Prescribing guidance and practice: exploring the factors that have an impact on prescribing in a mental health environment

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Abstract

The study used in-depth interviews to explore how prescribing practice, and hence patient outcomes, could be improved by a range of stakeholders; namely GPs, pharmacists, psychiatrists, representatives from the pharmaceutical industry and service users.

The author, as Chief Pharmacist for Dudley and Walsall Mental Health Partnership Trust (DWMHT), is responsible for the strategic leadership in medicines optimisation across the organisation. In the role of Chief Pharmacist, the author has identified that there are disparate prescribing patterns across the trust, in addition to a distinct lack of clarity on prescribing responsibility with the local health economy.

There is a paucity of research which incorporates the views of a variety of healthcare professionals and service users on prescribing practice in a mental health setting; furthermore, the author is unaware of any study that has incorporated the views of the pharmaceutical industry on joint working with the NHS in a mental health context.

Fifteen healthcare professional interviews were conducted, which included pharmacists, psychiatrists and GPs. In addition, 5 expert by experience service users were interviewed about their experiences of shared decision-making whilst managed under the care of mental health services. The study also explored with representatives from the pharmaceutical industry, the scope for collaborative working with the NHS to optimise the use of medicines. Semi-structured interviews were conducted and the data was analysed using Framework analysis.

This study revealed that four core tensions exist in the delivery of prescribing in mental health. These are:
1. The notion of guideline driven care versus the individual needs of patients
2. The need for holistic, patient-centred care versus the constraints on healthcare professional to deliver this
3. The rhetoric about patient choices versus the realities of shared decision-making in a resource-limited system
4. The acknowledgement of the need for joint working with the pharmaceutical industry, which is based on the current NHS financial climate, versus the inherent mistrust by healthcare professionals of the industries’ motives.
Further to the identified tensions the study also identified three areas of concord across the stakeholder groups which are:

1. The importance of communication with service users
2. The role of prescribing guidelines
3. The meaning of wellbeing for the recipients of care

The complexity of decision-making in prescribing practice was highlighted by the study. The success of patient centred care is reliant on healthcare professional attitudes, patient empowerment, and resources such as electronic prescribing to support evidenced-based prescribing practice. Scarcity of resources impacts heavily upon the decisions that are made which can have a substantial impact upon variability in treatment decisions and on the ability to facilitate patient choice in a meaningful way.
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### Abbreviations

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<td>ABPI</td>
<td>Association of the British Pharmaceutical Industry</td>
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<td>ADHD</td>
<td>Attention Deficit Disorder</td>
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<td>BMI</td>
<td>Body Mass Index</td>
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<td>BMA</td>
<td>British Medical Association</td>
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<td>CASP</td>
<td>Critical Appraisal Skills Programme</td>
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<td>CCG</td>
<td>Clinical Commissioning Group</td>
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<td>CPD</td>
<td>Continual Professional Development</td>
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<td>CPN</td>
<td>Community Psychiatric Nurse</td>
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<td>CTO</td>
<td>Community Treatment Order</td>
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<td>Care Quality Commission</td>
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<td>Commissioning for Quality and Innovation</td>
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<td>COPD</td>
<td>Chronic Obstructive Pulmonary Disease</td>
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<td>GP</td>
<td>General Practitioner</td>
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<td>Health and Social Care Information Centre</td>
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<td>JCPMH</td>
<td>Joint Commissioning Panel on Mental Health</td>
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<td>MHRA</td>
<td>Medicines &amp; Healthcare products Regulatory Agency</td>
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<tr>
<td>MTRAC</td>
<td>Midlands Therapeutic Review and Advisory Committee</td>
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<td>NAS</td>
<td>National Audit of Schizophrenia</td>
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<td>NHS</td>
<td>National Health Service</td>
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<td>National Institute for Health and Care Excellence</td>
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<td>National Service Framework</td>
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<td>Payment by Results</td>
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<td>Prescribing Observatory for Mental Health</td>
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<td>Primary Care Trust</td>
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<td>Patient and Public Involvement Programme</td>
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<td>Pharmaceutical Price Regulation Scheme</td>
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<td>Quality-Adjusted Life Year</td>
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<td>QIPP</td>
<td>Quality, Innovation, Productivity and Prevention</td>
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<td>Scottish Intercollegiate Guidelines Network</td>
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<td>SNRI</td>
<td>Serotonin Noradrenaline Reuptake Inhibitors</td>
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<td>SSRI</td>
<td>Selective serotonin reuptake inhibitors</td>
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<td>SMC</td>
<td>Scottish Medicines Consortium</td>
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<td>WHO</td>
<td>World Health Organization</td>
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Dedication

I dedicate this thesis to the memory of my loving mother Barbara Campbell, who was a mentor, friend, and the best counsellor I have ever known. I can still hear the soft echo of your voice whispering encouraging words.

“Love endures long and is patient and kind; its hopes are fadeless under all circumstances, and it endures everything.”

1 Corinthians 13:4,7
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I wish to thank my wife Diane for all help, support, encouragement and the countless hours spent discussing this research, without your constant love and care I would never have started or completed this thesis.

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Finally, I would like to express my gratitude to all participants for their time, honesty and invaluable insights, without which this research would not have been possible.
Declaration

The findings and conclusions of this thesis are the work of the named candidate and no portion of the work referred to in this thesis has been submitted in support of an application for another degree or qualification of any other university or other institute of learning.
Chapter 1: Introduction

1.0 Overview
The author, as the current Chief Pharmacist for DWMHT, has responsibility for the strategic oversight of medicines optimisation across the organisation. This involves the review of evidence and the production of formularies, clinical guidelines and treatment policies/protocols which are designed to facilitate standards of prescribing which are uniform, high quality and cost-effective. The author often receives communication from prescribers within the Trust detailing poor prescribing practice from primary care colleagues, who would, in some circumstances, refuse to prescribe psychiatric medicines for patients with enduring mental health illness. The author has also received numerous reports from GPs, detailing poor communication from mental health prescribers in terms of the rationale for prescribing and clarity regarding the need for continual patient monitoring.

This thesis is grounded in the author’s ongoing interest and experience of working in mental health. The study is situated in a time of the greatest organisational change in the NHS since its inception. The thesis is based on the author’s observations and discussions with service users, prescribers, pharmacy colleagues and representatives from the pharmaceutical industry. The author considered the question of what could be done to improve prescribing practice across the local health economy and how the service user experience could be improved.

1.1 Current Context
Financial drivers & mechanisms for cost control
The costs associated with specialist led prescribing in mental health across Dudley and Walsall was approximately £1.4 million during the 2015/16 financial year. As part of the initiative to deliver cost savings, there is an expectation of a year on year cost improvement programme to deliver savings, which includes the allocated drug budget for the trust. The need to deliver efficiency savings has to take into consideration the potential for reduction in costs due to generic availability of previously branded medicines, annual inflationary increases in drug costs, and the entry of new drugs to market for the treatment of mental health conditions which are significantly more expensive than generic alternatives.

The pharmaceutical industry has a potential role to play in optimising the use of medicines through transparent and value for money partnerships with the NHS that help secure better outcomes for service users. At present, representatives from the pharmaceutical industry
market their drugs to healthcare professionals across the trust and their major focus is with consultant psychiatrists, who are the drivers for the uptake of new medicines.

**Demographics**
Dudley and Walsall boroughs are in the top third of the most deprived councils in England, however they have lower than the national average for people who are recorded by their GP as suffering with severe mental illness.

There is an anticipated growth in the populations of Walsall and Dudley over the next decade. The population in Walsall is expected to increase by 5.1% from 270,900 to 284,700 in 2026. In addition to this, Walsall’s older adult population (those aged 65 and above) is also predicted to increase by 13.8%, with the number of people 85 years and older increasing from 47,200 in 2016 to 53,700 in 2026. Similarly, the population in Dudley is projected to increase by 6.4% (20,000 people) to 334,000 between 2016 and 2026. The most significant feature is the anticipated growth of older age groups, with the 60-74 population projected to increase by 11.5% and the 75+ age group by 67.9%. These age groups alone equate to 26,000 more people. The anticipated growth in population will have implications for healthcare resources, increasing demand at a period of limited funding.

1.2 **Background**
The mechanism for the entry of new drugs for use across DWMHT involves approval via the Trust Medicines Management Committee, which includes representation from across the local health economy. Once approval is granted at a trust level, a further application is made to the respective Clinical Commissioning Groups (CCGs) in Dudley and Walsall. The outcome of the approval by the CCGs determines whether the drug is made available for GPs to prescribe across the local health economy. The decision regarding the approval of a drug has clear implications for service users because if a drug is approved at a trust level, but not at a local health economy level, it means that the provision of pharmaceutical care for that individual will be restricted to DWMHT. The approval of drugs is further complicated by a lack of robust clinical trial data when compared with agents used in the treatment of physical health conditions. Typically, mental health clinical trials are characterised by smaller participant numbers and shorter duration than is experienced in a clinical practice.

Pharmacists across the health economy are instrumental in developing tools for reducing the range of drugs prescribed and assisting in implementing these in practice.
The three main tools which pharmacists routinely use for improving prescribing are:

- formularies, which recommend specific drugs and exclude others;
- clinical guidelines (e.g. the management of depression), which help to ensure that treatment of patients is based on evidence of best practice; and
- prescribing policies (e.g. the guidelines for prescribing on FP10 prescriptions) /treatment protocols (e.g. clozapine treatment guidelines), which assist prescribers in using the drugs in a formulary or implementing clinical guidelines.

At the outset of the research project in 2013 there were disparate prescribing patterns across DWMHT and limited formulary control, in addition to a distinct lack of clarity for prescribing responsibility with the then local primary care trusts in Dudley and Walsall.

One way to improve prescribing within the trust and to ensure clarity of prescribing responsibilities between primary and secondary care was the development of joint prescribing guidelines (Grant, 2006, p. 32). This approach was designed to establish prescribing practice that is consistent with the available evidence and which could lead to potentially improved use of drug therapy (Fleury, Imboua, Aubé, Farand, & Lambert, 2012, p. 11) detailing issues such as:

- Agreeing suitable endpoints for prescribing.
- Physical monitoring associated with psychotropic prescribing.
- Agreement on the cost burden for prescribing across primary and secondary care.
- Managing the entry of new drugs and the exit of old ones across the healthcare economy.

At present, an educational outreach approach is adopted across the trust to support the implementation of prescribing guidelines. Prescribers receive face-to-face updates at postgraduate educational meetings, senior clinical forums and as part of a rolling programme of feedback to consultant teams which is led by the pharmacy team. In additional to face-to-face meetings, newsletters are also used to convey prescribing information across the trust and updated policies are communicated to the trust Quality and Safety Committee which includes senior medical and nursing staff.
1.3  

**Gap in knowledge**

Prescribing in mental health and monitoring of treatment has been found to be deficient in previous research and it is important to understand the influences on prescribing practice in this area (Chapman, Rough, Garnett, Longley, & Wilson, 2014, p. 28). Mental health clinical practice guidelines have proliferated, in recent years but there is little evidence regarding the degree to which they are implemented in clinical practice (Bauer, 2002, p. 139). This research will explore the perceptions of key stakeholders on optimising prescribing practice in mental health across a local health economy.

At present, there is minimal evidence to suggest that guideline dissemination alone affects the behaviour of mental health clinicians or GPs (Forsner et al., 2010a, p. 2). Prescribing guideline studies are further complicated by the fact that implementation can take several years to achieve in many organisations (Forsner et al., 2010b, p. 10).

**Service Users**

The views of service users were sought to explore decision-making and prescribing practice. The findings from the service users will be used to inform guideline development and service delivery.

There is evidence to suggest that mental health patients feel disempowered with respect to their involvement in their drug treatment (Rethink 2006, p. 9) and so this study sought to explore the service user perspective on how they should be engaged in the prescribing process and what recommendations they would give to healthcare professionals to improve pharmaceutical care.

**Representatives from the Pharmaceutical Industry**

To date no study has attempted to explore the views of representatives from the pharmaceutical industry on prescribing practice in a mental health setting and the wider engagement with mental health services across the UK.

With the NHS facing the prospect of making efficiency savings of £22 billion by 2020/21, and the state of the economy set to increase pressure on public services, access to commercial skills and resources will be more important than ever for the foreseeable future. Collaborative working with the pharmaceutical industry is one way of optimising existing resources to benefit patient care. The views of senior personnel within the pharmaceutical industry were sought to
determine how working in collaboration could promote initiatives leading to improved health for patients across the local health economy.

**Consultant Psychiatrists and GPs /GP commissioners**

There is a lack of studies that compare the attitudes of different groups of doctors to prescribing guidelines (Carlsen & Bringedal., 2011, p.158). By comparing the attitudes of GPs / GP commissioners and *consultant* psychiatrists within the same health economy it is anticipated that this will lead to greater clarity in determining the key issues which are barriers to guideline implementation. The current study will consider the economic drivers for cost effective prescribing and will seek the perspectives of GPs/ GP commissioners and consultant psychiatrists on prescribing guidance.

**Pharmacists**

Pharmacists are integral to prescribing guidance development (Grant., 2006, p.30) and are often responsible for:

- Reviewing the evidence for medicines.
- Producing prescribing guidance.
- Monitoring compliance with guidance.
- Highlighting cost effective options.

At present, no studies have evaluated the perspectives of pharmacists on the development and implementation of psychiatric prescribing guidelines. This study will seek the opinions of those actively engaged in prescribing guideline development across the local healthcare economy.
1.4 Aims and Objectives

Aims
This study sought to explore different perspectives on prescribing practice and the potential for optimising patient care. The study therefore explored the views of service users, healthcare professionals and representatives from the pharmaceutical industry.

Objectives
1. To explore the extent to which service users perceive they were involved in making treatment decisions about their prescribed medication and the factors that influence the service user’s involvement in treatment decision making.

2. To explore the perceived factors that influence prescribing from the perspective of healthcare professionals (consultant psychiatrists, pharmacists involved in formulary/guideline development across the local health economy and GP/GP commissioners) and representatives from the pharmaceutical industry with a national or international remit.

3. To develop an understanding of the perceived factors that influence the implementation of prescribing guidelines in a mental health setting from the perspective of consultant psychiatrists, pharmacists involved in formulary/guideline development across the local health economy, GP/GP commissioners and senior representatives from the pharmaceutical industry.

4. To provide a framework of recommendations for optimising the use of medicines across the health economy.
1.5 The importance of the research

In the current era of economic, demographic and technological challenge it is critical that service users achieve the best possible quality outcomes from medicines. However, there is a growing body of evidence which indicates that service users are not achieving this, and for service users with enduring mental illness adherence rates have been shown to be as low as 24% (n=1493) (Lieberman & Stroup, 2011, p. 770). The evidence suggests that service users with serious mental illness desire greater involvement in their care and the decision making process within the consultation with a healthcare professional (Lester, Tait, England, & Tritter, 2006, p. 415).

Treatment guidelines are designed to improve quality of care by articulating evidence-based best-practice models and by making explicit the rationale for the guidance and the steps needed to implement optimal treatment (Bauer, 2002, p.138; Charani et al., 2013, p. 193). The successful implementation of prescribing guidelines is dependent on a multiplicity of factors. These include the judicious use of evidence in the context of the individual and the need for respecting the importance of choice to the service user. In recent years, there has been a move towards treating service users in the community and, where appropriate, under the care of a GP. The treatment of patients in primary care is linked to the wider government agenda of achieving parity of esteem between mental health and physical health as well as reducing the cost of treatment (BMA, 2014, p. 34). However, despite this ideal, in 2014/15 a national review saw the removal of the requirement for GPs to undertake annual monitoring of weight, cholesterol and glycaemic levels in patients with severe mental illness. This is particularly problematic as there is evidence that physical health monitoring of patients with mental illness is inadequate (Patel et al., 2014, p. 507; Barnes & Paton, 2011, p. 330).

A transition of patients from specialist services to primary care necessitates clear communication across the local health economy between healthcare professionals as there is some evidence to suggest that some GPs lack sufficient knowledge to treat mental health patients effectively (Phelan, Stradins, & Morrison, 2001, p. 444; Fleury, Imboua, Aubé, Farand, & Lambert, 2012, p. 2). Furthermore, there is evidence to suggest that some GPs are reluctant to treat mental health patients in primary care (Crawford, Carr, Knight, Chambers, & Nolan, 2001, p. 218) which can, in addition to a lack of knowledge, be linked to case-load capacity (Fleury, Bamvita, & Tremblay, 2009, p. 4). One way in which GPs may be supported to care for patients with enduring mental illness is with the use of shared-care agreements with the mental health trust which would outline monitoring requirements, referral information and specific prescribing details (Smith, Allwright, & O'Dowd, 2007, p. 15).
A review of the existing mechanisms for the development and implementation of prescribing guidelines, which takes into consideration the perspectives of service users and healthcare professionals, is key to optimising the use of medicines for people with enduring mental illness. The study seeks to identify a series of recommendations for improving prescribing practice across the local health economy.
Chapter 2: Literature review

2.1 Overview
This chapter provides a review of the literature for the 2013 transformational changes to the NHS and the relationship between the pharmaceutical industry and the NHS. The review also includes the development of service user engagement with mental health services and finally details the emerging evidence associated with guideline development and implementation.

First, the literature review provides an overview of the new NHS in light of the reforms of the Health and Social Care Act of 2012, which came into effect on April 1st 2013. The review will focus on the impact of CCGs and the Department of Health (DoH) policy drivers for service user engagement with health care. The review links the transformation in the NHS with the economic imperative to achieve cost-effective prescribing as part of a wider medicines optimisation agenda. Following on from the transformation of the NHS the review will consider its relationship with the pharmaceutical industry, the implications for innovations in mental health and the industry influence on research findings. The review will then consider the implications for joint working between the pharmaceutical industry and the NHS and the implications for risk sharing initiatives between them.

This chapter will then provide a review of the literature of service user engagement in mental health service development and will focus on policy directives and the historical context and evolution of service user engagement. The final part of the review discusses the evidence for translating prescribing guidelines into clinical practice and identifies the current gaps in knowledge associated with implementation.

2.1.1 Literature search strategy
Certain topics within the literature review were conceptual in nature, such as the NHS transformation and the relationship between the NHS and the pharmaceutical industry. As such, the literature review in this regard did not lend itself to a formal systematic review, but the principles of the approach, as outline by the Critical Appraisal Skills Programme (CASP), were adhered to. To supplement the search, expert opinions from the pharmaceutical industry, key contacts within NHS England and the Department of Health were sought for additional information which was relevant to the study aims and objectives. Further sources were identified by following up internal citations and references within the documents retrieved from the searches.
The overall literature search was kept deliberately broad to incorporate the complexities of the literature relevant to the following aspects of the study:

- The impact of the Health and Social Care Act and subsequent NHS reforms
- The relationship between the pharmaceutical industry and the NHS
- Service user engagement within the NHS
- Prescribing guidance in mental health

Any publication with a focus on these subjects was considered relevant to the literature review and an initial search was started in 2014 using the following databases:

- MEDLINE
- PsycINFO
- EMBASE
- The Cochrane Library
- Department of Health Database
- Health Management Information Consortium
- Health Business Elite

Following initial searches, an auto-alert was set up to ensure the identification of new and relevant publications. A final search of the above databases was undertaken in February 2016. The final reference manager database (Mendeley) contained 777 records and included papers from a variety of sources. Detailed records of the exact number from each search were not recorded, as many papers were picked up by multiple methods, and because the nature of the searches was iterative, rather than being conducted all at a single point in time.

Other relevant sources of information were identified by sourcing related publications, reports, research studies or relevant policy documents:

- Department of Health database
- The Office of National Statistics websites
- ABPI website
- Conference proceedings
- Press releases
- Reference lists of retrieved articles
• Search of relevant journals online via the University of Portsmouth Library services and NHS Athens
• Recommendations from experts in the field

The search was conducted using a mix of subject headings (see examples below) and freetext terms. Relevant terms were combined for different chapters.

### Table 2.1: Literature search terms

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<thead>
<tr>
<th>Main headings &amp; subheading</th>
<th>Key search terms</th>
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<td>Shared-decision making</td>
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<td>Patient/service user choice</td>
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#### 2.2 NHS transformation overview

The review focuses on the impact of financial drivers for change and the role of the clinical commissioning groups (CCGs) against the background of reduced expenditure on public services. Furthermore, the review will consider the drive for public engagement with health care.

#### 2.2.1 Legislative changes to the NHS

The 2012, the Health and Social Care Act introduced the most significant change to the NHS since its inception in 1948. The changes have been described by the former Chief Executive of the NHS as being “so big it could be seen from the moon” (Ramesh & Davis, 2011, para.
The Act faced substantial criticism when it was first published in draft form and its process through parliament proved politically difficult (Timmins, 2012, p. 118).

For some staff working within the NHS the transformation has been a time of uncertainty and a shift in focus from patient care to understanding the new NHS landscape and its infrastructure.

The integration of health and social care has been on-going for over 40 years (Cameron, Lart, Bostock & Coomber, 2012, p. 2) and is viewed as a way to reduce costs and make more efficient use of resources, while achieving better patient outcomes. This is of particular importance with the increasing demands on health and social care due to an aging population, alongside declining investment in the public-sector infrastructure. Thus, the relationship between health and social care can prove challenging as both try to deliver services while sharing limited resources.

The transfer of responsibility for around £60 billion of NHS spending from PCTs to CCGs is one of the most visible aspects of the reforms. CCGs now control much of the budget for mental health expenditure and therefore there is greater scrutiny on all aspects of expenditure by mental health trusts. As part of the NHS reform, the existing regulator of NHS foundation trusts - Monitor has become the economic regulator for providers of NHS-funded care. The push to convert all NHS trusts into quasi-independent foundation trusts, combined with the financial pressures being experienced by many providers, means that a significant number of mental health trusts may be forced to merge with other provider organisations to achieve economic viability. Such mergers are likely to impact negatively on the idea of providing ‘care closer to home’ as organisations seek to centralise service delivery. There is also minimal evidence to suggest that service users have had meaningful engagement in the NHS service reconfigurations.

Figure 2.1 shows the diagrammatic representation of the new NHS structure and the interrelationships with care organisations, the relationship between mental health services, clinical commissioning groups and local government.
2.2.2 The economic imperative - NHS

Following the global economic crisis of 2008, the United Kingdom government has enforced a series of measures aimed at reducing expenditure in the public sector. This has led to static NHS funding since 2010 (Ford, 2013, p. 1) and the need to reconfigure the NHS infrastructure. This comes at a time where the demand for NHS Services is rising at a rate of 4% per annum, coupled with an increasingly elderly population, increased costs of treatment, and a rise in public expectations of service delivery (NHS England, 2014, p. 3). The impact of the static funding has partly contributed to the financial deficit of £841m across NHS providers during 2014/15 and which increased to £2.3bn by the third quarter of the 2015/16 financial year (Lafond, Charlesworth, & Roberts, 2016, p. 3).

The NHS faces the triple challenge of improving health outcomes while facing increasing demand for services and achieving efficiency savings as part of the Quality, Innovation, Productivity and Prevention (QIPP) initiative (Faria, Barbieri, Light, Sculpher & Heslington, 2014, p. 5). QIPP exists in the context of a global drive to improve the quality of care and health outcomes whilst maximising efficiencies in healthcare provision (Ferguson, 2012, p.
One way in which organisations have attempted to reduce expenditure is by reducing staff costs. Critics of this approach have highlighted concerns raised by the Francis inquiry which identified a focus on savings in staffing costs, while delivering inadequate services (Pollock & Price, 2013, p. 2).

