number of studies, some of which explore and describe implementation of PP in different healthcare settings including secondary care. A lack of implementation of PP following a pharmacist qualifying as a prescriber and a lack of organizational recognition are reported in secondary care. (130,197) Lack of succession planning to ensure continuity of service, (130) and issues around funding, (131) were also reported. These issues need to be resolved if pharmacist prescribers are to reach their full potential, making better use of their skills and benefits gained by the patients in better services. This was highlighted in the Crown Report which recommended the introduction of non-medical prescribing. (76) The author believes that this possibly identifies an area where further guidance to facilitate implementation of PP is required in secondary care and these guidelines may contribute to this area of prescribing literature.

Some applications of the Delphi method or approach in other areas of pharmacy practice were identified in the literature. Within the UK, this has been used to: develop criteria against which the quality of medicines use review referral documentation can be accessed (224) and to establish a dispensing error definition within a community pharmacy setting. (227) Specifically within Scotland, a Delphi approach has been used to develop competencies associated with training needs of public health for community pharmacists, (226) and to generate a model of pharmaceutical care for the patient with type 2 Diabetes Mellitus in primary care. (225) Unlike this research, none of the studies described involved a service delivered in secondary care. Outwith the UK, studies described were mainly from the US and involved: developing components required for training of community

pharmacists (228) and determining challenges facing pharmacy executives. (229,230) A further study focused on developing a list of clinically significant drug-drug interactions with oral anticancer and non anticancer drugs.(231)

Most of the studies report using a Delphi approach where questionnaire statements in round 1 were derived from the literature (224,226-7,231-2) or through previous research.(225) Similarly, a Delphi approach was applied in this research where questionnaire statements in round 1 were derived from previous focus group research and grouped into categories as described in the literature. As in this study, more recent research has also used electronic delivery considering this to be ideal for ease and speed of response.(224,226,229-231) Reported response rates vary and range from 18% to 83% with most studies reporting a drop in response rate when comparing round 1 to subsequent rounds. Comparatively, response rates in this study were high with 87.5% in round 1 and 72.5% in round 2.

5.5.4 Discussion of findings

Overall, there was a high level of agreement with statements derived from focus groups (27 out of 30). Therefore this validated and confirmed information which was derived from the focus group discussions. This agreement was of particular significance since the panel included healthcare professionals with a more strategic role (e.g. Directors of Pharmacy, Chairmen ADTC) as opposed to focus group participants who were solely ward-based practising pharmacists. There was a high response rate with the literature reporting that relevance and salience of a topic to participants as being one of the most important reasons for a high response rate to survey questionnaires [though there is no specific evidence about response rates in a Delphi].(221,223,233) This engagement of the participants shows an interest and possibly indicates a need for the guidance.

In round one, there were more statements about service management (20 out of 30) compared to role development derived from the focus group discussions. The author believes that there may be a number of reasons for this. It may reflect the composition of the focus group discussion participants all of whom were ward-based practising pharmacists. Consequently, in their view, service management may have a priority over role development. In fact, most statements derived from the discussions were about succession planning involving implementation and ensuring continuity of a PP service. This may reflect the frustration on the part of the focus group participants that there is a lack of implementation of PP in secondary care with a consequent lack of utilisation of the pharmacist prescriber's skills. This lack of implementation has also been reported elsewhere in the literature.⁽¹³⁰⁾ The lack of implementation may have led to having fewer statements in other categories such as quality evaluation, outcome measures and practice development. Despite the different composition of the expert panel which included a strategic element together with non-pharmacist professionals, there was a high level of agreement with these statements (19 out of 20) with 90% or more agreeing with 15 of these statements. Only one statement was rejected in the service management section. This may reflect a concern on the part of the expert panel to ensure sustainability of a PP service following its implementation. The author believes that the guidelines may facilitate a service redesign involving PP by allowing consideration of areas such as succession planning even before the pharmacist has embarked on a training course. This may minimise the frustration expressed by focus group participants who felt that there was no such planning and they were being trained as prescribers just to build up the numbers. The guidelines may also prompt the consideration of other important areas of implementation such as ensuring appropriate structures are in place to allow safe practice, the support needed by pharmacist prescribers once they are in practice and the integration of pharmacist prescribers with other professionals within the multidisciplinary team.

Having more statements in the service management rather than the role development category may also reflect the fact that the focus group participants were not as involved in the forward planning of the role as were the expert panel. The level of agreement with statements in the role development was less than that in the service management. There was agreement with eight out of ten statements (agreement over 90% with five of these statements) and two statements were rejected. The author believes that this may reflect a role that is still under development with a high response rate showing an interest in the future development of this role. It is believed that the guidelines will stimulate discussion on the orientation of the specialist pharmacist prescriber role in secondary care to allow maximal potential. Interestingly, criteria that have been associated with role development in other areas of the nursing literature (217) including research activity, leadership qualities and consultancy, have not been considered in this research, neither by the focus group participants, nor by the expert panel, again reflecting the infancy of the pharmacist prescriber's role in secondary care.

The expert panel rejected the statement "Encourage the development of non-medical prescribing teams." All comments in round one were made by pharmacists in both practising and strategic roles and reflect a desire to have one integrated multidisciplinary team that would promote inter-professional working and incorporate both medical and non-medical prescribers. This statement was also rejected in round two with comments again emphasizing a need and desire to work within a single team made up of medical or non-medical prescribers as appropriate. A modified statement in round two developed from round one encourages "participation of PP within multidisciplinary teams;" as expected, agreement was reached confirming the need for non-medical prescribers not to work in isolation but to be integrated with other healthcare professionals. Others have also reported that pharmacists believe PP may result in better integration with the healthcare team.(131) Interestingly, the importance of good communication and

promotion of a team approach required for integration of non-medical prescribers has also been highlighted by the medical profession.(129)

The statement “Encourage all hospital pharmacists to prescribe in any speciality” was rejected in rounds one and two. Comments indicated a polarized opinion among participants; some felt that all pharmacists should prescribe: “prescribing is the future for all hospital pharmacist practitioners” (Acute health board director). Others perceived this to be a more specialist role – “prescribing should be limited to defined specialties with the appropriate pharmacists in post” (Pharmacist prescriber). Other participants commented that prescribing within any specialty might lead to pharmacists prescribing outwith their competence and comfort zone. Concern was also raised about newly qualified pharmacist and pharmacists new to the job who would need additional mentoring to take on such a role. Agreement was reached with the statement “Encourage the development of prescribing specialist roles” and the panel consequently indicated that this may be the more feasible direction and future orientation of the pharmacist prescriber’s role in secondary care. This may be an area that will develop or change as the pharmacist prescriber’s role develops and becomes more established in secondary care.