In response to the need to achieve improved efficiencies, the NHS commissioned a strategy outlining how this might be achieved. The publication of the ‘5 Year Forward View’ was developed by NHS England, Monitor and the NHS Trust Development Authority to propose a model of NHS service delivery within the context of the financial constraints facing public sector organisations. The strategy includes several themes including the importance of public health and ill-health prevention, empowering patients and communities, integrated care and making further efficiencies within the health service. As part of the progression of the ‘5 Year Forward View’ integrated primary and acute care systems have started to link GP, hospital, community and mental health services under what is known as vanguard sites (DoH, 2015, p. 3). Despite the acknowledgement of the need for greater integration of healthcare providers, critics have pointed out that there is limited evidence that previous mergers have achieved better value for money or led to meaningful improvements for service users (Audit Commission, 2009, p. 50).

The NHS has been challenged to deliver £22 billion of productivity improvements by 2020/21 (Ham, McKenna and Dunn, 2016, p. 1). This target has been deemed by some as unrealistic (Appleby, 2014, p. 1) and has led to an increased scrutiny of prescribing costs, which are approximately £15.5 billion per annum; 13.7% of the total NHS expenditure (HSCIC, 2015, p. 6). The idea of cost-effective prescribing is both a national and international concern and there are interventions which are aimed at reducing prescribing costs, including increasing the prescribing of generic drugs where possible (Godman et al., 2010, p. 710). In a move to minimise waste and improve adherence the government is set to introduce a scheme to display the cost of medicines with a value of over £20 to the NHS on packaging, along with the statement “funded by the UK tax payer.” It is possible that some individuals may feel that they are a financial burden to the healthcare system, and the potential impact of displaying the costs of medicines on adherence in vulnerable patients is yet to be considered.

The cost of hospital prescribing has risen by 15.4% during 2014/15 compared with a rise of 2.8% in primary care which is largely due to hospitals prescribing costlier, NICE approved medicines (HSCIC, 2015, p. 16). The recent findings of a cost analysis conducted by health
economists at the University of York concluded the NHS is paying too much for new drugs (Claxton et al., 2015, p. 98). The National Institute for Health and Care Excellence (NICE) uses a threshold of £20,000–30,000 per quality adjusted life year (QALY) to gauge the benefits of new drugs, but the research team concluded that the upper threshold is out of sync with the £13,000 per QALY that the NHS spends on other services (Claxton et al., 2015, p. 98). It is possible that the upper threshold takes into consideration the contribution of the pharmaceutical industry to the UK trade surplus which is approximately 3 billion per annum.

Improving the use of medicines has been demonstrated to improve health outcomes and reduce costs. Recent reports indicate that 30–50% of medicines are not being taken as intended; resulting in a loss in health gain of billions of pounds (NICE, 2009, p. 1). The rates of non-adherence with medication in patients with schizophrenia and related psychotic disorders chronic mental health have been shown to be as high as 70-80% (Breen & Thornhill, 1998, p. 459). The failure to benefit from effective drug treatment has financial implications in terms of wasted medicines, poor symptom control, relapse and re-hospitalisation, long-term functional disabilities, loss of autonomy, education or employment possibilities, homelessness, disengagement with mental health services and ultimately suicide.

2.2.3 Clinical Commissioning Groups

In the new NHS structure, the responsibility for commissioning mental health services rests with the CCGs which came into effect on April 1st, 2013. The CCGs largely superseded PCTs as the commissioners of health services for the local health economy. It is acknowledged that the commissioning of mental health services is complex and can involve health, social care and the third sector. Critics of the current commissioning of mental health services have highlighted the need for improved communication between healthcare providers, better technological infrastructure, and greater clarity about responsibility and accountability for monitoring physical healthcare (Rodgers et al., 2016, p. 27). Due to the complexity of commissioning mental health services, guidance was made available to CCGs (Campion & Fitch, 2015 p. 5). The Joint Commissioning Panel on Mental Health (JCPMH), a collaboration of 17 organisations has produced guidance on commissioning specialist areas of mental health including perinatal mental health, rehabilitation services and mental health services for young people.

In a survey conducted by Rethink, over half of GPs reported not having the right skills to commission mental health services—much higher than other service areas (Rethink, 2010, para 3). The longstanding commissioning of mental health services has been viewed by critics
as inadequate, which in part has been attributed to the lack of understanding of mental health service provision by PCTs (Turner et al., 2013a, p. 10). In addition to potentially failing service users, a complex care system that is not fully understood by its commissioners can lead to an inefficient use of resources and the continuation of clinical services that are of minimal benefit (Turner et al., 2013a, p. 10). For CCGs to seek an innovative and responsive service requires them to have a clear picture of the service delivery by the provider organisation. It is acknowledged that expertise in mental health commissioning is varied, which can be attributed in part to the loss of organisational memory in light of the dissolution of PCTs and the formation of CCGs (Miller & Rees, 2014, p. 150). It is estimated that approximately 70% of CCGs have mental health leads in place, although this does not imply that they have significant experience in commissioning mental health services (Dent, 2013, p. 1; Gilburt, Edwards & Murray, 2014, p. 33). Many CCGs have opted to continue the existing contracts as it is too early for them to be able to challenge the status quo (Dent, 2013, p. 1).

One way in which CCGs work with provider organisations is to implement the nationally driven Commissioning for Quality and Innovation (CQUIN) targets. CQUINs are part of a national framework that was first established as part of the 2009/10 NHS Operating Framework as an incentive scheme which forms part of the contract between a commissioner and a provider organisation. CQUIN schemes link successful delivery of specific outcomes and actions with a financial incentive for the provider organisation. CQUIN schemes include a measure of the quality of medicines optimisation across a provider organisation. The cost associated with, and the complexity of a medicines optimisation CQUIN can vary across providers within the same health economy. The payment for a CQUIN scheme is withheld by commissioners until the target is achieved, thus failure to achieve an agreed target can compound existing cost-pressures faced by provider organisations.

2.2.4 Payment by results

Mental health services account for the largest proportion of programmed expenditure in the English NHS, at nearly 11% of the healthcare budget (DoH 2011, p. 64). The introduction of payment by results (PbR), is now being rolled out in mental health services and will be the single biggest change in the way NHS psychiatric and related services are financed (Jacobs, 2014, p. 155).

At present, NHS mental health services are primarily funded through block contracts agreed between commissioners and providers of care, or based on levels of existing ‘inputs’ such as the number of beds (Mason 2011, p. 235). Without a link to quality and activity, this will not deliver incentives to improve quality or efficiency. Indeed, research suggests mental health
services have significant scope to improve their efficiency, with very large variations in activity levels (Naylor & Bell, 2010, p. 18). Critics of the system have highlighted that there are large variations in activity levels between provider organisations which could lead to efficiency savings (Naylor & Bell, 2010, p. 36). Despite this view there is an acknowledgement that mental health services have experienced approximately 40 per cent reductions in income in 2013/14 and 2014/15 (Gilburt, 2015, p. 8) and that this has been linked to a reduction in service user access as mental health trusts transform service delivery models to achieve efficiency savings (Gilburt, 2015, p. 20). The issue of quality is notable in that only two out of seventy-one (2.8%) of English mental health trusts have achieved a rating of ‘outstanding’ as determined by the Care Quality Commission.

A care cluster has been adopted which will involve clinicians assessing the clinical need of service users using secondary mental healthcare services. Service users will then be allocated into one of 21 clusters depending on their care needs which will correlate with the payments received by the provider organisation.

One issue that is yet to be resolved between the commissioners and provider organisations is the tariff price for the drug therapy associated with the care clusters. One possibility is that the tariff price will include the cost for the pharmacological treatment with the lowest acquisition cost. This will lead to increasing scrutiny of prescribing costs and adherence to agreed prescribing guidelines.
2.3 NHS changes – Summary

There are several re-organisational factors that have impacted on mental health services in recent years. The most significant change has resulted from the Health and Social Care Act 2012 and the subsequent emergence of CCGs. Coupled with the implementation of CCGs, mental health trusts are facing increasing financial pressure with an expectation of delivering year on year cost improvement targets (Ham, McKenna and Dunn, 2016, p. 1). During the 2014/15 financial year, the cost of hospital prescribing has shown an increase of 15.4% which is linked to the prescribing of costlier medicines by secondary care. Across the local mental health trust, the main drivers for increased drug expenditure are the prescribing of the newer long-acting antipsychotic injections that are not currently prescribed in primary care due to their high costs. In addition to the expectation of cost containment by the mental health trust, there is an increasing scrutiny on the quality of service delivery by external organisations such as the CCGs and the Care Quality Commission (CQC). At present, very few mental health trusts are achieving demonstrable achievements in high quality services as outlined by the CQC and there is evidence to suggest that strong financial performances have been delivered at the expense of cuts in staff and risks to patient care.

Against a backdrop of unprecedented financial constraints on the new NHS there is an increasing need to ensure the optimal use of allocated resources. With a current expenditure of approximately £1.4 million by the trust per annum; there is a need to ensure that the investment in, and use of medicines is fully realised by healthcare professionals and the recipients of care.
2.4 Pharmaceutical Industry – Overview

This study seeks to understand from the pharmaceutical industry how prescribing practice can be improved in line with current evidence and how the industry perceives the future working relationship with the NHS. This section of the literature review outlines the historical context of the pharmaceutical industry’s relationship with the NHS. The review considers the economic factors impacting on the pharmaceutical industry and the conflicting findings of the costs associated with research and development and the potential implications for the NHS. The impact of innovation in mental health therapeutics is reviewed and considered from the perspective of the pharmaceutical industry and the NHS. The influence that the pharmaceutical industry has on research findings is identified, as well as the influence on service users in the UK. The review then considers the context of and drivers for joint working between the pharmaceutical industry and the NHS. Finally, the review considers the historical context of risk sharing between the pharmaceutical industry and the NHS.

2.4.1 The Industry and the NHS

Since 1957, drug prices in the United Kingdom have been regulated at company level through the Prescription Pricing Regulation Scheme (PPRS). The scheme applies to branded medicines (under patent) which comprise around 70% of NHS spending on medicines (Raftery, 2013, p. 1). Generic medicines make up the bulk of prescriptions as they cost much less than branded equivalents, therefore there is an imperative to optimise their use where possible (Godman et al., 2010, p. 707). NHS patients contribute minimally to prescribing costs, via prescription charges, which accounts for less than five per cent of expenditure on prescription medicines (Abraham, 2009, p. 947).

The PPRS is renegotiated periodically by the government and the Association of the British Pharmaceutical Industry (ABPI), usually every five years. The ABPI aims to secure the provision of safe and effective medicines to the NHS at reasonable prices, promote a strong and profitable pharmaceutical industry in the UK, and encourage the efficient and competitive development and supply of medicines (Raftery, 2013, p. 1). Prior to 2009 there was minimal interaction between NICE and the PPRS, however since 2009 revisions to the scheme have enabled the negotiation of price reductions for drugs that have been initially refused by NICE. The resulting “patient access schemes” have been used by companies to offer price reductions for some drugs unlikely to meet NICE’s cost-effectiveness criteria. Following an agreement on a revised price, NICE can subsequently approve the drug. The added complication is that the UK is a price referencing country and therefore the agreed discounts are kept confidential, so that the pharmaceutical industry can maintain their listed prices.
internationally, thus NICE could be viewed as complicit with the industry in lacking transparency.

These elementary features of the relationship between “consumer demand” and the setting of prices for NHS drugs, together with the consequential need for a system of pharmaceutical price regulation, has been recognised by governments as early as the 1950s.

2.4.2 The economic imperative
Despite the global recession of 2008, some of the larger pharmaceutical companies have managed to maintain healthy profit margins and in 2013, five pharmaceutical companies made a profit margin in excess of 20%; Pfizer, Hoffmann-La Roche, AbbVie, GlaxoSmithKline (GSK) and Eli Lilly (Anderson, 2014, para 6).

These profit margins have largely gone unnoticed by the general public. This is in contrast to the public outcry when the UK energy regulator predicted energy companies' profit margins would grow from 4% to 8% during 2014. One key difference is that the general public do not pay directly for the true cost of their medication and have minimal awareness of the price of medicines (Sukkar, 2015, p. 174).

In the years of low and negative growth in developed economies that have followed the 2008 global financial crisis, some pharmaceutical companies have been forced to restructure to reduce costs; often cutting back in areas that do not have an immediate impact on the perceived short or intermediate term financial advantage.

The sustainability of healthy profit margins by the pharmaceutical industry in the long-term is questionable and the current challenges facing them have been well documented in the literature (Forster, Stegmaier, Spycher, & Seeger, 2014, p. 1; Holmes, 2012, p. 1863; Khanna, 2012, p. 1101; Bennani, 2012, p. 779). Some of the main challenges facing the pharmaceutical industry include: declining research and development budgets, coupled with patent expiries of income generating pharmaceuticals, national austerity measures, regulatory bodies such as NICE tightening their approval processes and drugs failing in the late stage of development in the face of rising research and development costs. In an attempt to overcome some of these challenges, pharmaceutical companies have undergone mergers and acquisition.

One expected outcome of reconfiguring organisational structures is an expansion of research and development pipelines, this could be viewed as advantageous in marketing and clinical
trials. Despite the expectation of expanded research portfolios there is evidence to suggest that growth in research and development is negatively impacted by mergers and acquisitions (Rafols et al., 2014, p. 25).

### 2.4.3 Research and development costs

The costs of research and development associated with the development of a new drug have been widely debated (Light & Lexchin, 2012, p. 4; Collier, 2009, p. 279). Industry estimates for the cost for developing a new molecular entity is approximately £834m (DiMasi, Hansen, & Grabowski, 2003, p. 151). Critics estimate the true cost to be £209m, and have drawn attention to the lack of scientific rigor associated with the proposed industry model on which costings have been based (Light & Warburton, 2011, p. 44). The projected cost of new drug development and the associated research and development is often used by the pharmaceutical industry as a way of rationalising the high cost of newer drugs even if the newer drugs have no significant therapeutic advantage over cheaper alternatives.

In an attempt to reduce expenditure on medicines, generic substitution is a common practice in NHS hospitals (Duerden & Hughes, 2010, p. 335; Ferner, Lenney & Marriott 2010, para, 2) including DWMHT.

One commonly pursued strategy by which the pharmaceutical industry attempts to compensate for patent loss is to extend the life cycle of existing branded medicines through reformulations (Hitchings, Baker, & Khong, 2012, p. 3). For example, in view of Aricept (donepezil), an acetylcholinesterase inhibitor used for the treatment of Alzheimer's-type dementia, losing its patent protection in 2010, the manufacturer developed two reformulations: a sustained release oral formulation and a once-weekly transdermal patch.

The development of the sustained release preparation of Aricept was set against a backdrop in which the drug was the highest income generating therapy in the market for the treatment of Alzheimer’s disease, with over $2bn in annual sales in the United States alone (Schwartz & Woloshin, 2012, p. 1). Four months before its patent protection expired, the US Food and Drug Administration (FDA) approved a new 23mg daily dose. As generic donepezil is available only in 5mg and 10mg tablets, a 23mg dose cannot be administered except by using the branded product. This preparation is associated with marginal improvement in efficacy, of doubtful clinical importance, but with substantially more side-effects (Schwartz & Woloshin, 2012, p. 2).
A further example of a patent extension in psychiatry occurred when Astra Zeneca, the manufacturers of Seroquel, in an attempt to extend the patent which expired in March 2012, created an extended-release preparation, with a formulation patent that was due to expire in May 2017. The patent on the extended release version was ruled unlawful by a UK court judge following challenges from multiple generic manufacturers.

2.4.4 A crisis in innovation

A critical issue to the current NHS is the lack of new drugs entering the market that represents a therapeutic advance (Light & Lexchin, 2012, p. 1; Dix, 2015, p. 210). At present, there is a disconnection between the NHS perception of innovative treatment and the pharmaceutical industry perspective. This is reflected in the below average uptake of new drugs in the UK when compared with other developed countries which was reflected in the findings by the Department for Business, Innovation & Skills (DBIS) report (2015, p. 35). The NHS views innovation in pharmacotherapy as the development of therapeutically superior medicines (Abraham, 2010, p. 613). The pharmaceutical industry however, measure innovation in terms of new molecular entities which in most cases have provided only modest benefits over existing treatments (Light & Lexchin, 2012, p. 3). The conservative approach to the adoption of new drugs in the UK, coupled with industry pressure has led the UK government to publish the Accelerated Access Review which plans to speed up to access to new drugs whilst at the same time acknowledging the financial pressure the NHS is facing (DBIS, 2015, p. 7).

During the period 1974-94, the pharmaceutical industry’s Barral Report on all internationally marketed new medicines concluded that only 12% were therapeutically and pharmacologically innovative (Barral, 1995, p. 21). Similarly, a French study (La Revue Prescrire, 2005, p. 73) reviewed 3100 new medicines or new indications for existing medicines internationally, from 1981 to 2004, and concluded that only 10% offered moderate to significant therapeutic advance. A more recent study of the Canadian national approval process for new medicines between 2004 to 2009 concluded that only 10% of new drugs were innovative which was comparable with the findings a French review during the same time period in which 8% of new medicines were deemed to be innovative (Lexchin, 2012, p. 223).

Since the mid-1990s, further independent reviews have also concluded that about 85-90% of all new medicines provide few or no clinical advantages for patients (Angell, 2005, p. 53; Van Luijn, Gribnau, & Leufkens, 2010, p. 446). There are clearly not enough medicines entering the market place that represent a therapeutic advance over existing treatments, furthermore
there is an increasing pressure to curb prescribing costs and maximise the outcomes for service users.

2.4.5 The influence on research findings

The pharmaceutical industry has been shown to exercise excessive influence in a number of mental health domains including clinical trials, research funding, scientific journals, psychiatric conferences, professional organisations, medical education, government policy, clinical guidelines, regulatory bodies and prescribing by individual prescribers (Read & Cain, 2013, p. 431; De Freitas et al., 2014, p. 220; Herxheimer, 2003, p. 1210; Spurgeon, 2008, p. 742; Muijrers, Grol, Sijbrandij, Janknegt, & Knottnerus, 2005, p. 627).

Drug company sponsored research is the mainstay of available information on which local prescribing committees base their decision to approve a new drug for use in a psychiatric setting (Heres et al., 2006, p. 191). Often the use of medicines in psychiatry is not mandated by NICE, therefore their use at a health economy level is based on local approval. There are few new medicines in development or approved for depression, bipolar disorder, schizophrenia, or anxiety disorders and non-industry funding for clinical trials has, with few exceptions, diminished substantially in the past 6 years (Nierenberg, 2009, p.528).

The value of clinical trials has been undermined, fuelled by suspicion that negative results have been withheld by pharmaceutical companies and that these same companies have emphasised minimal benefits while hiding the risks of their products (Rafols et al., 2014, p. 35; Turner, 2013b, p. 457; Das, 2011, p. 17).

A particular example of this was highlighted by Kirsch et al. (2008, p. 262) who reviewed data on all clinical trials submitted to the FDA for the licensing of the four new-generation antidepressants (fluoxetine, venlafaxine, nefazodone and paroxetine). Most of the studies were of six weeks duration, despite the fact that these agents are promoted and prescribed for long term use (Kirsch et al., 2008, p. 262). Further studies have also called into question the long-term benefits from psychotropic medication (Khan et al., 2001, p. 113; Gitlin et al., 2004, p. 1839; Mann et al., 2005, p. 2071; Moncrieff 2009, p. 15; Das, 2011, p. 16). The randomised controlled studies indicated that placebo was 80% as effective as drugs and that clinically significant differences only occurred in patients who were severely depressed (Kirsch et al., 2008, p. 266). This has led others to question why so many patients are treated with antidepressants in light of the fact that they have minimal benefit over placebo (Jelinek & Neate, 2009, p. 218; Lenzer & Brownlee, 2008, p. 533).
Eyding et al. (2010, p. 9) in their meta-analysis of reboxetine for treatment of major depression, analysed published and unpublished studies and identified that 74% of patient data was unpublished at the time of marketing the drug. When all the data were analysed, the perceived superiority of reboxetine versus placebo shown in published data was reduced to a non-significant difference and the non-significant difference between reboxetine and SSRIs antidepressants resulted in the demonstrable inferiority of reboxetine (Eyding et al., 2010, p. 8).

Arguably the most publicised controversy in psychiatry occurred when the manufacturers of paroxetine (GlaxoSmithKline) were publicly shamed by the BBC’s Panorama when it aired ‘The Secrets of Seroxat’. Not only was the drug company shamed but to a lesser extent it called into question the robustness by which the Medicines and Healthcare Products Regulatory Agency (MHRA) had executed its duty to assess the safety, quality and efficacy of medicines.

In the United Kingdom, paroxetine was widely prescribed “off label” (outside of its licensed indication) for use in children and adolescents and in response to the allegations made by Panorama, the MHRA was forced to issue recommendations that paroxetine should be not be used in children and adolescents for the treatment of depressive illness because of concerns about an increased risk of self-harm and potentially suicidal behaviour (Doshi, 2013, p. 1). In 2012, GSK agreed to pay $3bn in a fraud settlement with the United States government. In a statement connected with the lawsuit, the Department of Justice declared that “the centrepiece of GSK’s efforts to market Paxil (the brand name in the US) for childhood depression was the GSK funded Study 329.” The justice department concluded that the “article distorted the study results and gave the false impression that the study’s findings were primarily positive, when they were, in fact, primarily negative” (Thorpe, 2011, p. 9).

A further example of publication bias is evident with the drug agomelatine which is licensed for the treatment of depression. In ten premarketing trials: five were positive and published, while the five negative trials remained unpublished (Howland, 2011, p. 11). The limitations in trial data for agomelatine have also been noted in a recent review by Taylor, Sparshatt, Varma, & Olofinjana (2014, p. 6).

Such practice by the pharmaceutical industry is inconsistent with the NHS constitution which affirms that decisions regarding pharmacological treatment will be made following comprehensive consideration of the evidence (DoH, 2009, p. 7), furthermore there are clear
public health risks, if trial data is withheld from scrutiny coupled with unjustified hopes of potential benefits for patients.

The lack of transparency in clinical trials has implications for service user choice as a healthcare professional cannot fully facilitate the process of shared decision-making if they are unaware of unpublished studies.

2.4.6 Influence on prescribing
The impact of the pharmaceutical industry on research findings coupled with their role in dissemination of clinical trial data, has caused concerns about their undue influence on prescribing practice (Royal College of Physicians, 2009, p. 4). These concerns led to the publication in 2005 of the House of Commons Health Select Committee report. The committee expressed concerns about the over reliance on medicines which was influenced by the pharmaceutical industry. Thus, as identified by other studies the influence of pharmaceutical industry is experienced through the dissemination of largely industry sponsored research findings, which in turn, impacts on prescribing practice (Jelinek & Neate, 2009, p. 220; Spurling et al., 2010, p. 22). Furthermore, psychiatry has been identified as being more prone to publication bias than other therapy areas, thus compounding the problem of delivering evidenced-based practice in a clinical setting (Fanelli, 2012, p. 895).

A more recent study of the impact of industry sponsored hospitality on prescribing, concluded that receipt of industry-sponsored meals was associated with an increased rate of prescribing the brand-name medication relative to other agents in the same class (DeJong et al., 2016, p. 1121). The findings from the study included the impact of advertising which was linked to increased prescribing of desvenlafaxine over other Selective Serotonin Reuptake Inhibitors (SSRIs) and Serotonin-noradrenaline reuptake inhibitors (SNRIs) despite a lack of evidence to demonstrate superior efficacy.

2.4.7 The influence on service users
At present the pharmaceutical industry is prevented from direct marketing of prescription only medicines to patients in the UK. This is supported by general practitioners and hospital doctors who have expressed concerns that the practice would be unethical and could have negative impacts on patient care (Reast, Palihawadana, & Shabbir, 2015, p. 239). Despite restrictions on direct marketing to patients in the UK, the pharmaceutical industry has collaborated with patient groups. A particular example in mental health occurred when NICE recommended restrictions on use of cholinesterase inhibitors. The Alzheimer’s Society, which is partly funded by industry, mounted an intense lobbying campaign and joined the manufacturers of
donepezil in a legal challenge, despite a very modest evidence-base for patient benefit (Mintzes, 2007, p. 935).

Read & Cain (2013, p. 431) in their meta-analysis of pharmaceutical industry sponsored mental health websites, concluded that the internet has been used to provide consumer marketing internationally, which has also been used to shape public opinion in a manner consistent with increasing pharmaceutical sales. One recommendation of their review was to inform patients of the bias inherent in industry sponsored websites and to signpost them to more balanced websites that incorporate a range of evidence-based information about causation and treatment (Read & Cain, 2013, p. 431). At present employees of DWMHT are encouraged to signpost service users and carers to the Choice and Medication website which has been approved by the College of Mental Health Pharmacy. The site provides unbiased information on medicines used to treat mental health conditions and the associated clinical conditions.

2.4.8 Joint working with the NHS
Joint working has been defined as collaboration between the NHS and the pharmaceutical industry which requires the pooling of skills, experience and/or resources for the joint development and implementation of patient centred projects with a shared commitment to successful delivery (ABPI, 2015, p. 7). The concept differs from that of sponsorship in which the pharmaceutical companies simply provide funds for a specific event or work programme. While the definition of joint working outlines an ideal, the DoH and the ABPI acknowledge that it can be made difficult to initiate due to the variety of stakeholders involved and the lack of clear shared objectives (DoH, 2010a, p. 17). There are numerous barriers to joint working, which can include the disproportionality of the arrangement, which potentially would lead to one party undertaking most of the work and receiving limited benefits. Often the failure of joint working can be linked to attitudinal issues which are entrenched in a culture of mistrust between the NHS and the pharmaceutical industry (Megget, 2015, p. 29). Despite the inherent mistrust between the pharmaceutical industry, there are those that advocate that the NHS has much to gain in terms of the governance framework for research and development (Nelson, 2007, p. 117).

NHS organisations are under increasing pressure to achieve improved quality and productivity under severe economic pressure, thus they are increasingly having to call on external expertise to enable them to meet these challenges and there is a recognition that joint working can be beneficial (Ousey & Bielby, 2011, p. 154). Collaborative working with the
pharmaceutical industry is one way of optimising existing resources to benefit patient care and while there is some evidence that collaboration can lead to improved efficiencies (Angus et al., 2012, p. 429); there is a lack of systematic evidence to determine the impact of joint working with the pharmaceutical industry on patient outcomes. At present, there are some studies underway to determine patient outcomes as a result of joint working and the wider societal and economic impacts such partnerships are yet to be determined.

The DoH and the ABPI publication “Moving beyond sponsorship—joint working between the NHS and pharmaceutical industry”, states that the potential benefits for patients and the system include better care and improved health (DoH, 2010a, p. 7). Benefits for companies, according to industry documents, are “more and/or better use of medicines, including the company’s medicine(s)” (DoH, 2010a, p. 7). The implied notion a of common agenda between the NHS and the pharmaceutical industry has been criticised as the pharmaceutical industry aims to maximise profit, while the health system aims to maximise population health at minimal cost (Moynihan, 2011, p. 1).

Lockwood, Marinoni, & Ando, (2012, p. A290) in their survey identified a total of 165 of joint working projects, involving 37 pharmaceutical companies, of these 129 (78%) involved a single company, and 36 (22%) involved multiple partnerships. Most projects were related to respiratory medicine; by comparison 6% of projects were related to mental health. Joint working projects encompass a broad range of therapeutic areas, with most companies active in areas in which they have pharmacological portfolio. These projects can be classified into several different categories, including; service redesign, service appraisals in light of current guidelines, and techniques to better manage or educate patients.

Critics of joint working have highlighted the case of Janssen Cilag, the manufacturers of the antipsychotic risperidone and paliperidone who have entered into an agreement with the mental health network of the NHS Confederation (representatives of the NHS funded mental health and learning disability service providers in England) (Moynihan, 2012, p. 2). Janssen have developed a social networking site to help GPs in the commissioning of mental health services which has obvious implications for the use of their drugs (McCartney, 2011, p. 343). In addition, Janssen have also sponsored the NHS Confederation conference.

Increasingly, the pharmaceutical industry has been encouraged by the DoH to develop care pathways with CCGs (DoH, 2010a, p. 6). The move has been welcomed by industry officials but less so by GP commissioners who have expressed concerns regarding potential conflicts of interest. One of the concerns raised by GPs is the potential for joint working with the industry...
to identify under-diagnosis or an unmet need. The concerns raised are that such outcomes could be determined by the industry who have a vested interest in increasing their market share in pharmaceutical sales (ABPI, 2012, para 10). An example was shared by a colleague, who recently attended a conference in Canada, where clinicians were informed to consider the potential for adult attention deficit disorder (ADHD) in patients diagnosed with schizophrenia who were partially responsive to antipsychotic treatment (personal communication). There is, at present, no strong evidence to substantiate this claim of a link between schizophrenia and ADHD; however, the association could lead to increased prescribing of ADHD medication.

A further example of joint working between the pharmaceutical industry and the NHS is highlighted by the collaboration between Lundbeck and the Wessex Academic Health Science Network. The project aims to engage with local commissioners to develop treatment pathways for patients with increasing and higher risk drinking levels, thus facilitating the prescribing of their drug. Lundbeck has received approval from NICE in November 2014 for the use of their drug Selincro, which is licensed to treat people with alcohol dependence (NICE, 2014, p. 38). This approval was given, despite independent reviews such as the Midlands Therapeutic Review and Advisory Committee (MTRAC), which concluded that the evidence for nalmefene was weak (MTRAC, 2013, p. 1).

It has been acknowledged that there is a knowledge gap in diagnosing and treating mental health conditions in primary care (Fleury et al., 2009, p. 9). One way of addressing the knowledge gap would be to adopt a model of guided consultation, in which the guidelines would incorporate guidance for diagnosis, treatment options and follow-up monitoring. In the UK this approach has been used in the treatment of chronic obstructive pulmonary disease (COPD) and has led to improved monitoring of patients with increased referrals for smoking cessation, oxygen assessment, and pulmonary rehabilitation (Angus et al., 2012, p. 429). This typifies an example of the potential for joint working with the pharmaceutical industry that could support the development of software, to enable more accurate diagnosis of common mental health conditions in primary care, with guidance for appropriate physical health monitoring. In the USA, there have been trials incorporating the use of decision aids in electronic medical records which has been successfully implemented by healthcare professionals (Milner et al., 2009, p. 1012).

The implications for joint working across the local health economy are that the evidence for a drug needs to be fully evaluated, proven to be effective by local appraisal of the evidence and
that any joint project should be led by the NHS for the benefit of service users and aligned with the unmet needs of the population served by the mental health trust.
In the current economic climate, joint working should be also be able to demonstrate a cost benefit for the health economy.

2.4.9 Risk sharing with the NHS
As part of the exploration of the factors that impact on prescribing, it is important to consider the context for joint working between the NHS, in particular DWMHT.

Risk sharing is an arrangement in which the pharmaceutical industry and the NHS agree a rebate for the full cost of a drug if there is a failure to achieve a defined clinical endpoint (Barros, 2011, p. 462).

One of the earliest examples of a national risk-sharing agreement between the pharmaceutical industry and the NHS occurred with beta interferon. NICE concluded in their review of the drug that it should not be funded by the NHS (Sculpher, Drummond, & O’Brien 2001, p. 944). The decision by NICE not to approve the drug led to a subsequent appeal by the pharmaceutical manufacturers, patient groups, consultant neurologists, and the Royal College of Nursing who challenged NICE’s scientific methodology of calculating treatment cost per quality-adjusted life year (QALY). Nevertheless, having considered these appeals, NICE concluded that beta interferon was not cost-effective enough for use in the NHS (NICE, 2002, p. 10).

The pressure on the government led to the DoH negotiating a “risk-sharing scheme” with the pharmaceutical manufacturers Biogen, Teva-Aventis, and Serono that would provide NHS funding for beta interferon (Crinson, 2004, p. 40). The government presented the risk-sharing scheme as clinical research intended to confirm the cost-effectiveness of the drug via post market monitoring. This approach was criticised by some as lacking scientific rigor (Sudlow & Counsell, 2003, p. 391).

One of the potential benefits of adopting a risk-sharing agreement across the local health economy would be the potential to reinforce the principle of ‘paying for performance’. In addition, such an approach would allow the local health economy to determine the confidence of the manufacturer in their product as well as post-marketing evaluation of the drug. As payment for a drug would be dependent on outcomes, one of the challenges that such an approach would pose is that the NHS provider organisations would be likely to require more robust outcomes than would be agreeable to the pharmaceutical industry. The use of risk-sharing may lead to a more cost-effective use of pharmaceuticals.
Nationally there are no risk sharing schemes in place for mental health treatment; however, there are on-going discussions with the pharmaceutical industry on a local level to adopt risk-sharing initiatives. In particular, for the use of newer antipsychotic agents which lack evidence for superior efficacy to existing agents, but for whom specific patient groups might benefit.
2.5 Pharmaceutical Industry – Summary

The UK expenditure on pharmaceuticals exceeds £15 billion and consumes around 13% of the NHS budget (Andalo, 2015, p. 1). In the current time of static NHS funding, the opportunity costs of pharmaceuticals are all too clear. There is evidence to suggest that there are minimal innovative drugs entering the UK market which confer a therapeutic advantage over existing medicines in mental health, this is coupled with a paucity of robust evidence from clinical trials which are largely industry sponsored in mental health (Turner, 2013, p. 459). The limited evidence as well as multiple approval processes that exist in the UK, account in part for the modest uptake of newer medicines compared with comparator countries (DBIS, 2015, p. 35). Despite the limitations of clinical trial data, there is evidence to suggest that the pharmaceutical industry has an influence on prescribing practice in mental health which has been identified in a recent study which involved antidepressant therapy (DeJong et al., 2016, p. 1121).

Joint working with the industry offers the potential for post-marketing evaluation and greater consideration for risk sharing between the NHS and the pharmaceutical industry. Risk sharing has the potential to facilitate greater emphasis on the value proposition of newer pharmacological agents; while such a collaborative approach has been adopted in other therapy areas, it is in its infancy in mental health.
2.6 Service user engagement within the NHS – Overview

This study seeks to understand the service user perspective on their involvement in the treatment they receive, and the extent to which they feel that they are involved in the decision-making process. This section of the literature review explores the historical context and policy drivers for service user engagement in mental health. The review considers the importance of choice for the service user and the factors that impact on adherence to treatment.

2.6.1 The background and history

The language used to describe service users is perhaps more varied in mental health than in any other sector of health and social care. The term ‘service user’ has been in use for over 25 years to varying degrees (Beresford, 2005, p. 472). Users are most frequently portrayed as patients and defined by their clinical diagnosis (Rogers & Pilgrim, 2014, p. 120). However, users can also be consumers, survivors and providers, all of which imply different notions of the roles and responsibilities of people with mental health problems and the relationship between them and mental health services (Tait & Lester, 2005, p. 168).

Service users are increasingly seen as consumers who can exercise an informed choice about the services they receive, and can shop around, which means that if they are not satisfied, they can take their ‘business’ elsewhere (Tait & Lester 2005, p.168). Despite the consumeristic view of service users, the review by Nilsen, Myrhaug, Johansen, Oliver, & Oxman, (2006, p. 15) concluded that there was minimal evidence to suggest that consumers of healthcare have achieved meaningful strategic engagement in service delivery at a health economy level.

Service user involvement in health care has become increasingly important in many countries. In the UK this is driven by various agendas including democracy as tax paying citizens and the desire to increase accountability throughout the health service and above all consumerist principles which is linked to the patient choice agenda (Lester, Tait, England & Tritter, 2006, p. 415). While accountability to service users is considered the ideal (Weinstein,2010, p. 81) there is minimal evidence to suggest that service users are empowered to hold healthcare providers to account; in fact, the converse was highlighted by the Francis report into failings at Mid Staffordshire. The findings of the report revealed that patients often felt prohibited from voicing concerns, even when they were extremely concerned about safety or the quality of care they are received (Francis, 2013, p. 245).

The origin of service user involvement in statutory health policy and guidance can be traced back to the establishment of the Community Health Councils in 1973 (Noorani, 2013, p. 51). Service user involvement continued through the proliferation of NHS consumer based

From 1997, the then Labour government, envisioned patient and public involvement as a central tenet of their modernisation agenda. The NHS Plan (DoH, 2000, p. 69) was committed to creating a patient-centred NHS, with service user needs central to service design and delivery. Furthermore, Section 11 of the Health and Social Care Act (2001) required all NHS organisations to engage users in planning and evaluating services, as well as in decision-making on issues of treatment (Tait & Lester, 2005, p.169).

The *Expert Patients Programme* (2001) was hailed by England’s Chief Medical Officer as “ushering in a new era of opportunity for the NHS” (Donaldson, 2003, p. 1279). The programme was based on self-management for people living with a chronic (long-term) conditions and was designed to promote self-care and to alleviate the burden of care by these individuals on the NHS. Despite the rhetoric, Wilson, (2001, p. 141) in her critique of the Expert Programme, noted that although the initiatives focuses on the rights and responsibilities of those with chronic illness, there is no corresponding strategy to challenge professionals’ assumptions and actions toward those with chronic illness, thereby limiting its implementation.

In 2003, a ‘Patient Tsar’ was appointed to advise on improving the service user experience (Tait & Lester, 2005, p. 169), and to publish measures to increase patient choice across the NHS (DoH, 2003, p.11). Despite the appointment of a tsar, little is known about the impact this has had for service users.

The guidance on the *Care Programme Approach* (DoH, 2008, p. 3) and the New Horizons Strategy (DoH, 2010b, p. 17), further supported service user involvement in all levels of decision making. The more recent strategy, written by the Conservative-Liberal Democrat coalition government, *No Health Without Mental Health* (DoH, 2011, p. 34), appears to focus on emphasizing ‘choice’, together with a focus on active service user and carer involvement. It is possible that this reflects an assumption that market-driven choice is synonymous with involvement; however how this concept will evolve, especially with the current financial constraints on the NHS, is yet to be fully determined.
2.6.2 Consumerism and service user participation

Consumerism in the NHS has its origins in the Conservative government of the 1980’s (Gabe & Monaghan, 2013, p. 203), but is currently set against a backdrop of a consumeristic society in which service users have increasing expectations about the standard of care they receive (O’Neill, 2002, p. 9). In the age of the internet and 24-hour news coverage, service users are more informed and able to make informed decisions. In an early attempt to determine service user preference and increasing the focus on individuals exercising choice, managers were employed across the NHS infrastructure to champion the preferences of ‘consumers’ of health care provision and to integrate this into healthcare decision making. One limitation in the use of managers was that their focus was based on the hospitality aspect of care (for example, cleanliness and food) rather than their perception of the clinical effectiveness of care (Calnan & Gabe, 2001, p. 122).

The 1990s saw the introduction of further policy developments aimed at enhancing consumer choice, an example of this was the introduction of the Patients Charter in 1992. This sets out the rights and service standards that patients could expect (Stocking, 1991, p. 1148). The charter was designed to improve quality and make the NHS more responsive to recipients of care. Despite the introduction of the charter, the extent to which service users could exercise choice and influence service provision is minimal. Critics note that the notion of consumeristic principles is at odds with the potential for individuals to be detained under the Mental Health Act (Sayce, 2016, p. 147).

In 1997, the Labour party gained power and the focus was shifted from accountability of the NHS to its consumers, to one of engagement with them in decision making (Gabe & Monaghan, 2013, p. 204). In the NHS Plan, published in 2000, it became a statutory duty for Strategic Health Authorities (responsible for the oversight of trusts), PCTs and NHS trusts in England to involve users and the public in the planning and operation of services (DoH 2000, p. 68). The extent to which this was achieved is unknown as there are no studies evaluating the impact of the NHS plan.

2.6.3 Involvement in mental health services

During the 1980s, with the shift from institution to community based care, service user groups grew in the UK. The growth in the service user groups was, in part due to the deconstruction of mental health institutions and a growing confidence on the part of service users to advocate on their own behalf.
Following the UK community care reforms of the early 1990s, there was an additional drive that contributed to official acceptance and encouragement of the role of user organisations.

The UK NHS and Community Care Act 1990 transformed the NHS into an internal market with purchasers and providers of healthcare, while reaffirming the principle of healthcare being free at the point of use. Provider organisations were incentivised by being given the opportunity of becoming self-governing trusts, with the promise of increased financial freedom and autonomy. Purchasers GPs were permitted to become fundholders, who could purchase non-emergency care on behalf of their patients. The rationale for the development of this market healthcare was that it would focus attention on the needs of patients and not the providers of healthcare. GPs were however, purchasing services on behalf of patients, thus acting as proxy consumers, with patients having no rights of their own (Gabe & Monaghan, 2013, p. 204). Given that patients lack the necessary knowledge or inclination to shop around in the medical marketplace, critics have argued that there is little evidence that this reform markedly increased consumer choice (Calnan & Gabe, 2001, p. 121).

The NHS and Community Care Act 1990 also required service providers to consult with users of their services and their ‘carers’. With associated funding for local groups becoming more available this gave a new impetus to the activities of service users. There was however, minimal evidence to suggest that meaningful engagement with service users was achieved and critics have highlighted that there was a degree of confusion about the meaning and purpose of user engagement (Bowl, 1996, p. 178).

A succession of policy directives has introduced service user involvement into every aspect of the planning and provision of mental health services (DoH, 1999, p. 4), the education and training of professionals (Postgraduate Medical Education & Training Board 2008, p. 4) and people’s own treatment plans through the Care Programme Approach, introduced in 1991.

Service user involvement has been far from an unqualified success but has established the legitimacy of service users’ views (Read, 2009, p. 4; Wallcraft, Rose, Read, & Sweeney 2003, p. 62; Campbell 2005, p. 77). There has been an associated centralised funding for local service user groups which has given a new impetus to the activities of these networks. It has been argued that funding has changed the focus of these groups. Instead of deciding on their own priorities and campaigns, service users were being asked to respond to more limited agendas set by the DoH (Read, 2009, p. 4).
In 2014, a survey of community based service users (n=303) took place across DWMHT, 53% responded that they were ‘definitely’ given information about newly prescribed medication in a way they could understand (Care Quality Commission, 2014, p. 4). The survey findings indicated that 55% of people said that the mental health services had involved their family, or someone close to them, as much as they would like. The authors of the report have identified family engagement as an area for improvement, which is consistent with the findings of a Scottish study in which family support was considered as one of the most important factors supporting recovery (Reid, Hinchliffe, & Waterton, 2014, p. 3). Furthermore, the importance of a supportive network including family and friends has been well documented (Braunholtz, Davidson, Myant, Mori, & O’Connor, 2006, p. 6; Fisher, 2003, p. 3; Smith-Merry, Sturdy, & Freeman, 2010, p. 98).

There is a belief by some, that in the light of national policy drivers, stakeholder projects and national campaigns, that it is inevitable that there will be some significant changes in relationships between healthcare professionals and service users (Read 2009, p. 7). This view, however, is contested by others and there is evidence to suggest that the intentions of policy makers can sometimes fail to move beyond rhetoric into reality, particularly for mental health service users (Tait & Lester, 2005, p. 169). User representatives on a national group convened by the DoH in 1998 to develop the National Service Framework (NSF) for Mental Health resigned when it became clear that the government was going to insist that compulsory treatment orders were non-negotiable (Donnelly, 1998, p. 4). The final document (DoH, 1999, p. 10) stated that “specific arrangements should be in place to ensure service user and carer involvement in their care plan”, but there are few other references to user empowerment throughout the seven standards of the NSF or directly in the Five Years On review (DoH, 2004, p. 53).
2.6.4 The rationale for user involvement

Involving users of health services in healthcare planning may serve a number of related functions for healthcare providers. First, public involvement may improve the quality of services, by clarifying what the patients want. This has tended to be the motive emphasised by UK policy directives. The perspective of user involvement as a goal in itself is reinforced by the World Health Organization (WHO) who state that;

“The people have the right and duty to participate individually and collectively in the planning and implementation of their health care” (WHO, 1978, p. 3).

Secondly, service user involvement in the planning of free access health services paid for by taxation is a sound democratic principle (Milewa, Valentine, & Calnan, 1999, p. 445). This approach emphasises equity and empowerment with participation as a key concept (Lupton, Peckham & Taylor, 1998, p. 45). The principles underpinning the approach is that public participation is beneficial to maintaining a healthy democracy and in allowing people to become full citizens, and second, that the diversity of interests in society should be a fully represented model of care offered by the NHS (Lupton, Peckham & Taylor, 1998, p. 10). A third reason for public involvement is that it may be viewed as legitimising unfavourable change or rationing of services, allowing politicians to deflect blame on the basis of a wider consensus (Redwood, 2000, p. 13). The tension between public demand and political appeasement was highlighted following the NICE rejection of drugs for renal cancer in 2009. Following public and healthcare professional lobbying, the government required NICE to apply less stringent criteria for “end of life” drugs, reversing the decision of NICE on one of these drugs (Raftery, 2013, p. 2).

Although successive UK governments have encouraged healthcare providers to include service users as part of service delivery, evidence of changes resulting from service users is minimal (Crawford et al., 2003, p. 413). Uncertainty of outcome is exacerbated by uncertainty about the process, as policy guidance has offered minimal clarification on the meaning of ‘involvement’. Terms such as ‘partnership’ and ‘consultation’ are used interchangeably (Barnes & Wistow, 1994, p. 348). The consultation is a model in which the professional retains control of both the process and outcomes of service users, while partnership implies similar status, shared power and some equality of influence over both the agenda and outcomes of shared decision-making (Chadderton, 1995, p. 227).
2.6.5 Optimising the use of medicines

Defining optimal outcomes in individuals with enduring illness is complex and incorporates three inter-related, but somewhat independent, dimensions: clinical response, functional ability and quality of life (see Figure 2.2).

Clinical improvement is symptom focused and response driven; which can transition into remission over time. Symptomatic remission favours improved functional outcome and quality of life but guarantees neither. Quality of life can be enhanced by both clinical and functional improvement but is not simply the product of these; it is, at least in part, determined subjectively by the recipient of care. Recovery, as currently conceptualised, is a process rather than dichotomous, incorporating each of these dimensions on an individualised basis (Remington, Foussias, & Agid, 2010, p. 15).

![Figure 2.2 Outcomes in Mental Health](image-url)
Service user engagement has wide ranging implications for care. The use of medication is key issue for service users and healthcare professionals alike. In the author’s experience, it is often a source of conflict between them.

Enabling service users with enduring mental illness to achieve the best outcomes from medicines (medicines optimisation) is set against a backdrop of evidence that suggests that engagement with healthcare providers is poor and that nonadherence with medication in this group remains a challenge (BMA, 2014, p. 25; Farooq & Naeem, 2014, p. 1070; Reilly et al., 2012, p. 7; Velligan et al., 2009, p. 6).

Optimal prescribing may be affected by poor compliance with best-practice guidelines (Van Fenema, Van Der Wee, Bauer, Witte, & Zitman, 2012, p. 76), inappropriate prescribing – under or over use of medicines (Lang et al., 2010, p. 379) and prescription errors (Duerden & Payne, 2013, p. 5). In addition, suboptimal prescribing may occur from misdiagnosis or failing to detect that a particular symptom is caused by another medicine (Faria et al., 2014, p. 5).