The panel rejected the statement “Ensure that pharmacist prescribers are financially compensated in line with their added responsibilities” in both rounds one and two. A range of comments was provided with some healthcare professionals showing strong agreement while others expressing concern that PP cannot be assumed to include added responsibilities. Overall, these comments seemed to indicate that a prescribing role and the responsibilities this may bring with it should be reflected in the agenda for change banding associated with a specific post. It is evident that this is still an area of much debate and again reflects a role that is still being developed. Such economic aspects of non-medical prescribing have also been reported in the nursing literature where “nurses reported colleagues being dissuaded from prescribing due to meagre salary increases relative to the extra responsibility.” (197)

5.5.5 Further research

Further research is required to test the guidance for usefulness and to determine whether it will help in the planning and implementation of PP. This may take the form of an initial pilot study where both pharmacists in strategic posts and practising pharmacists are asked to evaluate each statement within their healthcare settings and ease-of-use of guidelines. Follow up in-depth interviews may then be conducted with these professionals to gain insight into whether the guidance would help in the planning and implementation stages of PP and any recommended changes.

As the role develops, the guideline may need to be reviewed and updated such that other criteria in the literature associated with role development may need to be incorporated (previously discussed). Should PP be more widely implemented in secondary care, focus groups with practising pharmacist prescribers may help further inform the process of guideline review and update. This guidance has been developed specifically within the Scottish healthcare system – further research may indicate whether it is also applicable within other healthcare systems. It has also focused on secondary care; it may be worth exploring whether the process of development used to produce these guidelines may inform other areas of pharmacy practice such as primary care. Again, focus groups with the relevant pharmacists may help provide the evidence to inform and guide modifications required.

5.5.6 Conclusion

Consensus guidelines have been developed to facilitate a service redesign involving PP in secondary care. Evidence obtained from focus group discussions was used to draw up these guidelines which were validated by seeking the opinion of an expert panel and using a Delphi approach. There was a high level of agreement with the statements derived from the focus groups. Statements where consensus was achieved were included in the final guidance.

Chapter 6

General Discussion

6.1 Introduction

This chapter summarises the way the phases of research evolved and key findings in relation to their stated aims and objectives. Aspects of validity and reliability and potential applications of the research for future policy and practice are then described. The chapter concludes with ideas for future direction in this pivotal area of pharmacy practice.

6.2 Evolution of the research programme

A reflective approach was employed throughout this research, promoting consideration of research findings and implications for practice at each phase. In addition, such an approach allowed the consideration of any emerging policies or modes of practice. This iterative process enhances the robust nature of the research.

The original research aim (in 2005) was "To explore the structures, processes and outcomes involved in pharmacist prescribing of antimicrobials in secondary care." This was considered a timely area of research, since legislation for pharmacist SP had been introduced in 2003, and hospital pharmacists embraced the opportunity to extend their practice. (86,111) The increasing role of the pharmacist in ensuring optimal antimicrobial use was also highlighted in various Scottish and UK documents, (33-4,44-5) and specialist antimicrobial pharmacists were of the opinion that a further expansion of the role was both likely and desirable given the introduction of pharmacist SP. (47,48) To inform the evolution of the research aim, a general literature review was conducted, presented in Chapters 1 and 2 and in three distinct sections. In the first section, strategies aimed at optimising antimicrobial use, driven by a concern over increasing antimicrobial resistance were reviewed, with a focus on EU and UK strategies. Within these strategies, the concept of an antimicrobial team

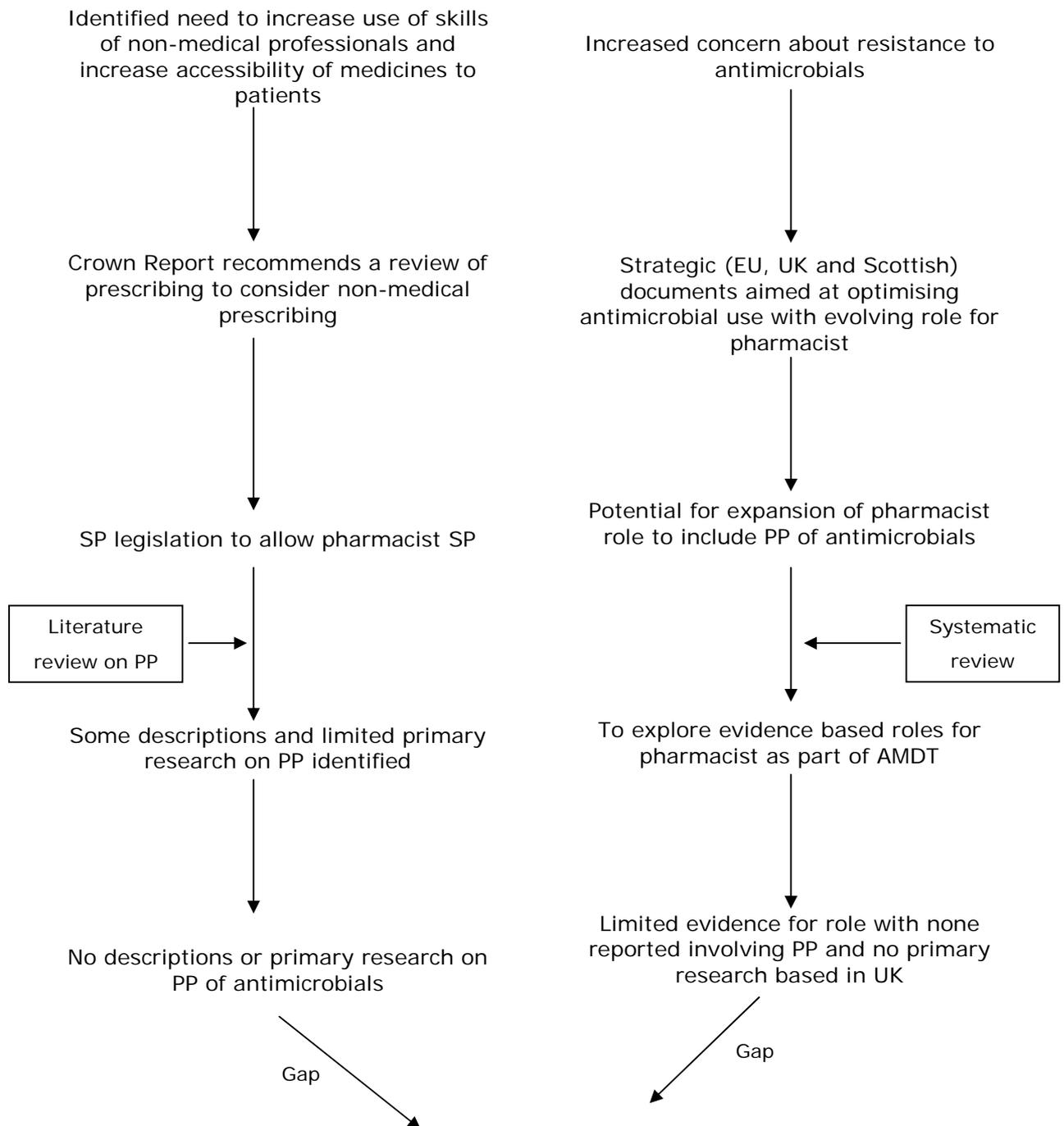
with pharmacy involvement emerged and was developed.(13,14,27) The role of the pharmacist within these teams evolved from a “policing” role, controlling prescribing and checking adherence to guidelines, to an “advisory” role, providing support and advising on prudent antimicrobial use within the AMDT. Specific recommendations were made to develop roles for specialist antimicrobial pharmacists, particularly within hospitals (33) [or specialist infectious diseases pharmacists in EU literature (24)]. This approach has been endorsed by the Scottish Government.(44-5) A summary of the development of this pharmacist role within the UK is in Table 2.