One of the ways in which service users can gain optimal benefit from medication is if healthcare professionals engage with them to understand their concerns and involve them in the decision making process (RPS, 2013, p. 5). This may include: discontinuation of medicines, the use of medicines to treat associated comorbid disease states or the provision of non-medical interventions such as psychological therapies, as well as, holistic advice based on the individual’s lifestyle (Cole, 2014, p. 342; Pampallona, Bollini, & Tibaldi, 2004, p. 718). Furthermore, service users have expressed dissatisfaction with the care provided by psychiatrists and the need for them to take a more holistic view beyond the focus on symptomatology (Smith-Merry, Sturdy, & Freeman, 2010, p.130; Borg & Kristiansen, 2004, p. 502).

A meta-analysis of differences in prescribing for physical disorders found that individuals with enduring mental illness received lower than expected prescriptions for essential drugs used to treat cardiovascular diseases, including ACE inhibitors, beta-blockers, and statins (Mitchell, Lord, & Malone, 2012, p. 437). The findings by Mitchell et al, is particularly concerning because of the higher incidences of comorbid diseases in this patient group; which include: cardiovascular disease and diabetes mellitus (De Hert et al., 2009, p. 413). This is further compounded by the side effect profile of some psychotropic medication which can induce weight gain or worsen other metabolic cardiovascular risk factors.
2.6.6 Choice and medication

Service user involvement in their treatment and care is one of the most important elements in the recovery process. Enabling individuals to have a choice in the treatment they receive in a holistic, reliable way with flexible support systems is critical to promoting recovery (Smith-Merry et al., 2010, p. 120; Picton & Wright, 2013, p. 1).

The issue of how decisions are made regarding pharmacological treatment in mental health and the arbiter of the final decision, service user or practitioner is a fundamental one. In the United Kingdom all medical treatment, including the administration of medicines, normally requires the informed consent of the service user requiring treatment. To be informed there are a set of criteria that must be fulfilled, which includes an understanding of the rational for the treatment, what it involves, the intended impact, likely adverse effects, the implications if treatment is withheld and the alternatives. Usually, service users are entitled to a second opinion prior to giving consent. There are circumstances under which consent is not required. These include the immediacy of harm to the service user, or another individual, or if the service user is incapacitated or detained under the Mental Health Act 2007.

A lack of capacity can be defined by an inability to understand, retain and evaluate information to decide or the inability to communicate their decision-making process. Doctors can be required to give treatment in the best interests of the person in accordance with the legal framework of the Mental Health Act 2007. If the service user has made an advance decision regarding their treatment preference, this decision applies to the treatments the individual does not wish to receive and is only taken into consideration if the individual is not admitted for care under the Mental Health Act (Nicholson, Cutter, & Hotopf, 2008, p. 323).

All developed countries have legislation governing the compulsory detention and treatment of individuals with mental health illness. However, the power to treat individuals while they are living in the community is somewhat controversial and less universal (Read, 2009, p. 31).

There has been a decline in the psychiatric inpatient population in developed countries since the 1950s (Torrey, Entsminger, Geller, Stanley, & Jaffe, 2008, p. 2). Compulsory supervision in the community setting has been developed internationally for the treatment of mentally ill people following widespread deinstitutionalisation (Churchill, 2007, p. 17). Community treatment orders (CTOs) for psychiatric patients became available in England and Wales in 2008 (Burns et al., 2013, p. 1627). CTOs require service users to accept clinical monitoring and allow rapid recall for assessment. CTOs do not authorise forcible treatment outside
hospital setting but do allow for this within the hospital setting. The focus on deinstitutionalisation has led to treating individuals in the community setting and many service users, particularly those with a psychotic illness now receiving routine care outside of a hospital setting and in some cases in a GP setting by mental healthcare specialists (Lind, 2015, para 2).

Many individuals are subject to repeated compulsory admissions “the revolving door syndrome” (Appelbaum, 2001, p. 348) and the absolute rate of involuntary admissions has increased (Priebe et al., 2005, p. 125). Legislation for compulsory outpatient psychiatric treatment has been widely introduced in the USA, Australasia, some Canadian provinces, the UK, and several other European countries (Churchill, 2007, p. 9).

Critics of CTOs view it as a system that is open to abuse and conclude that this is independent of the treatment setting (Lawton-Smith, Dawson, & Burns, 2008, p. 97). The opponents have expressed concern that CTOs can be used too extensively, for too protracted a period of time, or for the wrong reasons, and it can be implemented in a manner that contravenes human rights. However a study of service user views which was conducted in New Zealand found that service users were broadly positive about CTOs and expressed a preference for treatment under a CTO to treatment in an inpatient setting (Gibbs, Dawson, Ansley, & Mullen, 2005, p. 366).

The NHS Modernisation agenda focused on the issue of patient choice, however there is a degree of scepticism about the rhetoric of choice. This is understandable in view of the potential for compulsory treatment or the lack of service user engagement and poor prescribing practice which has created a culture of mistrust (Read, 2009, p. 30).

While the number of service users who are detained under the Mental Health Act is small in relation to the overall number of mental health service users (Mental Health Network Confederation, 2014. p. 3), the stigma of admission to a hospital under compulsion has a disproportionate impact on how service users perceive mental health services, and how healthcare professionals perceive service users, and how the public perceives mental illness. The fact that mental health professionals can detain service users under compulsory detention orders is at variance with the conceptual idea of service user choice. For this reason, the extension of compulsory powers through the CTOs that were introduced to the Mental Health Act 2007 was bitterly resisted by service user groups (Batty, 2007, para 4).
The importance of choice is internationally recognised, and national strategies have been adapted to include the language of patient empowerment, participation and choice (Sainsbury 2006, p. 7). The UK government has acknowledged that better healthcare outcomes are achieved when both the service user and healthcare professional share the decision-making process with regards to treatment and care, however, this has not been entrenched in the culture of the NHS. Furthermore, there is evidence to suggest that service users fear the consequences of open and transparent engagement with healthcare professionals (Francis, 2013, p. 245).

Service users from Black and Ethnic Minority backgrounds appear to be confused about the meaning of choice and are unclear about the options that were available to them, which is coupled with entrenched cultural attitudes held by healthcare professionals about service user choice (Sainsbury, 2006, p. 3). There is also an acknowledgement that this is compounded by a lack of investment in culturally sensitive and appropriate service provision for minority groups (Weinstein, 2010, p. 60; Read, 2009, p. 36).

2.6.6.1 The importance of Service User choice

There are several reasons for engaging with service users to empower them to have the right to determine their own treatment. Primarily, service user autonomy should be respected for its own sake and this is in keeping with human rights convention (Hope, 2002, p. 101). Furthermore, service user involvement underpins the concepts of citizenship and democracy. Another reason for engagement is linked to the idea of optimising the use of medicines for the individual and improving outcomes from the investment in pharmacological treatment. The implementation of service use choice as part of the healthcare professional-service user consultation has been demonstrated to produce improved outcomes (Heisler, Cole, Weir, Kerr, & Hayward, 2007, p. 1442) although systematic evidence is still lacking (Duncan, Best, & Hagen, 2010, p. 15).

Service user engagement supports the expectations of the individual and explores how pharmacological treatment fits within the context of their aspirations and desired outcomes. For example, a service user who is treated for bipolar disorder might not find value in the complete remission of manic symptoms. The presentation of symptoms albeit attenuated, might be important for creativity and so while an individual might have decided that medication contributes to their well-being, they might equally decide to be partially adherent to treatment.
It is estimated that half of the medicines which are prescribed for long term conditions are not taken as directed, representing a failure to translate potentially effective treatment into optimal outcomes for service users including the wider societal benefits (NICE, 2009, p. 3; WHO, 2003, p. 7). It is also acknowledged that there is a paucity of research on non-adherence in psychiatry (Farooq & Naeem, 2014, p.1070).

It is estimated that 50% of individuals with major depression for whom antidepressants are prescribed, do not take the medication beyond three months following initiation (Vergouwen, Bakker, Katon, Verheij, & Koerselman 2003, p. 1416) and rates of adherence among patients with bipolar affective disorder are as low as 20% (Lingam & Scott, 2002, p. 166). These findings suggest that service users are exercising some choice regarding whether or not to take prescribed medicines and there is also evidence that, when provided with information service, users usually make rational choices that are often more conservative than would be recommended by their clinician (Stacey et al., 2014, p. 30).

The need for individuals to comprehend the treatment options and probable outcomes is a key step in adherence to treatment. As is often the case in psychiatry, a pharmacological agent does not usually confer a clear therapeutic advantage over existing alternatives, therefore the service user is not faced with the potential option of choosing a therapeutically superior medicine but rather an option based individual preferences which can include convenience, associated stigma, and an acceptable side effect profile. An example of this can be seen in the treatment of schizophrenia. A pivotal meta-analysis of antipsychotics concluded that there was a lack of significant differences in effectiveness between most of the first and second-generation antipsychotic agents (Lieberman & Stroup, 2011, p. 771). One of the implications of the findings from this study is that a decision cannot be made for a single antipsychotic as a therapeutically superior option, but rather, the likelihood that the service user will experience the health outcomes that is acceptable to them which includes tolerability.

The study by Bolster & Manias (2010, p. 163) identified several steps as part of a collaborative process which they describe as patient centred. The steps include defining the nature of the risk of treatment versus non-treatment, clarifying the goal of communication; describing risk perspectives; managing the difference, prioritising risk perspectives; and deciding. Defining the nature of risk involves exploring medication use from both the service user and clinician perspective. The service user may have concerns about the risk to their lifestyle or well-being while the clinician may be concerned about relapse prevention (Perkins, 2001, p. 9). These concerns need to be explored and openly discussed. Clarifying the goal of communication
involves making it explicit that the discussion is about coming to a shared decision and not one of advice-giving regarding the need to take medication. The overall goal of the consultation is to incorporate both scientific evidence and personal feelings about the risks of taking long-term medication. Describing risk perspectives involves both patient and clinician sharing their perspectives on the treatment options. Managing the difference and prioritising risk perspectives involves the clinician and patient clarifying the values of the risks associated with treatment. Making a decision should be based on a shared understanding in which the patient is better equipped to make a quality decision because both the clinical evidence and their own perspective have been incorporated into the information sharing (Collins & Street, 2009, p 1511).

2.7 Adherence

Adherence has been defined as the “active, voluntary, and collaborative involvement of the service user in a mutually acceptable course of behaviour to produce a therapeutic result” (NICE, 2009, p. 3; Weiden & Rao, 2005, p. 206). This definition implies that the service user has a choice and that both service users and providers mutually establish treatment goals. This contrasts with compliance which is the extent to which the service users’ behaviour matches the prescribers’ recommendations (Felzmann, 2012, p. 407).

The largest clinical trial comparing atypical antipsychotics found that 74% (n=1493) of patients with schizophrenia were non-adherent with their antipsychotic medication over 18 months (Lieberman & Stroup, 2011, p. 770). The most common reasons for discontinuation were patient choice, lack of effect or intolerability linked to side-effects.

Medication adherence reflects a spectrum ranging from individuals who take no medication, despite verbally acceding with the healthcare professional to take prescribed medication, to those who take each dose as directed. Between these two extremes are patients who show varying degrees of adherence, taking some medication but not consistently as prescribed. This practice is termed partial adherence.

2.7.1 Measures of adherence

The methods for determining adherence can be stratified into direct and indirect methods of measurement. Directly observed therapy can include measurement of concentrations of a drug or its metabolite in blood or urine. This approach can be useful with certain medicines. For instance, the serum concentration of drugs such as phenytoin or valproic acid will probably give a useful indication of the extent of adherence to treatment; however, such approaches
are potentially costly and burdensome to the health care provider, and susceptible to distortion by the individual e.g. compliance with treatment prior to a clinic appointment.

Indirect methods of measurement of adherence include asking the patient about adherence to treatment, assessment of clinical response as a surrogate marker of adherence, counting unit doses of medication, use of pharmacy databases and patient diaries. Indirect methods can be subject to subjective analysis and misinterpretation (Sajatovic & Ross, 2009, p. 23). Unit dose assessments are also prone to error as patients can discard medicines intentionally or switch between medicine containers to give the appearance of adherence. In the study by Byerly et al. (2007) psychiatrists were found to underestimate non-adherence when compared with objective electronic measures (electronic detection 57%, 34 of 61 participants vs 7%, 4 out of 60 for prescriber estimates). The recent review of self-reported adherence by Stirratt et al. (2015, p. 477) concluded that this method of ascertaining adherence is imperfect, and that adherence is overestimated when compared with other assessment approaches. Despite this acknowledgement the authors contend that self-reporting is the most common method for assessing adherence behaviour in clinical care, and suggest that the validity of self-report adherence measures may be enhanced by using validated scales. In routine clinical practice, adherence is reported in variety of ways which makes objective determination of adherence difficult to achieve. Stirratt et al. (2015, p. 477) asserts that the use of rating scales in clinical practice can be used to determine if further investigation is warranted when an individual reports issues related to adherence.

2.7.2 Determinants of poor adherence

*Intentional non-adherence*

Intentional non-adherence is linked with the individual’s rationale for and against taking medication and in the review by Mitchell & Selmes, (2007, p. 338) was identified as a common reason not to start a course of medication, but was minimally associated with missing individual doses. This is consistent with the later review of adherence by (Chapman & Horne, 2013, p. 449). Predictors of intentional non-adherence include: patient perception of whether medication works and the general impact on their quality of life (Jimmy & Jose, 2011, p. 157; Higashi et al., 2013, p. 210). In a recent systematic review by Mohammed, Moles, & Chen, (2016, p. 12) the authors concluded that medicated related burden experienced by the individual was likely to impact on their decision to adhere to treatment. Hence individuals were less likely to adhere to medication regimes that impacted negatively on the activities of daily living. This has important implications for clinical practice as it provides an opportunity for healthcare professionals to identify how medication might impact on service users and provide
individualised care through shared decision-making. As a minimum, such an approach is likely to lead to increased service user satisfaction and this finding was identified in the Cochrane review of shared decision making in mental health by Duncan et al. (2010, p. 15). Despite the acknowledgement by the review that shared decision-making supports the individual’s needs, the authors acknowledged that there was minimal evidence linking the approach to improved health outcomes.

Intentional non-adherence is predicted by the balance of an individual's reasons for and against taking medication, as suggested by utility theory. This reinforces the need for the clinician to engage with the service user in an on-going dialogue to understand the service user’s perspective on the prescribed treatment. The need for engagement and information was also identified by Coulter, Roberts & Dixon (2013, p. 14) who, in their report on long-term conditions recommended that patients receive copies of their care plans as part of the consultation process.

A further factor that has been identified in support of adherence to treatment is continuity of care. Kauppi, Hätönen, Adams, & Välimäki, (2015, p. 782) in their study of factors impacting on adherence from healthcare professionals and service users, identified the importance of continuity of care and recommended that healthcare providers maintain the same health care professionals for treating individuals. This finding is not surprising and is possibly linked to the provision of consistent information, leading to potentially improved medicine-taking behaviour.

Understanding and Information
The review by Mitchell & Selmes, (2007, p. 339) identified that patients’ understanding of their condition and the need for treatment is positively related to adherence, and in turn adherence, satisfaction and understanding are all related to the amount and type of information given. The importance of timely and relevant information has been identified in a number of studies in which services users have felt disempowered (Hill & Laughrane, 2006, p. 86; Olofinjana, 2005, p. 371; Smith-Merry et al., 2010, p. 123). While service users have indicated a desire to engage in shared decision-making there is minimal evidence to suggest that this is common practice; furthermore, this approach to consultation may have implications for legal and professional responsibility and accountability (NICE, 2009, p. 20). At present service users and healthcare professionals enter decision-making with very different levels of knowledge and informational asymmetry. It is possible that shared decision-making will require structural changes to health services and the current delivery model. Perhaps, more fundamentally there
will be a need for a cultural change in the nature of engagement between healthcare professionals and service users.

A lack of insight has also been linked with non-adherence and in the case of individuals with schizophrenia or bipolar disorder, the level of insight into their illness, can have implications for the perceived need for medication. In a survey involving clinical experts, illness severity and poor insight was deemed to be the most important factor contributing to non-adherence (Velligan et al., 2009, p. 16). This finding is contrasted in the review by Mitchell, (2007, p. 18) in which the individual's fluctuating clinical need was identified as the key factor in adherence to medication regimens; thus, healthcare professional perspectives may be at odds with the recipients of care as to the most important factors driving medication taking behaviour and the subsequent determination of the impact of medicines on patient outcomes.

**Side effects**

The side-effects of medication are a cause of distress for service users and have been linked to non-adherence with treatment (de Boer, Castelein, Wiersma, Schoevers, & Knegtering, 2015, p. 675; Mitchell & Selmes, 2007, p. 338; Weiden, Mackell, & McDonnell, 2004, p. 55). However, in a review of factors impacting on adherence in schizophrenia, the authors concluded that, experts gave more prominence to side effects as a contributor to adherence problems than has been reported in the literature (Higashi et al., 2013, p. 215).

A study by Hudson et al. (2004, p. 213) identified non-adherence associated with side effects in approximately 35% (n=153 total) of patients with schizophrenia; similarly, Loffler et al., (2003, p. 108) in a study of non-compliance in patients with schizophrenia found that 50% (n=307 total) of patients reported side effects as a reason for non-compliance. In the study by Baldessarini, Perry, & Pike, (2008, p. 99) of non-adherence in patients with bipolar disorder, adverse effects were associated with discontinuation in 13.1% of individuals (n=432 total). Fortney et al, (2011, p. 831) identified discontinuation with antidepressant treatment in 42.9% (n=35 total). Thus, non-adherence figures can vary widely; which is understandable in view of the different populations, variety of diagnoses, variable follow-up periods, and the different definitions and measurement methods used in studies.
2.7.3 Specific adverse effects

Discrepancies have been identified between psychiatrists and service users in their estimation of the degree to which psychotropic medicines exert their adverse effects (Rettenbacher, Burns, Kemmler & Fleischhacker, 2004, p. 2871). This has important implications for concordance as individuals can often discontinue treatment due to intolerable adverse effects. Furthermore, doctors can be reluctant to disclose information on adverse effects due to concerns that such disclosures may demotivate patients from engaging with treatment (Seale, Chaplin, Lelliott, & Quirk, 2006, p. 2870). Despite the doctors' concerns, the review by Desplenter, Simoens, & Laekeman, (2006, p. 340) which explored the impact of informing psychiatric patients about their medication, including potential adverse effects, concluded that there was a positive association between educational interventions and adherence to treatment.

Weight gain has been linked with non-adherence with treatment and subjective distress in individuals (Fakhouri, 1999, p. S285; Oehl, Hummer, & Fleischhacker, 2000, p. 84; Weiden, Mackell, & McDonnell, 2004, p. 56; Seale et al., 2006, p. 2866; Read, 2009, p. 138; Sajatovic & Ross, 2009, p. 30). In the study by Fakhouri (1999, p. S285), 39% of the 202 respondents reported weight gain as an adverse event. For those individuals that reported weight gain 74% of respondents described it as 'extremely distressing,' this percentage was higher than any other reported side effect. Furthermore, obese individuals have been found to be more than twice as likely as those with a normal body mass index to omit their medication (Weiden, Mackell, & McDonnell, 2004, p. 56). This is of particular concern as some of the second-generation antipsychotic medicines are noted for their propensity to induce weight gain.

Sexual dysfunction has been identified as a side effect of medication that is particularly distressing for service users and is linked with poor adherence (Sajatovic & Ross, 2009, p. 30). Ofson, Uttaro, Carson & Tafess, (2005, p. 331) studied sexual dysfunction in 139 out-patients with a diagnosis of schizophrenia who were treated with antipsychotic medication as the only treatments associated with sexual side-effects. Sexual dysfunction occurred in 45.3% of the patients and was associated with significantly lower ratings on the quality of life rating scale. In a review of the literature evaluating sexual dysfunction in patients with a diagnosis of schizophrenia the authors identified that between 16% for quetiapine (n=1446) to 60% for thioridazine (n=49) of the patients included in the studies reported sexual dysfunction, possibly related to the use of antipsychotics (Serretti & Chiesa, 2011, p. 135). Psychotropic-related sexual dysfunction in serotonergic antidepressants when compared with placebo was reported in between 25.8% for mirtazapine (n=49) to 80.3% for sertraline (n=970) of treated individuals.
(Serretti & Chiesa, 2009, p. 261). In a more recent review Montejo, Montejo & Navarro-Cremades, (2015, p. 419) acknowledge underreporting of sexual side effects and recommend that discussions should be held about the potential impact of psychotropic medicines on sexual function with all patients.

Rosenberg, Bleiberg, Koscis, & Gross (2003, p. 293) examined the effects of sexual side-effects on adherence in 51 severely mentally ill outpatients and found that 62.5% of men and 38.5% of women felt that their psychotropic medicines were causing sexual side effects; furthermore 41.7% of men and 15.4% of women admitted discontinuing their medication as a result. An important finding from the study is that 50% of the participants never, or infrequently, spoke about sexual functioning with their healthcare provider. Whilst this study has important findings it is limited by its small sample size. A recent meta-analysis by Reichenpfader et al, (2014, p. 28) identified that under-communication of sexual dysfunction is common and that there is a lack of specific research in this subject.

### 2.7.4 Adherence in mental and physical health

Despite a search of the literature there are no recent reviews or meta-analyses comparing rates of medication adherence between mental and physical health. This is possibly because of the variable methods which are used to measure treatment adherence and the inherent difficulties in making comparisons between them.

In an earlier systematic review by Cramer and Rosenheck, (1998, p. 199) the mean rate of medication adherence in patients with physical disorders was 76% (range 40 to 90%; n=7 to n=259), whereas in patients with psychoses the mean rate was 58% (range 24 to 90%; n=20 to n=591). One of the limitations of the review was that varying methods were used to determine compliance and it is possible that these differing approaches could account for the differences in adherence rates between physical and mental health. Rates of partial adherence have also been reported in asthma (30–70%), diabetes (36-93%, at 6-24 months) and hypertension (41-51%, at 6 months) reflecting the wide spread nature of non-adherence (Bender, Milgrom, & Rand, 1997, p. 177; Cramer, 2004, p. 1218; Mazzaglia et al., 2009, p. 1603).
2.7.5 Impact of non-adherence

In a study by Ascher-Svanum, Zhu, Faries, Furiak, & Montgomery (2009, p. 4) adherent patients were significantly less likely to have a psychiatric hospitalisation (17.1%; n=1758) compared with partially adherent (30.6%; n=36) and non-adherent patients (29.6%; n=216). In a study of 4325 Medicare patients with a diagnosis of schizophrenia, compliance with treatment as measured by no gaps in medication taking was associated with a hospitalisation rate of 6.4%, compared with 21.6% in those for whom there was greater than 30 days gap in medication taking (Weiden, Kozma, Grogg, & Locklear, 2004, p. 890).

In a one year observational study of over 60,000 patients with schizophrenia, the relationship between adherence and hospitalisation demonstrated that patients with sufficient medication 90% of the time, had on average an admission rate of 8.3%, compared with rates of greater than 20% for patients with sufficient medication for 50% of the time (Llorca, 2008, p. 238).

There are many factors that influence adherence, however a thorough discussion of these is beyond the scope of this review; these factors can be seen as falling into four main categories: patient, treatment, environment and physician-related.