In parallel with the development of the antimicrobial pharmacist's role, the recognised need to promote appropriate use of the skills of non-medical professionals and to increase accessibility of the medicines to patients, led to a change in UK legislation allowing PP. At the start of this PhD, legislation allowed for pharmacist SP, but policy evolved to allow pharmacist IP.(97) The practice of PP has been viewed by many as a natural extension to the role of the hospital pharmacist, potentially providing many opportunities for the pharmacist to optimise antimicrobial prescribing.(47,48,96) The next section of the literature review, consequently, focused mainly on development of PP within the UK and described and analysed the implementation and outcomes of PP within the UK. Despite the fact that PP was described as being implemented in different practice settings, including hospitals, a review of primary research revealed limited focus on clinical, economic and humanistic outcomes of PP, with no descriptions or primary research on PP of antimicrobials.

To explore further evidence based clinical roles for the pharmacist in optimisation of antimicrobial use as part of an AMDT in hospitals, and published outcomes of such interventions, a systematic review was conducted and is presented as the third section of the literature review in Chapter 2. A number of descriptive accounts and nine evaluative trials were identified. As discussed in section 2.4.2, the small-scale, single-site nature of the trials and the study quality (with only two being RCTs) made it difficult to draw any

definite conclusions about outcomes following interventions of an AMDT (note that despite descriptions of AMDT in the UK, none of the trials originated in the UK). A role for the hospital pharmacist was identified within the dispensary, on the wards, in the case of clinical pharmacists, and as a specialist infectious diseases pharmacist. None of the roles described involved optimising antimicrobial use through PP. These literature reviews have resulted in the publication of two peer-reviewed papers.(112,195)

These limitations and gaps identified within the literature led to evolution of the overall aim of this PhD as follows: To explore pharmacist prescribing in hospitals in Scotland, with a focus on antimicrobials. The development of this aim is presented at figure 7.



Overall research aim: To explore pharmacist prescribing in hospitals in Scotland with a focus on antimicrobials

Figure 7: A parallel and linked development of overall research aim

The research was conducted in three phases, and their evolution and development in response to results from each phase are described here. In view of the above, the aim of Phase 1 was:

“To explore pharmacists’ views and perceptions of pharmacist prescribing in secondary care with a focus on antimicrobials.”

A qualitative methodology in the form of focus groups was used to provide in-depth, rich narratives. Analysis of the data generated through these focus group discussions highlighted a general lack of implementation of PP in secondary care, and a lack of NHS organisational support for pharmacists to take on this extended role. Indeed, pharmacy hierarchical management was perceived as a major barrier hindering PP implementation. As discussed in detail in Section 3.4.3, key findings of barriers to implementation were in accord with other published studies. Notably, studies based exclusively in Scotland, reported higher numbers of pharmacists training and practising as SP in a primary care setting.(131) At the time of completion of focus group data analysis and interpretation, updated prescribing legislation permitted pharmacists to train and practise IP.(96) The combination of these factors strongly influenced the evolution and development of the next phase of the research. The lack of PP of antimicrobials and indeed any PP within secondary care facilitated formalising Phase 2 of the research which had the following aim:

“To conduct a scoping exercise to determine the extent of implementation of PP in secondary care in Scotland.”

This phase informed later research activities. Different methods and approaches were used in this scoping exercise and are discussed in detail in Chapter 4.

It was apparent from the scoping exercise that there had been little evolution of PP implementation within the Scottish health boards studied (see Table 20 in Chapter 4), with only one pharmacist identified as prescribing antimicrobials (Section 4.1). Strategic policy information

obtained from the Scottish Government at this time indicated priority for developments of PP within primary care with no framework for implementation of PP in secondary care.(207) Likewise, few Scottish health boards reported having a framework in place to facilitate implementation of PP in any setting. It is difficult to draw conclusions in an area of practice that is so fluid and dynamic, and it is not possible to determine to what extent the lack of frameworks (both on a national and local level) have influenced the lack of implementation of PP. It was evident, however, that there is a need to bridge the gap between training of pharmacists as prescribers and implementation of PP in secondary care.

To enable the research to be of national importance, thus contributing to practice and providing solutions to complex challenges, the final phase of the research took a broader approach focusing on the general implementation of PP in Scottish secondary care. The aim of Phase 3 of the research was:

“To develop consensus guidance to facilitate service redesign to involve pharmacist prescribing in secondary care.”

Draft guidance statements were based on evidence gathered from the focus group discussions and the scoping exercise and consensus was achieved using the Delphi method. A detailed description of the study design is presented at Section 5.3. The development of the final questionnaire was a very lengthy process involving numerous drafts, again involving reflection, discussions with the supervisory team and with key local and national experts together with identification of key documents adapted for use in this research.(217) Drafts illustrating the development of the questionnaire are available at Appendix 5.1 together with comments to illustrate the “development process” and consequently the evolution of this tool. The findings of the study are applicable to all PP within secondary care, irrespective of patient group, and drug therapeutic classes, and are likely to impact and also facilitate, PP of antimicrobials in secondary care. Factors influencing evolution of the research are summarised in Figure 8.

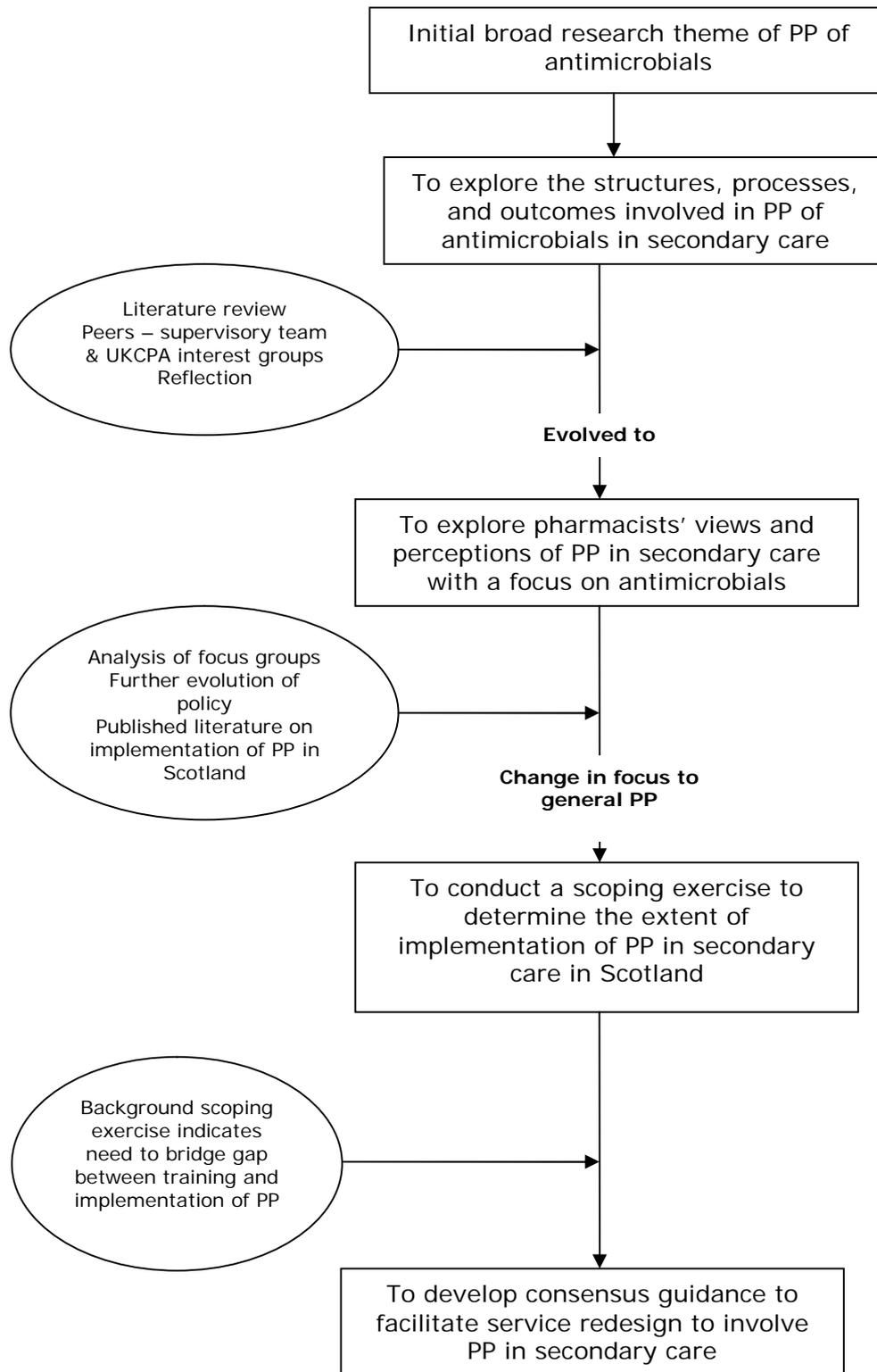


Figure 8: Factors contributing to evolution of the research

6.3 Review of key findings

As part of this PhD project, data were generated and collected:

- To explore pharmacists' views and perceptions of pharmacists' prescribing in secondary care, with a focus on antimicrobials.
- To conduct a scoping exercise to determine the extent of implementation of PP in secondary care in Scotland
- To develop consensus guidance to facilitate service redesign to involve PP in secondary care.

A critique of available methodologies and a justification of each choice are presented at Chapters 3, 4 and 5.