2.7.6 Illness beliefs and knowledge of medication

Concepts of health and disease state are important factors in determining adherence in mental health. A service users understanding and agreement with a diagnosis are key steps in determining the likelihood of adherence. In turn, adherence, satisfaction and understanding are related to the quality of information imparted to the individual service user, and where appropriate the carer of the individual. Sajatovic, Davies & Hrouda (2004, p. 268) suggest that successful strategies aimed at improving adherence, incorporate knowledge of the medicines as well as awareness and illness self-management.

One major factor that influences adherence is the patient’s ability to read and understand verbal instructions associated with their medication regime (Jimmy & Jose, 2011, p. 156). Patients with low literacy may have difficulty understanding instructions; which could ultimately results in decreased adherence and poor medication management (Praska, Kripalani, Seright, & Jacobson, 2005, p. 1441; Kochevar & Yano, 2006, p. S27). This is particularly relevant for this study as the literacy rates in Dudley and Walsall are below the national average (Sedghi, 2011, para. 2). Another factor that can contribute to non-adherence is the complexity of the medication regimen; this can include timing of administration, and amount of medicines.
Such complexities should be taken into account by the prescriber as part of the consultation process. A failure to address issues related to the complexity of a medication regimen is likely to lead to a decreased therapeutic outcome for the service user concerned.

There is often an assumption by healthcare professionals that service users understand a reasonable amount about their illness, yet a study conducted over 40 years ago by Joyce et al. (1969, p. 189) demonstrated that patients were unable to recall half of the information given to them by their doctor. A more recent study, in which there was a high report of patient dissatisfaction with communication, identified that less than half of the important discharge information, including the name of the prescribed medication, dose, frequency, duration of administration, signs of improvement or worsening clinical status, was recalled at an exit interview (Isaacman, Purvis, Gyuro, Anderson, & Smith 1992, p. 1204). The findings of the study identified that the addition of written instructions to standardised verbal instructions did not improve recall of discharge information. The findings from the study would suggest the need for a communication strategy, which is multi-agency in nature and focused on addressing the needs of the intended recipients. Such an approach is consistent with the concept of ‘Channel Management’ in which bespoke messages are targeted for specific stakeholder groups (Mehta, Dubinsky, & Anderson, 2002, p. 430).

Bezreh, Laws, Taubin, Rifkin, & Wilson, (2012, p. 13) in their study of physician-patient communication, undertook a content analysis of commentaries to an article that was published in the New York Times about low rates of medication adherence. The study identified three key themes: mistrust and criticism of health care institutions, patient empowerment secondary to independent research, and patients not wanting to discuss adherence with their doctor. The study also revealed the impact on individuals paying full prescription costs as a reason for non-adherence to treatment. The author recommended that doctors encourage their patients to be open and honest about issues related to trust.

A study by Olfson et al. (2000, p. 221) identifying predictors of noncompliance in patients with schizophrenia concluded that substance misuse was the strongest predictor of medication noncompliance. Social isolation was also associated with poor adherence. The study demonstrated that a significantly higher proportion of patients who were non-adherent had relatives who had refused to be involved with their care during hospitalisation (Olfson et al., 2000, p. 220).
2.7.7 Healthcare professional impact

The importance of good communication between service user and health professional is increasingly acknowledged in relation to adherence (Duncan, Best, & Hagen, 2010, p. 15). In essence, this means forging a joint therapeutic agreement with full end user engagement. This is a two-way process in which willingness to discuss mental health issues with a healthcare professional is predicted largely by the perceived helpfulness of, and trust in that individual (Laugharne, Priebe, McCabe, Garland, & Clifford, 2012, p. 499).

A lack of engagement in treatment decisions can lead to adherence which is based on an instruction from a healthcare professional. In the study by Gray, Rofail, Allen, & Newey (2005, p. 36) service users stated that they took medication only because they were told to. Service users typically leave the consultation with a poor understanding of the rationale for therapy (Weiden, Mackell, et al., 2004, p. 56). In one study of 30 patients, 50% claimed that they were offered no information on the medicines they were prescribed and 90% reported that they were offered no choice in the medicines that they were prescribed (Olofinjana & Taylor, 2005, p. 370). Another study identified that two-thirds of psychiatric in-patients did not understand why they were taking medication, and the vast majority had not given informed consent to their treatment, furthermore only one-tenth knew about the adverse effects of their prescribed medication (Brown, Billcliff & McCabe, 2001, p. 133). A more recent study, conducted in an elderly inpatient ward, comparing knowledge of psychotropic and non-psychotropic medicines identified that only 42% of respondents (n=86 total) demonstrated an understanding of the purpose of taking both psychotropic and non-psychotropic medication, 15% understood only their psychotropic medication, 16% understood only their non-psychotropic medication and 27% understood neither medication (Perecherla & Macdonald, 2011, p. 222). The study has important implications for adherence which is linked to service user understanding; as older adults are prescribed more medicines and therefore have a greater pill burden than their younger counterparts. This finding was consistent in both detained and informal in-patients. Similarly, many patients misunderstand prescription instructions. Demyttenaere et al. (2001, p. 32) in a study of n=272 patients with depression found that 53% believed they did not need their antidepressants and discontinued treatment within 6 months of initiation. The main reason for discontinuation was “feeling better.” Overall, 24% of the patients did not inform their clinician about discontinuation of treatment.

The public campaign Defeat Depression revealed that many people were wary of taking antidepressants because they believed that individuals with depression should ‘pull themselves together’ and more than three-quarters believed that antidepressants were
addictive (Paykel, Hart & Priest, 1998, p. 520). In addition, service users may have limited expectations about the benefits of pharmacological treatment (Lang, 2005, p. 584).

2.7.8 Non-adherence
Traditionally, non-adherence with medication has been viewed by healthcare professionals as misguided (Kane, Kishimoto, & Correll, 2013, p. 216). This view fails to take into consideration the complexity associated with medicine taking behaviour (Deegan & Drake 2006, p. 1636) and maybe underpinned by professional prejudicial attitudes (Jorm, Reavley, & Ross, 2012, p. 1035; Cook & Wang, 2010, p. 9). Askey, Gamble, & Gray (2007, p. 363) also suggest that the impact of coercive treatments and stigma may be important variables to examine in relation to medication use in service users with enduring mental illness.

Service users and prescribers bring pre-existing beliefs about the illness and treatment (Jorm, 2000, p. 399; Horne & Weinman, 1999, p. 562) which influence the individual’s evaluation of the prescribed medication, their adherence and even beneficial or adverse outcomes (Felzmann, 2012, p. 408). A new approach has been developed which acknowledges the service users right to discuss and negotiate with prescribers and ultimately, to make their own decisions. A NICE clinical guideline, ‘Medicines Adherence: Involving Patients in Decisions about Prescribed Medicines and Supporting Adherence’ describes a more equitable relationship between clinicians and service users which emphasises the importance of shared decision-making (NICE, 2014, p. 18). The guidance draws on expertise from both the medical and psychiatric evidence-base and lived experience of service users to contribute to the process of decision making.

Interventions which are aimed at improving compliance are often designed to increase service users’ behavioural conformity to the clinicians’ view of optimal treatment (Deegan & Drake, 2006, p. 1636). Interventions which have largely focused on service user compliance with recommended treatments have been criticised as being paternalistic (Horne et al, 2005, p. 117). While a paternalistic approach to medication taking may be justified under certain circumstances, for example, during an acute psychiatric emergency, there are a number of factors which should be considered, including the significant limitation of a person’s competency for decision making and the potential harm, including irreversible harm (Corrigan et al., 2012, p. 171). However the study by Hamann et al, (2006, p. 271) demonstrated the potential for achieving shared decision-making even during the acute phase of schizophrenia. The findings from the study indicated that patients who were engaged in shared decision-making reported improved knowledge about their disease and treatment.
Despite the considerable costs of non-adherence, a recent review concluded that there was a lack of evidence evaluating the cost effectiveness of adherence interventions (Oberjé et al., 2013, p. 1168). In the review by Garcia-Pérez & Serrano-Aguilar, (2011, p. 121) they identified four studies which assessed the cost-effectiveness of interventions to enhance medication adherence in psychiatric patients. The outcomes on adherence reported by the four studies were inconsistent.

2.8 Shared decision-making

Shared decision-making has been described as a transactional and interpersonal model of communication, in which health care providers and patients work collaboratively to select treatment and care. These include patients' health experiences and preferences (Curtis et al., 2010, p. 15; Adams & Drake, 2006, p. 90). In shared decision-making, “the practitioner becomes a consultant to the service user, helping to provide information, to discuss options, to clarify values and preferences, and to support the user’s autonomy” (Deegan & Drake, 2006, p 87; Horne et al., 2005, p. 6). This is in keeping with government policy, in particular the DoH paper ‘Equity and Excellence: Liberating the NHS’, which reflects the importance of shared decision-making by stipulating that it should become the ‘norm’ in clinical practice.

Shared decision-making differs conceptually from compliance because of the inherent assumption that there are two professionals (the service user and the practitioner) who are engaged to determine the optimal treatment (Corrigan et al., 2012, p.170). Many recipients of mental health care do not see themselves as equal partners or feel empowered to make decisions about their mental health treatment (Curtis et al., 2010, p. 14). Although there is evidence to suggest that service users typically want more involvement in their mental health treatment, this is often not often experienced by them (Tait & Lester, 2005, p. 170; Weinstein, 2010, p. 23; Read, 2009, p. 4).

There is a considerable gap between service users' preferences for information and their actual involvement in shared decision-making (Ford, Schofield, & Hope, 2003, p. 77; Fotaki et al., 2008, p. 182; Read, 2009, p. 59; Weinstein, 2010, p. 86). Furthermore, there is evidence to suggest that a substantial proportion of service users are inadequately informed to be able to exercise treatment choice effectively (Entwistle, Sheldon, & Watt, 1998, p. 220) and that for individuals with enduring mental illness the desire for autonomy is similar to that of other patient groups (Hill & Laugharne, 2006, p. 82).
Trevena & Barratt (2003, p. 267) identified that the suitability of a decision for shared decision-making is dependent upon the clinical context, patient preferences, practitioner responsibilities and the underpinning evidence. Montori, Gafni, & Charles, (2006, p. 25) further refined the shared decision-making concept in relation to long-term conditions to include “on-going partnership between the multidisciplinary team and the patient”.

The importance of shared decision-making has been well documented within the medical literature (Duncan, Best, & Hagen, 2010, p. 3). In non-psychiatric chronic diseases, shared decision-making has been proven successful in improving the therapeutic alliance between provider and service user, treatment adherence, self-care and overall treatment outcomes (Joosten et al., 2008, p.225; Coulter, 2006, p. 85). The study by Heisler et al. (2007, p. 1439) demonstrated that an informed and inclusive communication style of the physician, which included a participatory role for the patient in decision making, resulted in significant improvement in patient self-care and glycaemic control (glycated haemoglobin [HbA1c] improved by as much as 0.7%). In another study (Greenfield et al., 1988 p. 455) the improvement in HbA1c was found to be even greater (1.5%) as a result of patient engagement.

The emerging literature in psychiatry indicates that shared decision-making has led to improved clinical outcomes and improved concordance (Clever et al., 2006, p. 400; Bunn, O’Connor, Tansey, Jones, & Stinson, 1997, p. 244). Shared decision-making has also been shown to have an economical benefit by reducing hospitalisation for patients with schizophrenia (Hamann et al., 2007, p. 995). However, shared decision-making in psychiatry, can be complicated due to a lack of insight into the illness by the service user or predominant negative symptomatology; both of which can impact on the perceived need or benefit from pharmacological therapy.

Another factor which can influence shared decision-making is the individual psychiatrist and the importance of service user trust (Mather, Baker, & Laugharne, 2012, p. 166). However, this is contrasted with the findings of Hall et al., (2001, p. 628) who identified that the desire for shared decision-making is independent of the level of trust and based more on a desire for autonomy. Furthermore, Bezreh, Laws, Taubin, Rifkin, & Wilson (2012, p. 17) in their review concluded that mistrust of doctors was more widespread than was perceived by them. This led to them recommending that doctors encourage individuals to express their true feelings about prescribed medication.
Mitchell & Selmes (2007, p. 347), in their review of treatment adherence, concluded that a positive relationship with the prescriber contributed to improved adherence. The importance of continuity of care in which a positive relationship has been developed over a period of time has also been identified as an important factor in patient care (Laugharne, Priebe, McCabe, Garland, & Clifford, 2012, p. 499; NICE, 2014, p. 6). Furthermore, the quality of the relationship between clinician and service user has been demonstrated to empower and influence attitudes to prescribed medicines (Coulter, 2002, p. 669; Laugharne, Priebe, McCabe, Garland, & Clifford, 2012, p. 82; Bolster & Manias, 2010, p. 163). It has been suggested that research is needed to identify the psychiatrist factors that lead to a wide variation in engaging with patients (McCabe, Khanom, Bailey, Priebe, 2013, p. 328). Duncan, Best, & Hagen, (2010, p. 15) concluded in their review, that there was insufficient evidence to suggest that shared decision-making leads to improved health outcomes for patients with mental health conditions. They did however acknowledge that shared decision-making may increase patient satisfaction, without an increase in consultation times, or use of health services resources.

Despite the numerous studies in shared decision-making, there is limited evidence to suggest how service users wish to be involved in decisions related to their care (Woltmann & Whitley, 2010, p. 30).

### 2.8.1 The service user perspective

Choice, self-determination and empowerment are fundamental values for service users with enduring mental health diagnosis (Deegan & Drake 2006, p 1636). The shared decision model upholds these values and aims to bridge the empirical evidenced-base which is based on specific population averages with the unique concerns, values and lifestyle of the individual (Deegan & Drake 2006, p 1636). In many cases, it is unlikely that the individual will be able to assess the evidence for a specific drug; therefore, the contextualisation of the evidence for the individual service user remains the responsibility of the healthcare professional. Often the question of how the medication will impact on the individual becomes an open experiment for the service user and the practitioner (Deegan & Drake 2006, p. 1636). In psychiatry, the response rates to psychotropic medication are variable; this further complicates the ability to determine the potential impact on individuals. An example of this is highlighted in the study by Kirsch et al, (2008, p. 265) who, in their meta-analysis of antidepressant efficacy concluded that the overall effect of the new-generation antidepressants did not achieve the threshold for clinical significance.
There is evidence to suggest that service users are often dissatisfied with the communication aspect of a healthcare consultation (Henry, Fuhrel-Forbis, Rogers, & Eggly, 2012, p. 309; Mahone et al., 2011, p. 7; Curtis et al., 2010, p.16; Ford, Schofield, & Hope, 2003, p. 77) and further evidence suggests that doctors overestimate the amount of information that they have given to patients (Makoul, Arntson, & Schofield, 1995, p. 1252). This has important implications for successful outcomes with pharmacotherapy. Some studies have demonstrated that the quality of clinical communication is related to positive health outcomes (Kirkman, et al., 2015, p. 608; Ha & Longnecker, 2010, p. 42; Hamann et al., 2006, p. 272).

Woltmann & Whitley (2010, p. 33) found that, unless service users felt they had control over the decisions that were made for their care, they did not consider the process shared. They appeared to regard their own autonomy as central to any decision-making process, and if they were unsure about a particular decision, they specifically asked someone else they trusted for help with that decision. When service users believed a clinician was making decisions for them in a paternalistic fashion, they verbally acceded to the clinician and did not voice their own preferences. It is suggested this may be one of the reasons why noncompliance and disengagement with services occurs. Service users tended to view the decision-making process as one which occurred over time and in the context of the relationship they have with their case clinician which is based on trust and compassion (Cleary, Horsfall, & Escott, 2015, p. 563; Rethink, 2006, p. 10). This is in keeping with the findings of the review by Joosten et al. (2008, p. 224) who concluded that successful shared decision-making is an ongoing process rather than an isolated event.

The dissatisfaction with the quality and extent of information on prescribed medication has been expressed on a local level across DWMHT by service user groups. This has contributed to the decision to include trust pharmacists in an outreach programme with local service user groups to address concerns related to medicines they are prescribed. The programme is designed to provide information and to signpost them to the range of services available to support their needs.

**2.9 Expert Service Users in policy development**

In the past decade, there has been a significant increase in the contribution of service users, carers and members of the general public in the development of clinical guidelines (Harding, Pettinari, Brown, Hayward & Taylor, 2011, p. 352).
Recently, NICE has introduced its Patient and Public Involvement Programme (PPIP) to the Public Involvement Programme (PIP). The PIP is designed to incorporate a range of stakeholders including; patients, carers, service users, advocates, members of particular communities, parents or guardians, or other audiences. One of the ways in which NICE engages with stakeholders is through the technology appraisal process. This involves the submissions from various stakeholders via the NICE website and through the national press for service user groups and voluntary organisations. Another way in which NICE targets service users is via its Citizens Council. The council is comprised of 30 people who are intended to reflect the wider English and Welsh population. The Citizens Council are required to give their views on values, such as fairness and need.

Individuals are nominated by groups representing national patient or voluntary organisations and are co-opted to work on relevant work streams. The WHO has reviewed NICE’s experience of involving patients and the public in clinical practice guidelines and concluded that it is uncertain whether the right stakeholders were involved and whether their input was as efficient as it could have been (Légaré et al., 2011, p. 12).

The Guideline International Network Patient and Public Involvement working group (GIN-public) is an international corporative initiative that aims to support the development, implementation and evaluation of service user and public involvement in guidelines (Boivin et al. 2010, p. 1). In a review of patient and public involvement in clinical guidelines Boivin et al (2010, p. 4) concluded that there were several socio-political barriers limiting patient and public involvement in clinical practice guidelines development internationally. These barriers included professional resistance to service user engagement, the social isolation experienced by service users in a professional environment, the service user lack of knowledge of evidence-based medicine and the marginalisation of the evidence from patients’ and caregivers’ experiences.

In the UK, service users have contributed to the development of National Service Frameworks (NSFs) for mental health (as well as NSFs for older people, coronary heart disease patients and diabetes patients) which outlined national standards for service provision. The appropriate role of the public and service users is disputed because of the current emphasis on evidence-based medicine and technology. There is dissent among professionals in relation to the competence of lay people to understand the complexities of present day practice (Fudge, Wolfe, & McKevitt, 2008, p. 5). Nevertheless, service users are increasingly
represented on clinical governance committees of trusts (Crawford et al., 2003, p. 411). Part of the incentive for such involvement may be a more holistic approach to evaluating treatment.

Recently, there have been initiatives to involve the public and service users in practice guideline development and implementation; this could improve the consideration of patient preferences and values in the formulation of in practice guideline (Harding, Pettinari, Brown, Hayward & Taylor, 2011, p. 352). Although prescribing guidelines are designed for specific patient populations, they are in essence a 'one size fits all' recommendation and they cannot take into account all the individual differences in patient characteristics and preferences (Tambuyzer, Pieters, & Van Audenhove, 2014, p. 139). The development of guidelines which incorporate a broader context regarding prescribing practice would be useful to address the lack of holistic care that has been expressed by service users. One way which this could be approached is the use of multidisciplinary stakeholders including service users to develop guidelines which would then be targeted at a wider range of issues relevant to them.

In the study by Van der Weijden et al., (2013, p. 858) which included interviews with healthcare professionals and patient representatives, the key recommendations for facilitating shared decision-making included the adaptation of clinical guidelines to include a separate section for shared decision-making, also the use of encouraging language as well as an adapted form of the guidelines for use by patients.

This study seeks to understand from the service user perspective, what are the factors that matter to them with respect to the medicines they are prescribed. The study also seeks to explore the extent to which service users feel that they should be involved in guideline development and where appropriate, how best to achieve this. It is hoped that the findings of the service user interviews will be used to inform the production of future local prescribing guidance taking, into consideration key recommendations from this stakeholder group.
2.9.1 Service user in medicines priority setting

There is emerging literature on public and service user involvement in health care decision-making. One aspect of decision-making in the health sector, priority setting and resource allocation, also has received much attention in recent years (Mitton, Smith, Peacock, Evoy, & Abelson, 2009, p. 220). In their review Mitton et al. (2009, p. 227) concluded that on-going public engagement as part of the priority setting agenda was preferred to an ad hoc approach. However, one of the limitations of the studies reviewed was the lack of evidence of any formal evaluation of engagement efforts. This is consistent with the findings of Williamson (2014, p. 7) who also concluded that there was a lack evidence to determine how public views have been integrated when allocating resources.
2.10 Service User engagement in the NHS - Summary

Service user engagement has established itself as part of a significant feature of mental health service delivery. The importance of service user engagement has been reinforced by successive policy directives including the National Service Framework for Mental Health, the 2000 NHS plan, the 2001 Health and Social Care Act and more recently the 2012 Health and Social Care Act. While these policy drivers have focused on service user engagement, there is minimal information guiding providers of care on the extent to which users should be involved and how best to achieve this.

The review has identified that there is a clear desire by service users for a greater choice in the pharmacological treatments that they receive, and that non-adherence can be due to a multiplicity of factors including: adverse effects, the perceived or actual lack of benefit, regime complexity and impact on lifestyle (Crowe, Wilson, & Inder, 2011, p. 900; Mitchell & Selmes, 2007, p. 339; NICE, 2009, p. 7). The review also highlighted that shared decision-making increases service user satisfaction but identified that there is no specific, systematic evidence to suggest an improvement in clinical outcome measures for individuals with enduring mental health conditions (Duncan et al., 2010, p. 15).

The findings of this literature review are consistent with the Royal Pharmaceutical Society (RPS) principles of putting the individual at the centre of care. Figure 2.3 identifies in diagrammatical form the underlying principles that support patient-centred pharmaceutical care.

![Figure 2.3 Principles of Medicines Optimisation (Royal Pharmaceutical Society, 2013)]
2.11 Prescribing Guidelines in Mental Health – Overview

One of the objectives of the study is to understand the perceived factors that influence the implementation of prescribing guidelines.

This section of the literature review provides an overview of the context of guidelines in clinical practice and the rationale for their use. The review considers the factors that impacts on successful implementation of guidelines and makes reference to implementation studies that include, but which are not limited to, psychiatry. The review then considers the strategies for successful implementation of guidelines and the associated evidence underpinning them.

2.11.1 Evidence Based Medicine

Evidence based medicine (EBM) is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients (Sackett, Rosenberg, Gray, Haynes, & Richardson, 1996, p. 71).

In many western countries, psychiatric organisations have developed and implemented evidence-based guidelines for the pharmacological treatment of psychiatric disorders. Prescribing guidelines are based on international or national recommendations and it is expected that their implementation will lead to improved effectiveness of pharmacological treatments whilst reducing treatment variation (Bauer, 2002, p. 138). There are, however, many limitations to the assumption that adherence to guidelines will lead to improved patient care, including the robustness of the evidence incorporated into the guidance and the potential for the individual to have comorbid disease states.

The WHO refers to the ideal state of prescribing and use of medicines as ‘rational use of drugs’ which is defined as:

“The patient receiving medication appropriate to their clinical need, in doses that meet their own individual requirements for an adequate period of time, and at the lowest cost to them and their community. (WHO conference of experts, Nairobi 1985, p. 299)”.

The process of achieving evidence-based prescribing comprises of three steps: synthesising evidence, translating evidence into recommendations and implementing recommendations (Michie, 2008, p. 65). This is set against a backdrop of evidence, which suggests that this is not routinely achieved (Bauer, 2002, p. 138; Weinmann, Koesters, & Becker, 2007, p. 432). It is estimated that approximately half the patients visiting general medical practitioners receive treatment which differs from recommended best practice (Grol, 2001, p. II-50) which can lead
to suboptimal treatment based on outdated evidence. In psychiatry this figure is unknown due to a lack of studies (Forsner et al., 2010a, p. 1). The few existing studies that have examined barriers and facilitators to implementation have focused on the perspective of psychiatrists with very little attention given to other healthcare practitioners (Forsner et al., 2010, p. 2). There is also recognition of the importance of involving patients in the implementation (Tait & Lester, 2005, p. 170), as evidenced through the production of public versions of guidelines in the form of patient information leaflets, audio recordings and online databases (Michie & Lester, 2005, p. 367; Woolf, Grol, Hutchinson, Eccles, & Grimshaw, 1999, p. 527).

2.11.2 Guidelines in clinical practice

There are numerous prescribing guidelines which have been developed for use across DWMHT. These guidelines have been developed in conjunction with medical and nursing colleagues and involved consultation with expert by experience service users. The guidelines take into consideration the best available evidence and details the prescribing standards the clinicians are expected to adhere to across DWMHT and primary care. The standards as outlined in the guidelines incorporate the need to integrate appropriate physical health monitoring with key pharmacological treatments. At present, each guideline has an implementation plan associated with its development to ensure that clinicians are aware of its existence across the local health economy.

As part of a national mandate to publish a list of approved drugs in use for each provider organisation by April 1st, 2013, DWMHT published a formulary of approved drugs which included information on NICE technology appraisals. There are clear implications for this approach as it is possible for service users to compare the availability of pharmacological treatments across different provider organisations. Thus, difficult questions could be asked of organisations that, for some reason, have not approved a pharmacological agent when it is available at a neighbouring organisation.

2.11.2.1 The rationale for prescribing guidance

Clinical guidelines are “systematically developed statements to assist practitioners and patient decisions about appropriate healthcare for specific clinical circumstances,” they are often used for promoting evidence-based practice and have been demonstrated to be particularly beneficial with less experienced prescribers (Field & Lohr, 1990, p. 58; Grimshaw et al., 2004, p. 47; Pulcini, Williams, Molinari, Davey, & Nathwani, 2011, p. 85). Prescribing guidelines may lead to improved quality of care by decreasing inappropriate variation in clinical practice (Weinmann et al., 2007, p. 421) and they are often used to promote cost-effective prescribing (Grant, 2006, p. 28). The latter point is not without contention, as some psychiatrists have
highlighted suspicions that financial motives often lay behind clinical guidelines, and that cost control and standardisation of care might threaten the doctor or doctor-patient relationship (Forsner et al., 2010a, p. 4). This view is in contrast to that of GPs who are mindful of prescribing costs and the management of drug budgets (Horne, Mailey, Frost, & Lea, 2001, p. 192).

Despite the merits of an evidence-based approach, many prescribing guidelines fail to impact on prescribing practice due to poor implementation and the inappropriate variation that exists in cost and quality of care (Rashidian et al., 2008, p. 149).

High quality, contextual clinical guidelines are considered to be an expression of evidence-based medicine, combining a systematic approach to the review of established evidence with a multi-professional approach which includes service users, along with robust systems for consultation and review (Kendall, Pilling, Glover & Taylor 2011, p. 314). While Kendall et al. have expressed the ideal embodiment of clinical guidelines, in practice it is acknowledged that there is a significant challenge in the implementation of evidenced-based guidance which is both complex and widespread (Weinmann, 2007, p. 423; Bauer, 2002, p. 139).

A further complication of translating evidence-based practice in a psychiatric setting into clinical practice is that the evidence-base for pharmacological interventions are often limited by small trial size and relatively short durations. The selection criteria that are used in clinical trials would often exclude the type of patients that are treated in a clinical setting, thus clinicians tend to be cautious when generalising research findings to daily practice (Nierenberg, 2009, p. 529). One further complication in psychiatry, which has previously been highlighted in this thesis, is publication bias. A recent review by Fanelli, (2011, p. 895) concluded that publication bias occurred to a greater extent in psychiatry than in any other field of medicine. A further review by Turner, (2013b, p. 465) advised clinicians to insist that their drug regulatory agencies improve transparency. The recommendation by Turner was echoed in an editorial in the British Medical Journal (Lehman & Loder, 2012, p. 2).

2.12 Implementation of guidance
Factors influencing the effective implementation of guidelines in psychiatry remains poorly understood; a more detailed understanding of barriers and facilitators is therefore important for effective implementation (Bero, et al., 1998, p. 467). In addition to this, it is recognised that many guidelines do not have a clear implementation plan (Graham et al., 2001, p. 159) and
that the evidence for effective implementation strategies are modest (Grimshaw et al., 2004, p. 68).

A review of quantitative studies focusing on adherence to clinical guidelines in mental health, revealed that compliance was found in just 7 of 26 studies (27%) where there were no interventions for improvement (Bauer, 2002, p. 149). This was contrasted with six of nine controlled trials (67%) which demonstrated positive results indicating compliance with guidelines when interventions were made to improve adherence (Bauer, 2002, p. 148). These findings are consistent with that of Rashidian et al., (2008, p. 149) who concluded from their study that guidelines fail to impact on practice and inappropriate variation exists in the cost and quality of care.

2.13 Factors influencing the implementation of guidelines
The reported barriers to guideline implementation included lack of awareness, lack of familiarity, concerns regarding the quality of the guidelines, lack of organisational support, lack of outcome expectancy, impracticality of the guidance, the reluctance to change practice and external barriers which including patient characteristics (Cabana et al., 1999, p. 1458; Francke, Smit, de Veer, & Mistiaen, 2008, p. 7).

Theories of change suggest that individuals and organisations differ in their receptivity to change and perceive different benefits and barriers to change. Requiring others to change demands an understanding of the problems they face (Glasgow, Klesges, Dzewaltowski, Bull, & Estabrooks, 2004, p. 4).

Guideline implementation often fails because minimal consideration is given to address the barriers required to change practice in a healthcare setting (Cabana et al., 1999, p. 1463). Two types of barriers to the implementation of guidelines have been identified in the literature: those internal to the guideline itself, and the external barriers relating to the clinical environment and particular local circumstances, including a knowledge of the guideline existence (Ploeg, Davies, Edwards, Gifford, & Miller, 2007, p. 216).

However, even if clinicians are aware of clinical guidelines, there may still be a lack of familiarity with the specific content or details of the guideline which, in turn, may lead to non-adherence (Cabana et al., 2002, p. 36). To facilitate use, clinical guidelines must also be readable and readily accessible, however, this has to be balanced against an over simplistic approach which can impede clinician uptake (Addington, Kyle, Desai, & Wang, 2010, p. 1328;
It is important, therefore, for guideline authors to take into account the complexity of the guidelines. This is particularly important when developing prescribing guidelines for use across a health economy which is directed at several target groups of prescribers, as is the case with DWMHT.

With the advent of non-medical prescribing, there are an increasing number of prescribers from a range of professional backgrounds. For medical prescribers, there are a variety of specialisms and experience which presents a challenge to produce recommendations which are understandable and usable for all stakeholder groups.

There is broad consensus that the production of guidelines should be multidisciplinary in nature (Smith, Walker & Gilhooly, 2004, p. 559; Francke, Smit, de Veer, & Mistiaen, 2008, p. 7; Martens, Winkens, Weijden, De, & Severens, 2006, p. 2; Cabana, Rushton, & Rush, 2002, p. 41). In addition, involvement of representatives from the target group may imply that the guideline is first tested in practice before large-scale implementation takes place (Tansella & Thornicroft, 2009, p. 284). While such a collaborative approach may seem a logical to ensure end-user engagement, the study by Davis, Thomson, Oxman & Haynes (1995, p. 704) asserts that findings are not always unanimous regarding whether guidelines that are developed by end users are more often used. They conclude that future research will be required to provide more insight into this issue.

2.13.1 Level of agreement with guideline recommendation
Implementation studies have demonstrated that some clinicians do not consider clinical guidance as relevant, unless it originated from trials in a similar healthcare setting, including patients with co-morbid disease states (Cabana et al., 1999, p. 1463).

A lack of contextualisation of guidelines to reflect the clinical setting of the clinician and patient profile, has led some to conclude that the evidence is irrelevant or unconvincing (Rashidian et al., 2008, p. 153). Kochevar & Yano (2006, p. S28), in their review, identified that guidelines were also more likely to be used when they were made relevant to the local health economy.
2.13.2 Credibility of prescribing guidance

A key factor in the acceptance of prescribing guidance by clinicians is whether the information obtained is from reputable bodies with a national remit (Kyle, Wang & Desai, 2010, p. 1330). National bodies such as NICE and Scottish Intercollegiate Guidelines Network (SIGN) can be perceived as credible.

The high representation of secondary care consultants in guideline development across local health economies have been perceived to undermined guideline credibility. Consultants are viewed as seeing ‘filtered’ patients and are associated with a lack of appreciation of the patient–doctor communication in general practice (Rashidian et al., 2008, p. 149).

2.13.3 Lack of outcome expectancy

In a study conducted by Cabana et al. (2002, p. 37), it was suggested that clinicians may not adhere to depression guidelines due to low outcome expectancy and the belief that the performance of a behaviour will lead to the desired outcomes. In this case, it is the lack of confidence that implementing the guideline recommendations will lead to improved health outcomes (Cabana et al., 2002, p. 38).

In the review by Carlsen, Glenton & Pope (2007, p. 974) they concluded that the guideline format was a key determinant of GP attitudes towards guideline adoption. The guideline was expected to be clearly written, i.e. in terms of clarity and conciseness. The research provided insight into the value of quick reference guidelines and the algorithmic layout of guidelines. Connelly et al. (1990, p. 356) found that clinicians accessed guidelines if they felt they would achieve a more fruitful outcome from them in a time limit. Grol & Grimshaw (2003, p. 1228) found that doctors were more likely to adhere to guidelines when they were written using clear descriptive medical terminology over ambiguous language. The study recommended the use of ‘professional writers’ to review guideline drafts.

2.13.4 Influences to prescribe

A study by Lewis & Tully (2011, p. 10), which involved interviews with hospital prescribers, concluded that patients exerted an undue influence on prescribing practice which led to ‘non-scientific prescribing’. A similar influence was reported in the exploratory study of GP perceptions by Henriksen & Hansen (2004, p. 53). However, these findings contrast with the findings of the study by Rashidian et al. (2008, p. 154) in which the perceived patient pressure was not considered a significant factor in deviation from established guidance. Davis & Taylor-Vaisey (1997, p. 412) in their study identified patients with co-morbid disease states as contributory factor to non-compliance of clinicians with clinical guidelines.
2.14 Strategies for implementation of guidelines

Bauer (2002, p. 150) & Weinmann *et al.* (2007, p. 431), in their meta-reviews of adherence to mental health guidelines, concluded that ‘multifaceted and resource intensive’, specific interventions were the most effective in successful guideline implementation.

Grimshaw *et al.* (2004, p. 67), in their systematic review of the effectiveness and costs associated with guideline development, dissemination and implementation strategies, concluded that there was insufficient evidence to determine the most cost effective approach. Furthermore, as mental health services were not included in the review, the authors concluded that findings of the review would not be generalisable to a mental health setting (Grimshaw *et al*., 2004, p. 60). The results suggest that educational outreach, (a term which is used to describe a personal visit by a trained person, to health professionals in their own settings) may result in modest improvements in the delivery of care, but this needs to be offset against both the resources required to achieve this change and practical considerations (O’Brien *et al*., 2007, p. 2). The use of peer-led championing of guidelines is reflected in the findings of the review by Flodgren *et al.* (2011, p. 14) and has been demonstrated to have a moderate impact on prescribing practice.

Grol & Grimshaw (2003, p. 1228) in their review identified that educational input which encouraged the clinician to change their behaviour, rather than just suggesting knowledge based strategies were not found to be effective long term. The review by Grol & Grimshaw (2003, p. 1228) also identified that there was no one specific implementation strategy which works in all situations. Their recommendation was that implementation models should be devised to meet the clinical needs of the specific service providers, so that they are applicable to the audience that will be using them.

Barriers related specifically to the implementation of guidelines in psychiatry, have been described and relate to the tradition of prescribing with minimal constraint (Forsner *et al*., 2010b, p. 6). There is a recognised need for further studies to identify the barriers at which the implementation of evidence-based practice in mental health can fail, and to systematically understand how each can be successfully bridged (Tansella & Thornicroft, 2009, p. 284).

2.15 Shared decision-making – A healthcare professional perspective

A key issue in shared decision-making in psychiatry is the healthcare professionals’ willingness to enter into shared decision-making processes with service users (Kemp, 2011, p. 146). Curtis *et al.* (2010, p. 21) in their review noted that service user involvement in shared
decision-making about choice of medication was lacking, although such involvement is considered critical to the recovery process.

A survey of psychiatrists demonstrated that, although most endorsed shared decision-making, they did so up to a point (Hamann et al., 2009, p. 1111). That point was a judgement made by psychiatrists on the type of decision under review and the level of insight and compliance they believed the service user demonstrated. In particular, this was highlighted when a decision was required for the treatment of psychoses in an acute episode. Psychiatrists endorsed the view that, where noncompliance was a problem, shared decision-making could be a tool to improve compliance. Psychiatrists expressed concern about the capacity of service users to make sound decisions when they were very unwell, however, this concern did diminish when service users were stable. The findings of the survey are similar to an earlier qualitative study, in which psychiatrists showed a preference for a therapeutic alliance with patients with schizophrenia, but they also considered patient competence as a critical obstacle to participatory approaches (Seale et al., 2006, p. 2870).

It has been suggested that mental health practitioners, and not just those with prescribing powers, need knowledge of the effectiveness of medication and at least a working knowledge of psychotropic pharmacology. A more widespread understanding of medication, it is believed, would enable discussions amongst the multidisciplinary team members, and the service user on the most effective use of medication (Falloon et al., 2004, p.104).
2.16 Prescribing guidelines in mental health - Summary

Mental health practice guidelines have proliferated, but there is little evidence regarding the degree to which they are implemented in clinical practice. The lack of robust implementation strategies is coupled with a lack of expectancy and availability of guidelines in practice. This is of relevance for prescribers working within the mental health trust as there is no supportive electronic prescribing reminders which are available to primary care colleagues. Thus, in a mental health setting prescribing guidelines are often unavailable at the point of need. Furthermore, there is evidence to suggest that while the rationale for prescribing guidance may be understood, it does not mean that the guidance will be used (Cabana et al., 1999, p. 1463). There are at present no detailed studies in mental health which outline a broad recommendation for guideline implementation. This is in part due to the unique range of barriers that exist in a specific healthcare setting.

A range of implementation strategies need to be adopted and the development of guidelines needs to reflect the requirements of the end user as well as the service user. One of the keys to successful adaptation of guidelines is the level of engagement in its development and the continued education surrounding its use.

2.17 The current gap in knowledge

The author is unaware of any study that has attempted to explore the views on mental health prescribing by comparing specialists and CCG prescribers across a local health economy.

The author is unable to identify any literature in which the views of healthcare professionals and service users have been explored in the context of mental health prescribing practice.

To date no study has attempted to explore the views of representatives from the pharmaceutical industry on prescribing practice and joint working in a mental health setting.
Chapter 3: Theoretical basis of research method

3.1 Introduction

A discussion of the methodological foundations for the thesis will follow. An overview of research paradigms and a rationale for the approach adopted in this study will be provided. Specific details will be provided about the characteristics of the researcher and approaches implemented to enhance methodological quality. Finally, details regarding ethical and research governance approval and the identification of study sites will be outlined.

3.2 Research Aims and Objectives

Aims

This study sought to explore different perspectives on prescribing practice and the potential for optimising patient care. The study therefore explored the views of service users, healthcare professionals and representatives from the pharmaceutical industry.

Objectives

1. To explore the extent to which service users perceive they were involved in making treatment decisions about their prescribed medication and the factors that influence the service user’s involvement in treatment decision making.

2. To explore the perceived factors that influence prescribing from the perspective of healthcare professionals (consultant psychiatrists, pharmacists involved formulary/guideline development across the local health economy and GP/GP commissioners) and representatives from the pharmaceutical industry with a national or international remit.

3. To develop an understanding of the perceived factors that influence the implementation of prescribing guidelines in a mental health setting from the perspective of consultant psychiatrists, pharmacists involved in formulary/guideline development across the local health economy, GP/GP commissioners and senior representatives from the pharmaceutical industry.

4. To provide a framework of recommendations for optimising the use of medicines across the health economy.
3.3 Theoretical basis

In choosing an appropriate method, the author was presented with a number of challenges and a wide range of fundamentally different strategies to generate new knowledge. One approach involves starting from a philosophical perspective and the assumptions that the researcher brings to the research (Crotty, 1998, p. 66). Central to this approach are the assumptions of epistemology and ontology. Epistemology has been described as ‘the possible ways of gaining knowledge of social reality, whatever it is understood to be.’ In short, claims about how what is assumed to exist can be known (Blaikie, 2007, p. 18).’ Ontological assumptions focus on the ‘philosophy of reality’ (Krauss, 2005, p. 758).

‘...claims and assumptions that are made about the nature of social reality, claims about what exists, what it looks like, what units make it up and how these units interact with each other. Thus ontological assumptions are concerned with what we believe constitutes social reality.’ (Blaikie, 2007, p. 8).

Thus, epistemology is concerned with what it is possible to know, whereas, ontology concerns what there is to know in the world.

Research is rooted in philosophical beliefs about values, concepts, and the nature of knowledge held by researchers (Killman, 2013, p. 6). These belief systems were described by Kuhn as a paradigm (Kuhn, 1970, p. 16). The term paradigm was later defined as the “basic belief system or world view that guides the investigation” (Guba & Lincoln, 2011, p. 33). Paradigms have been identified as:

'[establishing] the parameters and [setting] the boundaries for scientific research and, in the ordinary course of events, scientific enquiry is carried out strictly in line with it.' (Crotty, 1998, p. 35).

Historically, research has been influenced by two major paradigms – positivism and interpretivism, which in turn influence the methods by which data are collected. This historical view has been challenged. Secker, Wimbush, Watson, & Milburn (1995, p. 85) have advocated a ‘horses for courses’ approach to the choice of paradigm, depending upon the object of the research. Rather than seeing the choice of methods as dictated by questions of ontology and epistemology, they argued that the researcher should choose his or her philosophical position on the basis of the task in hand. Such an approach is consistent with an emergent third paradigm – pragmatism.
3.3.1 Positivism

Positivism is a reality-based belief that the social world can be examined in terms of invariant laws like the natural world. Positivism is reality-orientated and posits that everything exists independent of consciousness.

These assumptions underpin the positivist perspective which is often regarded as a ‘scientific method’ involving knowledge being gathered in ways that are not subjective but are direct experiences (Crotty, 1998, p. 22) and which are replicable, involving logically deduced hypotheses and confirmed evidence (Charmaz, 2006, p. 5). Reality is said to exist on cause and effect principles which is subject to determination. Positivists seek methods that yield correspondence with the “real world”; thus this is sometimes referred to as a correspondence perspective. It has been argued such an approach fails to capture the complexity of human behaviour and social interaction (Jensen, 1989, p. 77).

Post-positivism is an evolution of the original positivistic paradigm and its revision has taken into consideration the limitations of rigid positivism and now informs much contemporary social science research (Patton, 2002, p. 92).

3.3.2 Interpretivism

Interpretivism was initially proposed as an alternative to positivism. Interpretivism is founded in the belief that the social world is actively constructed by human beings and that there is continuous involvement in making sense of, or interpreting, the social environment (Secker et al., 1995, p. 75). Interprevists believe that reality exists and can be measured, but recognise that interpretation of information cannot be wholly objective; rather there is a need to control or limit the biases present when collecting data (Hanson, 1958, p. 19). It thus proposes that there can be multiple realities of phenomena, and that these realities can differ across time and place.

Interpretivism aims firstly to understand the context and then to make an interpretation that is shaped by experience. Qualitative methods are frequently used when ‘little is known about a phenomenon’ (Green & Thorogood, 2013, p. 36) and where the investigator seeks to collect ‘information rich’ cases (Patton, 2002, p. 46). Qualitative research, broadly defined, means ‘any kind of research that produces findings not arrived at by means of statistical procedures or other means of quantification’ (Strauss & Corbin, 1990, p. 17). Data are collected by qualitative means through interviews, focus groups or observations and analysis involves examining the words that are recorded during these interactions. Qualitative studies are
regarded as being subjective and the researcher’s interpretation of the events recorded is paramount to address ‘research questions that require explanation or understanding of social phenomena and their contexts’ (Snape & Spencer, 2003, p. 5).

Over the past decades there have been numerous debates regarding the merits of the existing paradigms (Grbich, 1999, p. 6). The notion of adopting a single stance was held by many. However, a new era of research methods slowly emerged where it was considered by many ‘that the struggle for primacy of one paradigm over others is irrelevant as each paradigm is an alternate offering with its own merits’ (Guba, 1990, p. 27).

### 3.3.3 The Pragmatism Paradigm

The pragmatist approach is a theoretical stance that has been widely regarded as the ‘third paradigm’ (Patton, 2002, p. 71; Creswell, 2013, p. 10; Denzin, 2011, p. 29). The pragmatism paradigm eschews methodological orthodoxy in favour of methodological appropriateness as the primary criterion for judging methodological quality (Patton, 2002, p. 70). Studies conducted within health services research, where aims reflect the priorities of funders, often adopt this viewpoint (Green & Thorogood, 2013, p. 36; Lewis & Nicholls, 2014, p. 67). Patton (2002, p. 72) argued that methodological approaches should be flexible and appropriate for a specific inquiry situation or interest. In health care research, the choice between qualitative and quantitative approaches are likely to be determined by the degree of knowledge of the phenomenon to be studied. The more that is known about a programme and its underlying theories, the more possible and logical it becomes to use quantitative design. The less that is known, the more appropriate it is to understand concepts such as beliefs, experiences, motivations and intentions, a more qualitative approach (Murphy et al., 1998, p. 221). Pragmatists hold the belief that when making a decision about the method or methods to be adopted, the limitations and opportunities of the context in which the research is to be conducted are of primary importance (Greene et al., 2001, p. 28; Seale, 1999, p. 475). Patton (2002, p. 71) stresses the importance of not getting ‘bogged down’ with the opposing differences that different paradigms present but to use a pragmatic approach, responding to the context in which the research is conducted. Pragmatism is also associated with research using both quantitative and qualitative methods (Creswell & Piano-Clark, 2013, p. 13). Pragmatism does not consider that a specific method be adopted although, simultaneously, is not an approach where ‘anything goes’ (Denscombe, 2008, p. 274); it is one that is flexible in the approach to the collection and emergence of data (Patton, 2002, p. 255). The current study aimed to gather knowledge on the experiences of prescribing practice within a mental health setting. In achieving this aim, consideration of methodologies and the methods that could be used were undertaken by the author. Morgan (2007, p. 68) stated that while the theoretical
underpinnings of a methodology and the methods themselves should be considered of equal importance.

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'we need to use our study of methodology to connect issues in epistemology with issues in research design rather than separating our thoughts about the nature of knowledge and from our efforts to produce it.'

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3.4 Research purpose

The purpose of the research project has important implications for the design, measurement, analysis and reporting (Patton, 2002, p. 213). The significance of purpose in the choice of methods is evident when considering alternative research purposes along a continuum from theory to action:

- Theoretical research: to contribute to fundamental knowledge and theory.
- Applied research: to illuminate a societal concern.
- Action research: to solve a specific problem.

The following section considers the research continuum in the context of theoretical, applied and action research and the implications for the research project. The section also considers the prevailing debate regarding the distinctions which are made between applied and theoretical research.

3.4.1 Applied and theoretical research

A distinction is often made in the literature between applied and theoretical research. Theoretical research is concerned with the aim of testing, generating or enhancing thinking within a particular discipline (Ritchie & Ormston, 2014, p. 28). Patton (2002, p. 215) outlines the purpose of theoretical research as ‘the contribution to fundamental knowledge and theory.’