Research in Phase 1, was conducted with both pharmacist prescribers and pharmacist non-prescribers, and aimed to explore their views and perceptions of PP in secondary care, with a focus on antimicrobials. The perceived lack of management support to take on a prescribing role, the lack of planning to implement PP and the inability to sustain new services such as prescribing, were among the major barriers to the implementation of PP in secondary care. This was also true for pharmacist antimicrobial prescribing, where there was no specific drive or incentive to encourage PP, unless as part of a cost-cutting exercise. The CMP, as a requirement of SP, was especially difficult to implement in acute situations, such as prescribing of antimicrobials, likely to be characteristic of a hospital setting. The lack of skills to diagnose was perceived as the main barrier to pharmacists IP. Participating pharmacists believed that the patient's clinical condition and ward types were major determinants in the successful implementation of PP, with this likely to be more feasible if prescribing for a chronic condition and in an outpatient clinic setting. Numerous examples specific to antimicrobials were provided by the participants to support this (see Table 18). Areas where pharmacists were already providing considerable input and advice (Ex TDM advice relating to antimicrobials) and where guidelines and protocols were available (e.g. surgical prophylaxis), were other settings

where PP was perceived as likely to be a success. This research is the first published evidence that focused specifically on antimicrobials and on secondary care in Scotland. (234)

The next phase of the research set out to conduct a scoping exercise to determine the extent of implementation of PP in secondary care in Scotland, utilizing different sources of information, as discussed in Chapter 4. Follow up of focus group participants showed that despite a change in legislation allowing IP, and a desire for the participants to train as independent rather than supplementary prescribers, there was little evolution in implementation of PP in hospitals, within the sampled health boards. Information obtained from the Scottish Government reinforced the fact that the focus of the Scottish Government, at least during the first phases of PP, was mainly primary care, with no framework available for implementation of PP in secondary care. Likewise, few of the Scottish health boards reported having a framework in place to facilitate implementation of PP, including secondary care; however having a framework in place seemed to be linked with a larger number of actively prescribing pharmacists. [Table 20]

Results from Phase 2 led to the third phase of the research, which aimed to contribute to practice by bridging the gap between policy and practice and facilitating implementation of PP in hospitals. This was conducted by developing consensus guidance to facilitate service redesign involving PP in secondary care. The guidance was based on evidence obtained from the focus group discussions in Phase 1, with two rounds of a Delphi approach used to validate the evidence, by seeking the opinion of an expert panel. A detailed description of the process used is presented in Section 5.3. The expert panel comprised both strategic (including non-pharmacists involved in non-medical prescribing) and practicing professionals likely to be involved in a service redesign involving PP, and consequently differed from the participants in Phase 1, who were practicing pharmacists (both prescribers and non-prescribers). There was a high response rate (87.5% in round one, 72.5% in round two) and a high level of agreement with statements derived from the focus groups in round one, (27 out of 30) which is of particular significance since the expert panel included healthcare professionals with a

strategic role. Implications of these guidelines and indeed of all the phases of the research for policy and practice are discussed in section 6.5 below.

6.4 Discussion of method

6.4.1 Clarifying author bias

The author is an academic pharmacist, with around 15 years of hospital pharmacy experience mostly as a ward-based clinical pharmacist. Her interest in antimicrobials and the potential for pharmacist involvement in this area was generated during a period of practice in surgery where numerous opportunities and a potential for pharmacist involvement to optimise antimicrobial use through prescribing were noted. She therefore came into the research with positive views of the potential opportunities to optimise antimicrobial use, especially through PP. Likewise, members of the supervisory team were involved in ongoing research relating to PP and as educators of nurse and pharmacist prescribers. To minimise such inherent biases, a systematic approach allowing “auditing” by a peer was adopted as described in section 6.4.2 below. Regular meetings with the supervisory team were also conducted to discuss emerging findings and interpretation of the results. As an additional check, the author also had more formal opportunities to answer questions about different phases of the research at the student symposia organized by the school and during various conferences when the research was presented as a poster or oral communication (See Output at Introduction). Though the research was conducted within the NHS health boards in Scotland, there was no input or influence by the NHS on study design, data collection and interpretation of findings or dissemination of results.

Throughout the research, measures were incorporated in the different study designs to minimise other inherent biases and are described at length in Sections 3.2.4 and Section 5.3.

6.4.2 Focus group discussions

Discussion of the appropriateness of the qualitative methodology is given in section 3.2.2. In particular, the iterative nature of this approach was considered relevant to inform further phases.

There has been much debate as to how reliability and validity may be achieved in qualitative research, with some researchers arguing that the same principles of quantitative research are to be applied and others debating that different criteria should be considered in qualitative research. Murphy et al, in a systematic review of the literature, concluded that when assessing qualitative research, no checklists or rigid constraints may be applied; rather judgments need to be made as to the application of the criteria within the specific context. (182) A detailed analysis of different theories proposed is beyond the scope of this project; Bryman (181) and Murphy (182) offer a comprehensive description.

Criteria to establish quality of qualitative research have been proposed by Lincoln and Guba (181,182) and have been grouped as “trustworthiness.” The four criteria are described below with specific relevance to this research.

- Credibility – (may be matched with internal validity) ensures that the research is carried out according to good practice and involves submitting research findings to the participants to make sure that the “world” has been understood in the appropriate way. This may involve presenting the researcher’s analysis to the research subjects for feedback on validity of conclusions. There are however a number of disadvantages inherent in this approach in that feedback may become a source of generation of new data rather than a test for credibility. This issue has been discussed in depth by Murphy et al.(182) In view of the above, respondent validation was not adopted in this project. Confirmation of results through triangulation is another method for ensuring credibility which has been adopted in this PhD project and is described in Section 6.3.3.

- Transferability – (may be matched with external validity) involves providing the reader with a “rich” description to aid understanding and visualizing the context, allowing the reader to decide whether the conclusions may be transferred to another area. This has been provided at each stage of this PhD research and has included a detailed description of locations where focus groups have been conducted. To further aid contextualizing, extracts from the focus group discussions are included throughout the text. This study is limited in geographical location to Scotland. The author believes that results, especially those relating to barriers, may be different to the rest of the UK, particularly since the literature indicates that the devolution of the healthcare system may have resulted in countries having different priorities for implementation of PP (see section 3.4.3). Literature from Northern Ireland in particular, emphasizes the success of implementation of PP in hospitals and consequently barriers highlighted in this PhD research may not be relevant.(130) However, the different methods used, the different timescales and the rapid pace of development in this area of practice imply that any conclusions need to be considered with caution. The practice of ward-based clinical pharmacy is well established throughout the UK, and consequently, it is likely that both current and potential clinical activities involving PP highlighted in this research are applicable throughout the UK and may aid to inform expansion of PP in secondary care as described in Section 6.5 below.
- Dependability - this involves taking an “auditing” approach with detailed notes kept at every stage including: development of research aim or question, selection of participants, “ad verbatim” transcripts and the process by which findings are derived from data. To ensure this verification, another researcher must be able to come to the same conclusion using the raw data available. Each stage is then “audited” by a peer. Such a systematic approach is also recommended by Krueger.(189) To ensure this systematic approach, a very detailed step-by-step breakdown has been built into and provided as part of the study design of this PhD research (Section 3.2.4), including the method used for the analytical process. This enables other researchers and readers to

view the logical construction of conclusions. Transcripts of all focus group discussions were independently analysed by a member of the supervisory team. A descriptive account of the thematic analysis was produced independently, and then compared to that of the author to check for any discrepancies. None were found. The first group was analysed by 2 separate researchers to add an extra validity check.