Applied research is concerned with the use of acquired knowledge gained through research to contribute to the understanding or resolution of a contemporary issue. Applied research is the term often used to denote studies that have the objectives of developing, monitoring or evaluating policy and its related practice (Silverman, 2013, p. 276). The aim of this research is to obtain knowledge gained through face-to-face interviews to understand current prescribing practice across the local health economy. In essence, the research is designed to help the author understand the nature of prescribing practice and to facilitate a framework of recommendations for improvement which is consistent with applied research (Ritche, 2006, p. 24). Another characteristic of applied research is that it reflects the concerns experienced by
people and articulated by policymakers (Patton, 2002, p. 217). This has particular relevance to the research. The author, as Chief Pharmacist for DWMHT has received numerous reports from healthcare professionals and service users who have expressed concerns about prescribing practice and poor communication across the health economy.

In applied policy research, the questions that need to be addressed can vary depending on the research project, but can be broadly divided into four categories (see Table 3.1). The objectives are shaped by the specific information requirements, e.g. the need to understand how the use of prescribing guidelines can be improved, thus the research is targeted towards providing answers to the issues under consideration.

**Table 3.1: Applied policy research categories and questions**

<table>
<thead>
<tr>
<th>Category</th>
<th>Goal</th>
<th>Sample Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contextual</td>
<td>Identifying the form and nature of what exists</td>
<td>What is the nature of people’s experiences?</td>
</tr>
<tr>
<td>Diagnostic</td>
<td>Examining the reasons for, or causes of, what exists</td>
<td>What factors underlie particular attitudes or perceptions?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Why are decisions or actions taken, or not taken?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Why do particular needs arise?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Why are services or programs and not been used?</td>
</tr>
<tr>
<td>Evaluative</td>
<td>Appraising the effectiveness of what exists</td>
<td>How are objectives achieved?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>What affects the successful delivery of program services?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>How do experiences affect subsequent behaviours?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>What barriers exist to systems operating?</td>
</tr>
<tr>
<td>Strategic</td>
<td>Identifying new theories, policies plans or actions</td>
<td>What types of services are required to meet needs?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>What actions are needed to make programs services are more effective?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>How can systems be improved? What strategies are required to overcome the defined the problems?</td>
</tr>
</tbody>
</table>

There is some debate about the justification of articulating a distinction between applied and theoretical research (Ritchie & Ormston, 2014, p. 28). It is suggested that all research is based on theoretical assumptions, concepts or hypotheses. As Silverman states:

‘even down-to-earth policy orientated research designed to evaluate some social service will,.... embed itself in theoretical issues as soon as it selects a particular evaluation method’
(Silverman, 2013, p. 108).

Similarly, it is argued that all forms of social research can contribute to theoretical knowledge by providing greater understanding of, and knowledge regarding, the social world (Ritchie & Ormston, 2014, p. 28). Meanwhile Denzin & Lincoln (2011, p. 24) have argued that good theoretical research should have applied relevance and implications.

3.4.2 Action research

Action research has been defined as a participatory, democratic process concerned with developing practical knowing in the pursuit of worthwhile human purposes, grounded in a participatory world-view which is emerging at a given moment (Reason & Bradbury, 2001, p. 6). It seeks to bring together action and reflection, theory and practice, in participation with others, in the pursuit of practical solutions to issues of pressing concern to people, and more generally the flourishing of individual persons and their communities (Reason & Bradbury 2001, p. 84). This definition of action research is particularly relevant to the author’s research that seeks to explore potential ways of improving prescribing practice from those persons who are engaged in the prescribing process as either clinicians or recipients of care.

Action research is explicitly and purposefully part of a change process and one of the most important features of the approach is found in the relationship in those conducting the research and those ‘being researched.’ The subjects therefore become partners in the research process and share responsibility for identifying specific problems and applying local, action-oriented strategies (Denzin & Lincoln, 2011, p. 29; Whyte, 1989, p. 381). The idea of empowering stakeholders to articulate solutions to identified problems is consistent with the approach taken in this research project. Staley (2009, p. 26) takes the notion of stakeholder engagement further by recommending that the research population has a direct role in shaping the research project. In the context of the research project, the author did not explicitly consult with stakeholder groups to shape the research project; however, the author was mindful of the concerns expressed by all stakeholder groups and this helped to develop the research aims and objectives.
Russo (2012, p. 15) argues that as part of action research participants should, as a minimum, be provided with their data and the means to comment on and clarify it before the findings of the research are developed. In the author’s opinion the purpose of the interviews was to gain an honest and open account of experiences. The suggestion of subsequent amendments would detract from the research findings that represent specific perspectives at a point in time.

Therefore, in addition to the lack of access of participants to their interview transcripts, coupled with the lack of participation in shaping the study, this project cannot be considered to be action research.

3.5 Data collection methods
This section outlines the data collection methods that were considered for the research. The advantages and disadvantages of each method are considered, as well as, the rationale for acceptance of the data collection approach.

3.5.1 In-depth interviews
In-depth interviews were used in this research to provide a detailed investigation of each person’s personal perspective. According to Ritchie & Spencer (2003, p. 36) in-depth interviews allow “undiluted focus on an individual person” to understand their personal perspective in significant depth. The use of in-depth interviews allowed the collection of data within the context of a narrative, born of personal history or experience, such as the nature of the relationship between service user and clinician. Furthermore, in-depth interviews facilitated the exploration of a variety of issues, which were dependent on the individual’s circumstances, such as the impact on the service user of the therapeutic relationship with the clinician.

The complexity of understanding the service user’s perspective on their involvement in treatment decisions is multifaceted and is thus best addressed using in-depth interviews. The use of in-depth interviews for capturing complex and sensitive information is well documented (Kumar, 2014, p. 156; Yeo, et al., 2014, p. 177; Patton, 2002, p. 339). In-depth interviews facilitated the process of detailed discussion with service users and enabled the author to seek clarification and detailed understanding of the topic under consideration. Similarly, understanding the motivations and decisions, or exploring impacts and outcomes, generally requires the detailed focus that in-depth interviews allow. The use of in-depth interviews facilitated the process of exploring beyond what could be considered the expected norm. Thus, in the case of the pharmaceutical industry interviews, there was a focus on exploring the thoughts of the participants beyond the official company rhetoric, to understand the personal
views of its employees in terms of the historical relationship with the NHS and how the industry should engage with the NHS in the future.

3.5.2 Semi-structured interviews

Semi-structured interviews were used because they allowed the researcher to gain a detailed account of the participant’s beliefs or perceptions; this is because the interviewer retains the flexibility to follow up on themes that may illuminate a particular subject (Gray, 2004, p. 217). An example of following up on themes is shown below and is taken from the interview with Service User 1, who when asked about their psychiatric history expressed the following:

_Service User 1_. “in the early days, I wasn’t really given much choice, just given a prescription, and having no idea what the medication was about. Now I’m more vocal and do have a little bit more understanding of medication”

The mention of becoming more vocal over the years led the investigator to probe further to understand why the individual had become more vocal. This led to the following response:

_Service User 1_ “I guess, in a lot of ways, there’s nobody else that will actually speak on my behalf, so...you have to do it yourself, otherwise...some consultants and doctors you can trust, and some health people are very, very good, but if you just sit there and don’t say anything, then you will be given any tablets, just loads of tablets, basically.”

Semi-structured interviews have been used to explore the deep rooted and complicated issue of health professionals’ attitudes to prescribing guidelines (Rashidian et al., 2008, p. 151). This is exemplified by an extract from the interview with GP 1, which identifies the role of guidelines in enabling GPs to keep abreast of change.

_GP 1_. “For us, prescribing guidelines across whatever field are really useful. It acts as a massive safety net; it hems things in as to the range of things you can actually do. But once things are in guidelines it also gives you some security that somebody else has reviewed, tested, tried these things. So they’re established, accepted bits of practice.”

“The other thing is with the amount of change and variation in different fields, psychiatry for one for example, there’s various things that will progress, but being in general practice you might not be the forefront of new introductions to things and new drugs coming out, et cetera. So we also are quite dependent on guidance, so usually guidelines as to what we can prescribe, how we follow things and what we do”
3.5.3 The limitations of interviews

The use of in-depth interviews requires significant time and patience and necessitates coordinating of schedules with busy stakeholders. In addition to the logistic consideration of this method of data collection, there is a vast amount of data to analyse and the task of presenting the findings in a coherent manner can be challenging (Lichtman, 2012, p. 27). Interview driven research is characterised by an emerging design with data collection, merging into data analysis with countless hours devoted to transcription and no definitive clarity on what constitutes sufficient data (Mears, 2012, p. 171).

3.5.4 Focus groups

Initially, focus groups were considered as a means of data collection but they were subsequently rejected for a number of reasons which have been outlined for each key stakeholder group.

**Service Users**

The use of focus group discussion can provide ‘safety in numbers,’ and facilitate the process of research for people who might find, for a variety of reasons, a one-to-one encounter intimidating or uncomfortable. This was a concern which might have been of particular relevance to the service user group. ‘Expert by experience’ service users were chosen to participate in this research because they were actively engaged in representing the views of other service users and carers across a range of stakeholder groups in the wider community. Service users were encouraged to be open and honest about the pharmaceutical care that they had received and this required a degree of openness and transparency that is often difficult to achieve in a group setting (Oliveira, 2011, p. 3100; Stewart & Shamdasani, 2014, p. 101). The interviews with service users included the exploration of personal and sensitive information. It was felt that the use of focus groups would limit the public expression by service users of deeply held feelings in a group setting.
Pharmaceutical Industry
Focus groups have the potential to generate ideas through participant interaction and influence which is reflective of a ‘real-life situation’, however due to the sensitive nature of the enquiry, involving the perspectives of representatives from the pharmaceutical industry, the author felt that this would not lend itself to group discussions. Some of the topics covered as part of the research were confidential. Representatives from the pharmaceutical industry were encouraged to give an open and frank account of their perspectives on joint working, including an exploration of the complexity of the relationship between the pharmaceutical industry and the NHS. The commercial sensitivities for representatives from the pharmaceutical industry would limit the potential for focus group participation.

Healthcare Professionals
One of the aims of the research project was to explore the perceived factors that influence prescribing in mental health from the perspective of individual clinicians. The use of focus groups is more time efficient as more participants can be questioned in the same timeframe it would take to interview a single participant.

Both GPs and Consultant Psychiatrists are difficult stakeholder groups to arrange interviews with, and in one case the researcher had to book an interview with a GP six months in advance due to their work schedule. Furthermore, in the case of GPs and psychiatrists it is possible that group discussions would have been dominated by those with more senior roles and the views of less senior colleagues could have been suppressed.

A further practical limitation of using focus groups would be the need to attend a common location for participation in the research project. It is likely that this would have inhibited the accessibility of the research to potential participants. There would also be difficulties in trying to cluster sufficient numbers of participants across the Dudley and Walsall boroughs.

3.6 Data analysis method that were initially considered
Several data analysis methods were considered for the research. Many of these approaches were associated with specific disciplines and are underpinned by philosophical ideas which shape the process of analysis.

There are a number of approaches to qualitative data analysis, including those that pay close attention to language and how it is used in social interaction such as discourse analysis (Fairclough, 2013, p. 56).
The use of discourse analysis was briefly considered but not used because the focus of the project was not to analyse language in a social context, but rather to understand meaning in relation to current prescribing practice and how this might be improved.

**Phenomenology**
A phenomenological approach to data analysis was considered initially as a means of focusing on meaning, experience and language. This approach to data analysis is consistent with phenomenology (Larkin & Thompson, 2011, p. 102); however, as the author reflected on this approach he was mindful that the primary focus of the research was not to understand what a given experience was like (phenomenology) and how someone made sense of it (interpretation), but rather the use of experience and interpretation to generate potential solutions to the identified shortcomings in prescribing practice.

**Grounded Theory**
Grounded Theory was considered as a method of data analysis by the investigator, as its purpose is to understand how reality is constructed for people, to identify the concepts and then develop theory as the research evolves. Grounded theory leads to an exploration of emergent relationships between the concepts (Charmaz, 2006, p. 106). However, the aim of the author’s research project was not to develop theory from the concepts which emerge from the data, but to identify solutions to problems as articulated by research participants with respect to joint working, prescribing, prescribing guidance and shared decision-making, therefore grounded theory as a method of data analysis was rejected.

**Ethnography**
An ethnographic approach may have been considered as the ideal research method as the researcher or ethnographer becomes integrated within the lives of the people being studied, enabling an exploration of culture within a group (Richards & Morse, 2012, p. 54-55). However, the resources to recruit and follow people through their various day to day activities were beyond the scope of this research project.

**Framework Analysis**
Framework analysis was chosen for the following reasons:

- It provides coherence and structure to otherwise cumbersome, qualitative data (i.e. interview transcripts).
- It facilitates systematic analysis, thus allowing the research process to be explicit and replicable.
The detailed rationale for the use of Framework analysis is given below.

### 3.7 Rationale for using Framework Analysis

First, the Framework approach is particularly suited to analysing cross-sectional descriptive data, thus allowing thematic comparisons between the various stakeholder groups, enabling different aspects of the phenomena under investigation to be captured (Spencer, Ritchie, Ormston, O’Connor, & Barnard, 2014, p. 282). The Framework method would thus facilitate the analysis of divergent and convergent themes across the various stakeholder groups whilst maintaining the connection with the individual account. Second, it is easy to identify relevant data extracts and to determine if there is sufficient evidence for a proposed theme; hence the researcher’s interpretations of the participant’s experiences are transparent. This ensures rigour and transparency as part of the analytical process, which is essential in assessing the quality of the research and its confirmability. A third reason for using Framework analysis is that the transition from data management to developing the analysis sufficiently to answer research questions can be a challenging task for a novice researcher such as is the case for the author. The interconnected stages in the framework approach explicitly describe the processes that guide the systematic analysis of data from initial management through to the development of descriptive to explanatory accounts.

### 3.8 Framework Analysis

The Framework method is not aligned with a particular epistemological, philosophical, or theoretical approach. Framework analysis is a flexible tool that can be adapted for use with many qualitative approaches that aim to generate themes (Gale, Heath, Cameron, Rashid, & Redwood, 2013, p. 3). Framework analysis sits within the wider family of analysis methods known as thematic analysis or qualitative content analysis. These approaches identify commonalities and differences in qualitative data, before focusing on relationships between different parts of the data, thereby seeking to draw descriptive and/or explanatory conclusions clustered around themes.

The Framework method was originally developed for use in large-scale policy research (Spencer et al., 2014, p. 282) and is now used widely in health research (Jones, 2000, p. 555; Rashidian et al., 2008, p. 148; Sheard et al., 2012, p. 339; Ellis et al., 2012, p. 831; Gale & Sultan, 2013, p. 1; Ayatollahi, Bath, & Goodacre, 2010, p. 189). The unique feature of the Framework method is its matrix output: rows (cases), columns (codes) and ‘cells’ of summarised data, providing a structure into which the researcher can systematically reduce the data, in order to analyse them by case and by code. Most often a ‘case’ is an individual interviewee, but this can be adapted to other units of analysis, including predefined groups.
such as GPs, service users, specialist pharmacists or representatives from the pharmaceutical industry. While in-depth analyses of key themes can take place across the whole data set, the views of each research participant(s) remain connected to other aspects of their account within the matrix so that the context of the individual’s views is not lost.

Comparing and contrasting data is vital to qualitative analysis. The ability to compare with ease data across cases, as well as within individual cases, is built into the structure and process of the Framework method.

The Framework method is most commonly used for the thematic analysis of semi-structured interview transcripts and is consistent with the data collection method for this research. Reflexivity, rigour and quality are issues that are requisite in the Framework method just as they are in other qualitative methods.

### 3.8.1 Limitations of the Framework Analysis

The systematic approach and matrix format, is intuitively appealing from a quantitative perspective and the ‘spreadsheet’ look perhaps further increases the temptation to attempt to quantify qualitative data (e.g. ‘15 out of 30’ participants said prescribing guidelines were helpful). In the context of the research project this statement would be meaningless because the sampling is not designed to be representative of a wider population, but purposive to capture diversity around the stakeholder group of interest. In common with other qualitative analysis methods, the framework method is time consuming and resource-intensive.

### 3.8.2 Sample size

There is no definition of the ideal sample size for framework analysis (Fugard & Potts, 2015, p. 12). In the review by Gale *et al.* (2013, p. 2) the number of interview participants ranged from 20 to 76 and in one identified study there was a single participant in which a diary entry was subject to analysis (Jones, 2000, p. 559). Charmaz (2006, p. 114) for example, suggests that 25 participants are ‘adequate for smaller projects’ while according to Ritchie, Lewis, Elam, Tennant & Rahim (2014, p. 118) qualitative samples often ‘lie under 50.’ The results of a study which explored data saturation and sample size in qualitative PhDs showed that on average the sample size was 31 and in the case of action research the number of participants ranged from 3 to 67 (Mason, 2010, p. 8).
In this research project a sample size of 5 participants from each stakeholder group was decided on (total of 25 participants). There were a number of factors that governed the capacity for participant enrolment in the research project. At the time of conducting the interviews there were a total of six pharmaceutical companies actively promoting drugs in mental health. This was a key consideration for the author as it was unlikely that pharmaceutical companies would participate unless they were actively promoting a drug, or at least looking to bring a new drug to the UK market at the time of the interviews. A further consideration at the time of conducting the interviews was that there were five expert by experience service users employed across the trust.

3.8.3 Data Saturation
The term data saturation is often used in qualitative research, to define the point at which no new themes emerge from the data and may be used to determine the point at which no new participants are recruited to a study. As described by Ritchie & Spencer (1994, p. 175), applied research studies are often bound by constraints of time and resources. Framework analysis sits within the context of applied policy research and is an approach suited to facilitating systematic analysis of data to generate answers to specific questions, as is the case with this research; therefore, data saturation is not a requirement of this method of analysis.

3.8.4 Sampling
Framework analysis is suited to homogenous data and sampling is usually purposive (Gale et al., 2013, p. 3). With Framework analysis the data must cover similar topics or key issues so that it is possible to categorise it. Individual interviewees may have very different views or experiences in relation to each topic, which can then be compared and contrasted using this method. Homogenous samples were chosen to give a detailed picture of a phenomenon, for example, individuals who have extensive experience of treatment within mental health services. The use of homogenous subgroups allowed for detailed investigation of social processes in the context mental health services across DWMHT.

The methodology does not imply that findings can necessarily be generalised to, or held to be equally true of, the parent population from which the sample is drawn, nor does the method imply that the findings can be related to other settings or contexts beyond the one sampled, namely the Dudley and Walsall Mental Health economy.
3.9 Ethical issues

As the research project involved interviewing service users with enduring mental illness, ethical approval for the study was sought and granted by the NRES Committee London – City & East on October 22nd 2013. This approval letter is enclosed in Appendix 7.

As part of the local trust governance procedure the project was also subject to approval by the DWMHT Research Ethics Committee.

Written consent was obtained from all participants prior to interview and ongoing consent was used as a supplement to traditional informed consent, to repeatedly give service users the opportunity to stop the interview if they felt distressed. Participants were informed that consent would be sought to use interview material, and participants would receive routine feedback on the excerpts that are to be used in publication unless participants forbid the use of verbatim quotations.

3.10 Researcher context

The author, as the current Chief Pharmacist for DWMHT, has responsibility for delivering efficacy savings against the prescribing budget as well as strategic oversight of medicines optimisation across the organisation. With a background in mental health and experience of delivering cost-effective savings across a local primary care trust, the author understands the NHS focus on maximising cost-effective prescribing. The achievement of cost-effective prescribing is dependent on engagement with the recipient of care and meeting their needs. Thus, there is a recognition of the importance of distributive justice in the context of delivering health economy efficiencies while engaging with service users’ individual needs.

In the author’s experience GPs tend to lack expertise in mental health therapeutics and are more mindful than their specialist counterparts in managing prescribing expenditure. Specialists by contrast, are more focused on the individual patients and complexity of mental illness which often leads to less of a focus on wider health economy expenditure. These differences can be a potential source of conflict between GPs and psychiatrists.

The author is also keen to explore with the pharmaceutical industry new ways of working which will deliver efficiency savings and improve service delivery for service users.

Based on observations and discussions with service users, prescribers, pharmacy colleagues and representatives from the pharmaceutical industry, the author considered the question of
what could be done to improve prescribing practice across the local health economy and how the service user experience could be improved.

3.11 Researcher as data collector
The researcher was the data collector for this project which was subject to scrutiny by a project supervisor and work based supervisor as part of a strategy to ensure rigor as part of the research process. The interview schedules were designed to facilitate a free and open discussion by participants and were subject to inspection by the project supervisor.

3.12 Issues of quality in Qualitative Research
Quality in qualitative research remains a ‘complex and emerging area’ (Creswell, 2013, p. 227) and it has been argued that such research lacks scientific rigour. There is considerable debate as to whether the principles of validity, reliability and generalisability, which many consider to be deeply rooted within quantitative research, can be applied effectively to studies adopting a qualitative interpretative approach (Stenbacka, 2001, p. 555; Healy & Perry, 2000, p. 125). Researchers have argued that alternative criteria are more applicable in qualitative research and new terms such as credibility, transferability, and conformability have been argued to better reflect the interpretivist outlook (Seale, 1999, p. 466). Others, however, have argued that the same principles can be applied but that they need to be modified (Mays & Pope, 2000, p. 51) to take account of the differing features and goals of qualitative research. The concepts of validity, generalisability (external validity) and reliability within qualitative research will be outlined:

3.12.1 Generalisability (External validity)
Morse (1999, p. 5) stated that ‘if qualitative research is considered not generalisable then it is of little use, insignificant and hardly worth doing’. As Lewis, Ritchie, Ormston & Morrell (2014, p. 349) highlighted, there are several potential ways that the concept of generalisation can be applied. One of these is inferentially by generalising from one particular study context to another (representational generalisation). To facilitate this, it is imperative that in reporting the research a ‘thick description’ of the original research process and setting is provided (Geertz, 2002, p. 175). The importance of representational generalisation is also highlighted where there is clear demonstration that the sample is a true reflection of the population studied and that the conclusions drawn are an accurate reflection of the data provided by the participants (Lewis, Ritchie, Ormston & Morrell 2014, p. 350; Murphy et al., 1998, p. 18). Within the context of this study the data collection method was used appropriately to strengthen the interpretation
provided. The use of Framework analysis further facilitated the levels of interpretation and transparency.

3.12.2 Validity
Parahoo (2014, p. 67) described the concept of validity as 'the accuracy with which the findings reflect the phenomenon being studied. There are several methods to ensure that the research remains as truthful to reality as possible. Mays & Pope (2000, p. 51) suggest the following ways to improve validity: – triangulation of results from different methods of data collection; asking participants to validate the researcher’s interpretations; being aware of aspects of the research that may have influenced the way in which the data was collected e.g. researcher and participant characteristics; clear exposition of the data collection and analytical methods; taking into consideration participant data that may contradict other data collected by reporting fully and finally, ensuring that the research takes into consideration a wide variety of perspectives. For this study, the researcher was aware of the importance of transparency in relation to data collection and analysis. The dataset and emergent themes were subject to external scrutiny by work-based and project supervisors. Furthermore, the stakeholder groups facilitated the collection of a variety of perspectives.