- Confirmability – this ensures that personal values and biases of the research team have not adversely affected research conduct. Again this “double check” was adopted through data analysis as described above.

6.4.3 Scoping Exercise

As discussed in Section 6.2, Phase 2 was conducted to inform further phases of the research. Having been conducted exclusively in Scotland with a focus on Scottish health boards and the Scottish Government, devolution of the UK health system implies that information obtained from this stage of the research is only applicable to Scotland.

6.4.4 Delphi study

A consensus method was considered appropriate for Phase 3 of the research since it involved an area of pharmacy practice of little evidence. This phase was providing triangulation as a quality assessment step as discussed in Section 5.3.

There has been much debate on credibility, reliability and validity of consensus methods, with recommendations that a rigorous method and having a clear “decision trail” may overcome these issues. A discussion of this in the context of Phase 3 of this research has been provided in Section 5.3.5.

Since the research focuses only on secondary care in Scotland and the guidance provided is based on evidence generated in Scotland (through Phases 1 and 2), it therefore needs further consideration to be transferable to other healthcare settings and other geographical areas.

6.5 Implications for policy and practice

6.5.1 Potential for a pharmacist prescribing role to optimise antimicrobial use

More recently, further evidence (in addition to that reported in Chapter 2) has been published, supporting the role of the hospital pharmacist in optimising antimicrobial use. All such published trials and descriptions are single-site and none from the UK. The main drivers described are the need to minimise expenditure and to reduce bacterial resistance within hospitals. Interventions focus on post-prescribing evaluation combined with clinical pathways (235-237), or clinical pathways combined with restrictive policies (See Section 2.3.2.).(238) Specific interventions made by the pharmacists, as part of the AMDT, or by ward-based clinical pharmacists include recommendations for IV-to-oral switch when appropriate (235,239), streamlining in response to culture and sensitivity results (238,240), dose adjustment in organ dysfunction (235,238), and ensuring appropriate choice of antimicrobial based on patient's allergy status.(238) Although none involves pharmacists prescribing or altering antimicrobial treatment, the interventions reported are similar to the activities participants in Phase 1 of this research noted as feasible (Table 17).

As more emphasis is placed on implementing antimicrobial stewardship programmes in Scottish hospitals, policy makers may look to introduce PP as a novel way of optimising antimicrobial use.(45) Newer methods of identifying multi-drug resistant strains of bacteria, using polymerase chain reaction, make it possible to obtain rapid results (241,242) and PP may consequently enable more timely and effective therapy.

Pharmacists in Phase 1 of this research recommended a model for pharmacist IP which may offer a safe and effective option for potentially expanding and integrating PP of antimicrobials in Scottish hospitals. This would help overcome perceived barriers to both SP and IP raised during focus group discussion. The model outlined would involve a doctor making a diagnosis and initiating treatment, and a pharmacist independent prescriber adjusting and monitoring treatment without the need for a CMP and is

described in section 3.4.3 and elsewhere in the literature.(129,130) This model of prescribing has potential to translate to other therapeutic classes and patient groups, as identified by pharmacists in Phase 1 of the research. These include areas where pharmacists were already providing considerable advice, such as adjustment of doses in organ dysfunction, and in response to drug levels, clinical areas where protocols and guidelines are available and areas of care where there is a shortage of medical doctors. Indeed, many of the discussions were not limited to antimicrobial prescribing, but drew on examples from other therapeutic classes, such as warfarin, antihypertensive treatment and management of anaemia associated with renal disease.

6.5.2 A consensus-based analysis guide and action planning tool to facilitate implementation of pharmacist prescribing in Scottish hospitals

Evidence generated from this PhD research indicates that few pharmacists trained as prescribers were actually practising and few Scottish health boards reported having a strategy for implementation of NMP including PP. There is a need to urgently support the implementation of PP into secondary care practice in Scottish hospitals and is evident from all the information obtained from stakeholders involved in Phases 1 and 2 of this research.

To facilitate implementation of PP in Scottish hospitals, the final consensus guidance developed through Phase 3 of this research, has been developed as a self-assessment toolkit to encourage use (see below). Self-assessment toolkits have been previously used in addressing healthcare related issues.(243) The overall objectives of this toolkit are: (a) to provide an analytical strategy and an initial starting point to reflect on potential areas of implementation and role development of PP in different areas of care within an institution and (b) to inform debate on the managerial requirements and future orientation of health board developments in PP. The more experience gained through pharmacists utilizing their prescribing skills, the more these guidelines may be further developed and refined. This is especially so in the case of the role specific criteria presented in Section B.

Pharmacist Prescribing in Scottish Hospitals

A Self-Assessment Analysis Guide and Action Planning Tool to Facilitate Implementation

As more pharmacists qualify as prescribers, there is a greater need to find ways in which pharmacist prescribing may be implemented and supported in secondary care, while adding value to patient care.

These guidelines provide an analytical strategy and an initial starting point to reflect on potential areas of implementation and role development of pharmacist prescribing in different areas of care within an institution.

They may inform debate on the managerial requirements and future orientation of health board developments in pharmacist prescribing.

The more experience gained through pharmacists utilizing their prescribing skills, the more these guidelines may be further developed and refined.

The toolkit is divided into two sections:

A) Service Management – this aims to encourage the efficient provision of the service

B) Role Specific - this section aims to provide detail of the educational and training support which needs to be provided to promote role expansion, the work expected to be undertaken by a pharmacist prescriber, and the expected future orientation of the service

Date performed.....

Date for next review.....

Responsibility for assessment.....

A. Service Management

1. Succession planning: This means that there are managerial processes in place within a health board to ensure that the role is not reliant on one person alone and that a system of staff development, supervision and support is in operation to enable others to take on the role.(217) Statements within this section aim to assist successful planning, strategy development for pharmacist prescribing and implementation of pharmacist prescribing making best use of the resource available. They aim to highlight the importance of the planning phase of the service redesign consequently making it possible to identify areas where pharmacists may improve the quality of patient care by utilising their prescribing skills following qualification.

	Considered	Not Considered	Action Plan	By whom By when
1.1 It is important to undertake a systematic and objective assessment of pharmaceutical needs in order to identify gaps in the current service delivery and patient care.				
1.2 It is important to outline ways in which pharmacist prescribing may improve patient care or encourage better utilisation of staff skills and resources.				
1.3 It is important to have a strategy ^{xxiii} in place within the health board that is based on available national guidance and that would establish how pharmacist prescribing is to be implemented.				
1.4 Ensure that any strategy in place may be applicable across different practice settings and areas of care. This implies that the service is generic and transferable.				

^{xxiii} A detailed plan or scheme outlining the administrative and procedural structure relating to pharmacist prescribing and that ensures that practice is compatible with any relevant local or national standards or policies.

	Considered	Not Considered	Action Plan	By whom By when
1.5 Consider the benefits and limitations of both pharmacist supplementary and independent prescribing and determine which would be best suited to deliver the service in different areas of care.				
1.6 Involve pharmacists likely to be prescribing in discussions at the planning phase to ensure that they have both sufficient background information to prescribing prior to embarking on their course, and sufficient knowledge as to where prescribing will be implemented in their speciality.				
1.7 Consider in which practice settings it may be more feasible to introduce, implement and monitor pharmacist prescribing.				
1.8 Consider procedures that would allow the smooth and safe transition of patients from secondary to primary care if pharmacists are an additional prescriber.				

2 **Inter-professional working:** This means that the pharmacy role is part of a system of integrated professional working which is inclusive in nature.(217) Statements within this section aim to act as a trigger to ensure that other members of the multidisciplinary team likely to be stakeholders in the process, are involved at each stage of the service redesign. This is likely to assist the acceptance and uptake of pharmacist prescribing both within the institution, and within a specific area of care. This would also encourage the building of efficient multidisciplinary teams.

	Considered	Not Considered	Action Plan	By whom By when
2.1 Involve all key members of the multidisciplinary team who are stakeholders when planning the strategy for pharmacist prescribing.				
2.2 Determine how likely it is for other key members of the team to accept pharmacists as prescribers.				
2.3 Promote a good understanding of the pharmacist prescriber's role with other members of the multidisciplinary team.				
2.4 Promote clearly defined roles relating to pharmacist prescribing within the multidisciplinary team.				
2.5 Promote clearly defined lines of communication relating to pharmacist prescribing within the multidisciplinary team.				
2.6 Encourage participation of pharmacist prescribers within multidisciplinary prescribing teams.				

3. Quality Evaluation: This refers to the issues including quality assurance and audit processes, risk management and clinical governance which are used to evaluate the pharmacist prescribing service and ensure a safe and effective running of the service.(217) Statements within this section aim to highlight the need to analyse the implementation of a pharmacist prescribing service to ensure that its introduction does not compromise patient safety and quality of care. Any service redesign would need to take into account guidance issued by the Royal Pharmaceutical Society of Great Britain relating to this matter.

	Considered	Not Considered	Action Plan	By whom By when
3.1 Establish that systems are in place (and are defined, documented and regularly reviewed) to promote patient safety and encourage quality patient care when pharmacists are prescribing, which have taken into account the “Clinical Governance Framework for Pharmacist Prescribers and Organisations Commissioning or Participating in Pharmacist Prescribing” (218) and any other local governance structures or strategies.				
3.2 Ensure that legal responsibilities and accountabilities are defined and documented within the strategy and have taken into account the “Professional Standards and Guidance for Pharmacist Prescribers” which are part of the Pharmacist Code of Ethics.(219)				

4. Practice Development: This refers to the overall change in practice within secondary care which may be expected to accompany a service redesign which involves the establishment of pharmacist prescribing.(217) Statements within this section aim to act as a trigger to consider how the development of the pharmacist prescribing role will fit into current pharmacy service provision in secondary care. It may be necessary to analyse, review and change some current practices to ensure that these will not jeopardise the sustainability of a pharmacist prescribing service.

	Considered	Not Considered	Action Plan	By whom By when
4.1 Consider any changes in current pharmacy service provision in secondary care that may be needed to support the development of a pharmacist prescribing service.				
4.2 Consider any additional resource/s that may be needed to ensure provision and sustainability of a pharmacist prescribing service.				

5. Outcome measures: This refers to the evidence of both positive and negative consequences which are available to enable the professional merit of the role to be assessed at two levels: direct patient care and effect on other health professionals.(217) Statements within this section aim to act as a trigger to consider what outcomes may be indicative of the consequences of pharmacist prescribing. Outcomes must be valid, reliable and easily measurable and need to relate to both the clinical effects and the actual processes and procedures adapted. These may be of particular importance since there is little evidence available describing the outcomes of pharmacist prescribing.

	Considered	Not Considered	Action Plan	By whom By when
5.1 The strategy should include ways of assessing outcomes to measure any positive or negative impact of the role on direct patient care.				
5.2 The strategy should include ways of assessing outcomes to measure any positive or negative impact of the role on other healthcare professionals.				

B. Role Specific

1. Education: This refers to the individual continuing professional development and the opportunities for continuing education provided for prescribing trainees and following qualification as a pharmacist prescriber.(217) Statements within this section aim to highlight the importance of considering areas such as competencies and continuing professional development for pharmacists who are prescribers. These may be of particular importance with the advent of independent prescribing, where a pharmacist may prescribe any licensed medication (other than controlled drugs) for any undiagnosed condition. With prescribing being a relatively newer task for pharmacists in secondary care, it may be necessary to provide support both for prescribing trainees and prescribing pharmacists, to ensure they are comfortable within this expanded role.

	Considered	Not Considered	Action Plan	By whom By when
1.1 Provide support for pharmacists during training or pharmacists who are planning to train to be prescribers.				
1.2 Provide clearly defined pharmacist competencies to help pharmacists achieve and maintain competency when prescribing ("Maintaining Competency in Prescribing" produced by the National Prescribing Centre may be a good resource).(220)				
1.3 Clearly define the level and type of experience required to prescribe in different specialties.				
1.4 Provide the necessary opportunities for education and training following qualification as a prescriber.				
1.5 Ensure that pharmacists are able to demonstrate competency on an on-going basis to prescribe in their area of practice.				
1.6 Ensure that appropriate pharmacists are selected for the prescribing role by taking into consideration their individual views and attitudes towards pharmacist prescribing.				
1.7 Provide the necessary mentoring scheme to pharmacists who are prescribing.				

2. Future orientation of service: This refers to the advisory or supportive role of the pharmacist prescriber towards other healthcare professionals and patients. It also includes the level of practice that might be regularly expected from a specialist pharmacist prescriber and may include expanding the boundaries of pharmacy practice, demonstrating independent clinical decision making, carrying out systematic assessment and intervention and portraying a sophisticated use of clinical knowledge.(217) Statements within this section aim to project the likely future development of the role of the pharmacist prescriber, possibly moving from a “generalist” practitioner to a “specialist” practitioner.

	Considered	Not Considered	Action Plan	By whom By when
2.1 Encourage the development of prescribing specialist roles.				

6.6 Further research

The following section suggests some potential areas and the rationale for further research. These are based on results and the limitations of this PhD project.

1. Aim: To investigate drivers which facilitate implementation of PP within hospitals in Scotland.

The scoping exercise in Phase 2 indicated that having a framework for NMP, including PP, was potentially associated with more successful implementation of PP. This proposed research would further inform policy makers and managers on factors which assist the successful implementation of PP by gaining insight into views and perceptions of stakeholders other than those included in this study such as pharmacy and hospital managers, medical staff and patients.

Potential method: Initial focus group discussions involving stakeholders described above within a hospital where pharmacists are making use of their prescribing skills and one where pharmacist prescribers are not and aimed at exploring facilitators to implementation of PP in Scotland. This would inform a questionnaire which may then be sent out to all pharmacists-in-charge of hospital pharmacies in Scotland.

2. Aim: To evaluate the usefulness and applicability in secondary care settings of the toolkit developed in this PhD research.

This would allow any changes to be made prior to recommending potential use of the toolkit in all Scottish hospitals. The exercise may possibly be extended outwith Scotland to explore its potential relevance to other UK countries. This may be of particular relevance in view of recent evidence published indicating that only half of the trusts in England responding to the researchers had a strategy for developing IP. (244) Moreover, individuals emerged as the key drivers to implement pharmacist IP rather than a redesign of services. (This study could potentially be extended to evaluate the usefulness and applicability of the toolkit outwith the UK; e.g. Australia or Canada where PP is still in its infancy)

Potential method: Pilot in a sample of health boards where pharmacists in strategic posts and pharmacist practitioners will be asked to rank each statement on a Likert scale for ease-of-use and applicability.

3. Aim: To develop a toolkit to facilitate implementation of PP in community pharmacy and primary care settings in Scotland.

This would facilitate implementation of PP other than in secondary care.

Potential method: Focus groups with pharmacist prescribers and non-prescribers working in community pharmacies and primary care settings to explore their views and perceptions of barriers and facilitators to implementation of PP within these settings. Using the same method adopted in this PhD research, this may generate evidence to inform and guide development of a toolkit specific to these settings.

4. Aim: To survey current prescribing-related activities of hospital pharmacist prescribers within the UK.

This survey to all hospital pharmacist prescribers would enable a cross-sectional analysis of activities that are being taken on as part of the hospital pharmacist's expanded role. This would be potentially useful to explore in which therapeutic and clinical areas pharmacists have been most successful in implementing PP. It may inform policy makers who are in the process of planning a service redesign to incorporate PP.

Method: Questionnaire to all hospital pharmacists registered as prescribers.

5. Aim: To conduct in-depth case studies in locations where pharmacists are prescribing antimicrobials.

This research would help to follow up anecdotal evidence through UKwide discussion forums which indicate that some pharmacists may be prescribing antimicrobials for specific indications such as prescribing surgical antibiotic prophylaxis as part of pre-op clinics. This research would provide information to policy makers who are exploring further roles for the pharmacists, especially as part of the well established AMDT.

Method: In-depth case studies involving stakeholders likely to be involved in PP of antimicrobials such as different grades of medical and nursing staff

within the specialty, medical staff in microbiology, pharmacy management and patients.

6.7 Conclusions

This PhD research has explored PP in hospitals in Scotland, with a focus on antimicrobials. As part of the research, original data was generated using a number of methods including focus group discussions and a Delphi consensus method. An extensive literature review was also conducted to inform the project. The data generated has added to the body of evidence about the topic, as indicated by the three peer-reviewed papers focusing on the literature review, one peer-reviewed paper discussing an aspect of results in Phase 1 and a number of poster presentations and oral communications presented at both national and international conferences. Publication of results for Phase 3 of the research is planned in the next academic year.

Phase 1 of the research indicated that few of the pharmacist supplementary prescribers participating in the focus group discussions were using their prescribing skills with numerous barriers for implementation of PP in secondary care identified. Despite these barriers, pharmacists also identified numerous areas where they perceived PP to be successful in a hospital environment, mainly relating to antimicrobials, but with a potential to transfer to other therapeutic classes also. Overall, there was a lack of implementation of PP in the five health boards sampled, with an evident lack of strategic planning to incorporate PP. This evidence indicates that the pharmacists who were successfully prescribing were doing so out of their own initiative to improve services to their patients, rather than as part of an overall strategic plan. These results were supported by evidence generated from the scoping exercise as part of Phase 2, and reinforced the fact that there appears to be a gap between training of pharmacist prescribers and the implementation of PP in hospitals in Scotland.

Based on the above evidence, the last phase of this research aimed to bridge the gap between policy and practice, facilitating implementation of

PP in hospitals. Consensus-based guidelines to facilitate a service redesign involving PP in secondary care were developed based on evidence from the focus group discussions. To encourage use, these were developed as a self-assessment toolkit which could be used as an initial starting point to reflect on areas of implementation of PP within a hospital, or to inform debate on managerial requirements and future orientation of health board developments in PP.

While the results and conclusions generated through this research need to be interpreted with caution, the data generated through this research is an original contribution to the evidence base around PP.

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