3.12.3 Reliability
Parahoo (2014, p. 31) described the concept of reliability as: 'The consistency of a particular method in measuring or observing the same phenomena.' Another way of considering reliability is the extent to which results are consistent over time and an accurate representation of the total population under study. Determining reliability within qualitative studies can be challenging as the data collected are based often on face-to-face situations where participants are providing information on real-life experiences. Such methods are prone to elements of misinterpretation or personal biases of the researcher. Demonstrating and enhancing reliability in qualitative research is important therefore each step in the process of data collection and analysis should be open to external scrutiny. Several methods have been identified to assist with demonstrating the reliability of qualitative research, such as conducting and reporting the research in a systematic way, and ensuring that any interpretations provided are supported by the data (Lewis, Ritchie, Ormston, Morrell, 2014, p. 355). Throughout the research project the concept of reliability was addressed to minimise any possible misinterpretation or bias. This involved conducting fieldwork using a consistent approach that allowed participants to readily portray their experiences, clarifying any ambiguities with participants during the interview, confirming interpretations of interview data by multiple reviews with research supervisors and reporting the findings systematically. In order to ensure
that quality was maintained throughout the research process, various applications of these principles have been applied in context and demonstrated throughout this thesis.

3.13 Summary

Face-to-face interviews are integral to the research that was conducted and was considered to be the most appropriate data collection method for meeting the study aims and objectives.

Semi-structured interviews were used for an in-depth exploration of the experiences and perspectives of a range of stakeholders. This approach facilitated a flexible way of exploring the context of prescribing practice and ‘medication-taking behaviours’; in addition to this, the semi-structured nature of the interviews enabled an exploration of particular attitudes and perspectives as well as appraising the effectiveness of existing medicines optimisation systems.

The Framework method was used for data analysis because it provides a systematic model for managing and mapping interview data. The Framework method is suitable for thematic analysis of interview transcripts, where it is important to be able to compare and contrast data by themes across numerous stakeholder groups, while also contextualising each perspective by retaining the connection to other aspects of each stakeholders account.
Chapter 4: Methodology

4.1 Introduction

This chapter describes the method used to collect and analyse the data provided by the key stakeholder groups. The data was used to identify the factors that influence the implementation of prescribing guidelines in a mental health setting, the key influences on prescribing and the extent to which service users felt involved in making treatment decisions.

4.2 Stakeholder engagement

Purposive sampling was used in this research. This approach enabled the selection of individuals because they have particular characteristics or knowledge which would enable detailed exploration and understanding of the central themes which the researcher wished to study. In the case of this research, these features related to specific experiences and roles.

Pharmaceutical Industry

Representatives from the pharmaceutical industry, who were engaged in the promotion of drug therapy across the trust, were approached for the contact details of marketing managers and product managers with a national portfolio. The idea of interviewing senior personnel within the pharmaceutical industry was to identify individuals with a strategic remit at a national level to gain a more informed perspective on joint working between the industry and the NHS.

Expert by Experience Service Users

Expert by experience service users were chosen to participate in this research because they were considered central to the impact of prescribing practice as the recipients of care. In particular, expert by experience service users are highly active strategically across the trust and are able to impact on the development of policies and procedures.

Consultant Psychiatrists

Consultant psychiatrists, employed by the trust working in a variety of specialities, were invited to participate in the research. Those consultant psychiatrists actively involved in the Medicines Management Committee and/or guideline development were approached first to participate in this study. Consultants were chosen because of their seniority within the medical directorate and their medicines management remit.
**GPs /GP Commissioners**

GPs /GP Commissioners with an interest in mental health therapeutics across the local health economy were invited to participate in the research project. GPs actively involved in locality prescribing committees and those with a remit for commissioning mental health services were also invited to participate.

**Pharmacists**

Pharmacists who were involved in mental health prescribing guideline development or those with a remit for assuring medicines management standards in the mental health trust on behalf of the local commissioners were invited to participate in the research project. In addition, senior pharmacists with a strategic role across the local health economy were invited to participate.

The inclusion and exclusion criteria for the various stakeholder groups is shown in Table 4.1.
Table 4.1: Inclusion and exclusion criteria

<table>
<thead>
<tr>
<th>Group</th>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Representatives of the pharmaceutical industry</td>
<td>Representatives from the pharmaceutical industry with an active portfolio in psychiatric drug therapy or with an existing portfolio of psychotropic agents.</td>
<td>Representatives from the pharmaceutical industry without a mental health portfolio. Representatives from the pharmaceutical industry without a national portfolio.</td>
<td>Representatives from the pharmaceutical industry understand the key drivers for the delivery of mental health services and are familiar with a range of prescribing interface issues across health economies.</td>
</tr>
<tr>
<td>Expert by Experience Service Users</td>
<td>Service users with a diagnosis of psychotic or affective related disorder. Currently attending outpatients or being cared for by community mental health teams across DWMHT. Capable of giving informed consent to participate in the study.</td>
<td>Anxiety related disorders or Personality disorders. Relapse in the previous 18 months. History of substance misuse in the previous 18 months. Evidence of organic impairment. Those requiring an interpreter. Those currently receiving care in an in-patient setting.</td>
<td>A face-to-face interview can be anxiety provoking and therefore participants with a primary anxiety disorder will not be approached to participate in the study. Pharmacological therapy is not the recommended treatment for personality disorder and therefore this patient group will be excluded. Organic impairment is a complicating factor in the presentation of mental disorder and is generally a reason for exclusion unless the study is specifically focussing on this as the main issue of investigation. As a novice researcher, the investigator was unfamiliar with the social &amp; scientific methods that facilitate research in patients with cognitive impairment. Interviews will be conducted in English and as they will have to be transcribed, using an interpreter would introduce extra complexity in the communication that cannot be the focus of this study.</td>
</tr>
<tr>
<td>Consultant Psychiatrists</td>
<td>Consultant psychiatrists working for DWMHT.</td>
<td>Doctors working for the trust at a more junior level than consultant psychiatrist.</td>
<td>The researcher sought representation from consultant psychiatrists working in a variety of specialisms across the trust. As consultants assume ultimate responsibility for the impact of pharmacological therapy they were approached for interviews.</td>
</tr>
</tbody>
</table>
Table 4.1: Inclusion and exclusion criteria continued

<table>
<thead>
<tr>
<th>Group</th>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
<th>Rationale</th>
</tr>
</thead>
</table>
| GPs / GP Commissioners       | GPs working across the local health economy with a special interest in mental health.  
                              | GPs with involvement in commissioning local mental health services.                   | GPs who do not have a specialist interest in mental health and who are not involved in commissioning mental health services.  
                              |                                                                                      | GP's working outside of the local healthcare economy.                                                                               | GP commissioners of mental health services and those with a specialist interest in mental health are likely to be able to contribute to the understanding of the factors that influence prescribing across the local healthcare economy. |
| Pharmacists                  | Pharmacists working across the local health economy engaged in area prescribing committees and or involved in the development of mental health related prescribing guidance or commissioning of psychiatric services. | Pharmacists not actively engaged in the commissioning of mental health services or strategic remit for the development of mental or physical health prescribing guidance. | Pharmacists actively engaged in mental health related prescribing guidance and or commissioning are likely to have an understanding of the key prescribing issues across the local health economy. |

4.3 Design of the data collection tool

Open-ended questions were used to achieve both breadth of coverage across key issues, and depth of coverage within each. A combination of content mapping questions and content mining questions were used. Content mapping questions were used to open up research territory. In the case of service users, an example of this open-ended style of questioning included: “tell me about your relationship with your doctor.” To understand the relationship in more depth a follow-up question would ask about the specific aspects of the relationship, “what characterises a good relationship for you and how does it make you feel?” This allowed a more detailed understanding personal perspective on the nature of the relationship and its impact on the therapeutic alliance between the service user and doctor.

The initial interview schedule for service users was shared with an acquaintance with a longstanding mental health diagnosis to test understanding, language and appropriateness of the questions. As a result of this pilot some of the wording was simplified. Furthermore, all interview schedules were subject to scrutiny by a neuro-linguistic programmer at Keele University and project supervisors for comments. All schedules were refined and in accordance with relevant feedback which was based on the need to change the order of questions.
The interview schedules (Appendix 2), were designed to explore participant’s belief about prescribing and prescribing practice in mental health and how communication could be improved. The interview schedules were also informed by a review of the literature in relation to prescribing practice in mental health and took into consideration some of the broader themes from the review such as shared decision-making, information sources and the impact of the therapeutic alliance between clinician and patient. More specifically the interview schedules for healthcare professionals included the broad headers of implementation, choice (patient and clinician), cost effectiveness, joint working, interface issues and effectiveness. For service users the broad headers included communication, information, shared decision-making and wellbeing. Interview schedules were developed for each stakeholder group to reflect issues that were specific to that group; e.g. for the pharmaceutical industry, an area of exploration related to their ongoing relationship with the new NHS and the factors that might impact on this.

4.4 Pilot data collection

Pilot interviews were conducted with a service user, GP and pharmacist. Each of the interviewees was known to the researcher and contact was established via a telephone call to confirm participation. Each participant was provided with an “information for participants” sheet (Appendix 3) to ensure their understanding of the research project and consent form for completion prior to the interview.

Following the three pilot interviews some of the questions, prompts and order of questions were amended. This is consistent with the recommendations of Yeo, Legard, Keegan, Ward, Nicholls & Lewis (2014, p. 173) who suggest that pilot studies provide a valuable opportunity to see if the proposed interview questions allow the participants to give a full and coherent account of the central issues and incorporates factors that are of importance to the subjects. Gerrish & Lacey (2010, p. 22) suggest that pilot studies provide a valuable opportunity to determine if the proposed interview questions are understandable, relevant and appropriate.

The researcher started the first interview by following the interview schedule, however, it was difficult to follow the schedule as talk developed naturally, leading from one set of questions to the next. As the pilot interviews continued, the researcher allowed the questions to flow from the participant response. By the conclusion of the pilot interviews, the researcher did not follow the interview schedule but found that all the areas included in the schedule were at some point discussed during the interview. This approach felt comfortable and the pilot
interviews provided an invaluable opportunity to practice interview skills in advance of the formal interviews.

4.4.1 Feedback

Following feedback from each of the pilot interviews, some of the questions and prompts were amended and this formed the finalised interview schedules. Feedback from the service user led to the omission of a question regarding prescription charges as it was felt that this was largely irrelevant to the aims and objectives of the research project which sought to understand the level of service user engagement in the prescribing process.

For the purposes of this study the pilot interviews were not included for analysis in the research project as there was sufficient data emerging from later interviews.

4.5 Face-to-face interviews

Minor amendments were made to the interview schedule following the pilot interviews. The pilot exercise did confirm that a semi-structured interview approach was appropriate as it allowed the participants to move from one topic area to another in a natural way, combining structure with flexibility and allowing the researcher to control the overall interview. Although the interviews across the stakeholder groups were based on interview schedules, the structure was sufficiently flexible to permit topics to be covered in the order which naturally flowed from the interviewee. This also allowed responses to be fully probed and explored and enabled the researcher to be responsive to the relevant issues raised spontaneously by the interviewee. The researcher was mindful to allow the interviewee to talk freely when answering questions and to use a range of probes to achieve the depth of answers in terms of penetration, exploration and explanation. Follow-up questions were used to develop a fuller understanding of the participant’s meaning. The researcher was keen to fully explore the factors that underpinned a participant’s response including, reasons, feelings, opinions and beliefs.

4.5.1 Requirements of an interviewer

The researcher was aware of his relative lack of experience in conducting interviews and was mindful that part of the success of interviewing would depend on his interpersonal and professional qualities. The use of pilot interviews and subsequent feedback was used to help in later interviews. All pilot interviews were recorded and listened to by the interviewer to gain a sense of the flow of the interview and the wording of the respondents. Feedback was also sought from the participants in terms of the interview flow and timing.
4.5.2 The order of interviews

Interviews were conducted across the various stakeholder groups subject to confirmation of availability of the interviewee. This approach enabled the researcher to explore ideas across the stakeholder groups e.g. the meaning of wellbeing/efficacy as conceptualised by service users compared with healthcare professionals or representatives from the pharmaceutical industry. Service users largely articulated efficacy in terms of social functioning. An extract from Service User 4 is given below.

Service User 4. “Oh, absolutely enormous, I couldn’t…I think two generations ago, I’d probably be a long time patient in a psychiatric hospital, it’s set me free, It’s given me back a normal life.”

Healthcare professionals and representatives from the pharmaceutical industry defined efficacy in more clinical terms. An extract from Industry Representative 4 is given below.

Industry Representative 4. “Does it help me achieve my treatment goals and the outcomes that I want to get. Which then tolerability is an element, safety is another element, interactions with other medication is a big element.”

However, when prompted to consider efficacy from the perspective of a service user, Industry Representative 4 responded with the following statement:

Industry Representative 4. “Does it do what it should do, is it safe, is it tolerable.”

As a result of conducting interviews across the stakeholder groups the researcher was able to link ideas from prior interviews and to develop this in future interviews.

4.5.3 Field notes

Interviews were recorded using a digital voice recorder and field notes were made to supplement the information obtained from the recordings. The use of field notes enabled the researcher to record what was seen or heard outside of the immediate context of the interview. This included references to non-verbal cues, the dynamics of the encounter, ideas for inclusion in later fieldwork and issues that might be relevant to the analytical stage. The use of field notes was instrumental in linking the ideas from previous interviews.
4.5.4 Location

All interviews were conducted in a time and place of the choosing of the interviewee. Email confirmation was sought from participants 24 hours before the scheduled interviews. Potential participants were sent a copy of the ‘consent to participate form’ and details of the research project. In the case of service users, they were sent a screening questionnaire to determine their suitability for participation in the study; in addition to the ‘consent to participate form (see Appendix 3, 4 and 6).

4.5.5 Management of data

The interviews were digitally recorded by the researcher and the audio recordings were transcribed (by an independent company) and checked for accuracy, independently of the researcher, by the project supervisors and work based supervisor. Electronic copies of transcripts and digital recordings were held on a password protected computer and the digital recordings have been archived on an encrypted computer to be kept for 5 years after the date of publication of this thesis.

4.5.6 Analysis of the data

Transcription

Transcription of interview data is one of the most common ways to prepare it for analysis (Bazeley & Jackson 2013, p. 23). Whilst it was the initial intentions of the researcher to transcribe the interviews himself, due to time constraints, and the fact that data collection and analysis within the study were being conducted simultaneously, it was necessary to employ a transcriber. In order to ensure that the transcriber chosen was rigorous and professional in their approach, advice was sought from University of Portsmouth colleagues about suitable transcription services.

Following the receipt of the research transcripts, to ensure similarity in transcription style across the whole dataset, the researcher, project supervisors and work based supervisor examined the interview transcripts to ensure accuracy by listening to the audio-recording and reading the transcripts simultaneously. As the Framework analysis is focused on the content, rather than the structure of participants’ responses for analysis, long pauses, interruptions and nonverbal communication (such as laughter) were noted within the text. All transcripts were supplemented with field-notes made during and immediately after the interview, for example noting background information and instances where views were given after the digital recorder was switched off.
**Computer assisted qualitative data analysis (CAQDAS)**

In order to manage large amounts of qualitative data in a systematic way and to ensure efficient retrieval of that data, a number of computer software packages have been developed. Whilst such packages help to assist with the data analysis process, they are not an alternative to researchers’ time, effort and skills but have been viewed as a means of enhancing the rigour of qualitative studies (Bazeley & Jackson, 2013, p. 4) and can encourage proximity of the researcher with the data (Pope, Ziebland & Mays, 2000, p. 115). For these reasons, following transcription of interviews into Microsoft Word, data were stored and managed using specialist software for qualitative data, NVivo-10 (Bazeley & Jackson, 2013, p. 63).

**Familiarisation with the interview**

The researcher thoroughly read and re-read each transcript, and listened back to the audio-recorded interviews to become familiar with the whole data set. Initial thoughts and impressions were noted in the margins of the transcripts; for example, where participants expressed exceptionally strong or contrasting views to their counterparts. This included one service user who expressed a strong view against the merits of clinicians trying to empathise with patients suffering from a psychotic type illness. This view contrasted with other service user participants who strongly expressed the need for clinicians to communicate closely with their patients. Familiarisation through reading and annotating the interview transcripts also enabled ready access to prior thoughts emerging from the reading of the transcripts.

**Coding**

The researcher coded all transcripts which were then independently checked by the research project supervisors. All relevant segments of text were extracted and coded using the left-hand margin to describe the content of each passage with a label or code. This could range from only a few words, to parts of sentences or whole paragraphs. The right-hand margin was then used to record more detailed notes and ideas. Below, in Table 4.2 an excerpt of open coding is presented. The participant, a representative of the pharmaceutical industry, talks about the role of prescribing guidelines.

**Data analysis**

The stakeholder groups were analysed separately to enable the unique themes from each group to be identified. This approach to the analysis enabled an understanding of the emergent themes from each stakeholder group and facilitated an understanding of the areas of concord and divergence between these groups. The analysis of data by stakeholder group also allowed for issues specific to the stakeholder group to be explicitly identified as part of
the analysis; an example of this is the theme that emerged from interviews with pharmaceutical industry representatives in which their relationship with the NHS was identified as a key determinant of their future commercial success in the United Kingdom. The approach of analysing the stakeholder groups separately is consistent with other studies (Lester et al., 2006, p. 418; Bolster & Manias, 2010, p. 159) where the findings from healthcare professionals and service users were also analysed separately.
### Table 4.2: Excerpt of open coding from the Pharmaceutical Industry interviews

<table>
<thead>
<tr>
<th>Codes</th>
<th>Industry 2</th>
<th>Notes and Ideas</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescribing Guidelines</td>
<td>Para 15, p 2: Prescribing guidelines should inform clinical best practice, they should be research-based, evidence-based guidelines, and they should give the opportunity for the patient as well as the clinicians to understand what the best treatments may be for their individual circumstances</td>
<td>Industry perspective on the role of prescribing guidelines. EBM patient as well as clinician engagement. Holistic in nature.</td>
</tr>
<tr>
<td>Evidence base</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Choice</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Financial control</td>
<td>Para 2, p 3: Standardisation is needed to a degree to help control finance ……the NHS at the moment isn’t an endless pit of money</td>
<td>Financial aspect of prescribing guidelines</td>
</tr>
<tr>
<td>Need for patient specific care</td>
<td>Para 2, p 3: It shouldn’t discourage individualised treatment; because I think it does at times</td>
<td>Need to balance guideline driven care with the needs of the individual</td>
</tr>
<tr>
<td>Influence on prescribing</td>
<td>Para 4, p 3: the industry influence that, the industry’s marketing attitude influences that I think other clinical endorsement, key thought leaders, key opinion leaders, I think sometimes it’s exciting and new, I think it’s….. I think it’s the this is something different from my standard practice – which excites a lot of people – as opposed to is it necessarily the best thing to do in the organisation.</td>
<td>Multifactorial factors that impact on prescribing practice. Internal and internal in nature.</td>
</tr>
</tbody>
</table>

The researcher labelled this as ‘prescribing guidelines’ with sub codes ‘evidence’ and ‘choice’. The researcher’s extracts emphasise interesting parts of the data that he felt were worth coding or noting.

*Developing a working analytical framework*

The researcher coded all transcripts which were reviewed by the project supervisors. Feedback was received regarding the assigned codes and a discussion was held in terms of why the codes had been interpreted as meaningful and the relationship to the research aims and objectives.

A set of codes was agreed on, each with a brief definition. This formed the analytical framework for that stakeholder group.

The example below, in Table 4.3 from the pharmaceutical industry interviews shows one category from the analytical framework with codes and subsequent description of codes.
Table 4.3: Extract of the Analytical Framework for the Pharmaceutical Industry

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NHS Working Practices</strong></td>
<td></td>
</tr>
<tr>
<td>Relationship between primary and secondary care</td>
<td>Barriers, gaps, advantages and drawbacks, working relationships</td>
</tr>
<tr>
<td>Knowledge of EBM</td>
<td>Education, and source of information on prescribing practice.</td>
</tr>
<tr>
<td>Primary/Secondary care interface</td>
<td>Instances of working together from two or more different disciplines, working across care sectors</td>
</tr>
<tr>
<td>Changes in working practices</td>
<td>Impact / outcome in terms of changes to working practice (e.g. Saturday clinics), changes to clinician workload, consultant travel</td>
</tr>
</tbody>
</table>

**Applying the analytical Framework**

The final analytical framework was applied to each transcript using Microsoft Word. In practice, this meant exporting the assigned codes from NVivo ready for indexing. Each meaningful passage from the data set was selected and coded with the final analytical framework. The analytical framework was subject to scrutiny by the research supervisors. Below is an excerpt from 'Industry 2' where the text is highlighted that is relevant to the theme 'NHS working practice.’ The interviewee discussed the limitation of GP understanding of mental health diagnosis and treatment and the commissioning of mental health services.

“psychiatrists and mental health professionals know the GPs don't know anything about it, so there’s a lack of trust”

“but I don’t think, you know, mental health, the mental health arena hasn't got there yet.”

**Charting data into the framework matrix**

Once all the data had been coded using the analytical framework, the data was summarised in a matrix for each theme using Microsoft Word. As illustrated below in Table 4.4, the matrix comprised of one row per participant and one column per code. A separate sheet was used for each category. The data were taken from transcripts for each participant and code, and inserted into the corresponding cell in the matrix.
NVivo proved to be invaluable at this stage, as it allowed for quick and easy retrieval of indexed data for specific codes within each transcript. All charting was subject to scrutiny by the research supervisors. The example below is an extract from the ‘NHS Working Practices’ matrix, with page and paragraph references.

Table 4.4: Pharmaceutical Industry Matrix: Extract from philosophy of care

<table>
<thead>
<tr>
<th>Role of guidelines</th>
<th>Patient-centred care</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>I2</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Para 15, p 2:</td>
<td>Para 2, p 3:</td>
<td>Para 5, p 3: I think it’s easier to see a harder outcome and a clearer outcome in physical-health settings than it is in psychiatry. So that changes things.</td>
</tr>
<tr>
<td>Prescribing</td>
<td>It shouldn’t</td>
<td></td>
</tr>
<tr>
<td>guidelines should</td>
<td>discourage</td>
<td></td>
</tr>
<tr>
<td>inform clinical</td>
<td>individualised</td>
<td></td>
</tr>
<tr>
<td>best practice, they</td>
<td>treatment; because I think it does at times</td>
<td></td>
</tr>
<tr>
<td>should be</td>
<td></td>
<td></td>
</tr>
<tr>
<td>research-based,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>evidence-based</td>
<td></td>
<td></td>
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Interpreting the data

Themes were generated from the data set by reviewing the matrix and making connections within and between participants and categories. This process was influenced both by the original research objectives and by new concepts generated inductively from the data. During the interpretation stage, an overview of individual descriptions was developed to identify themes which offered possible explanations for what was happening within the dataset. This process was repeated several times until themes were developed which transcended individual accounts. Ideas were generated, explored and fleshed out using analytical memos and discussion with the project supervisors. Notes were developed with sub-headings, including a definition of the category, specific codes that were directly related to it, a summary of the raw data, discussion of any deviant cases, and further points for consideration and comparison.
Chapter 5: Findings and discussion

5.1 Overview
The findings and discussion have been combined in this thesis. A brief overview of the findings is presented in diagrammatical form at the start of each section. The diagrams indicate the major themes and subthemes.

The findings from the study presented in this thesis will be discussed in five interconnected sections, each relating to a specific stakeholder group (pharmaceutical industry representatives, service users, pharmacists, GPs and psychiatrists). A total of twenty-five people were interviewed; five in each stakeholder group. The findings of this study are based on the Framework analysis of the interview transcripts. The findings will reflect the main themes that emerged from the analysis of the interview transcripts and will incorporate the use of verbatim quotes to illustrate those findings.

A final discussion section in this chapter relates the findings of the study to existing research to set them in a wider context.

5.2 Pharmaceutical Industry representatives
The interviews with the pharmaceutical industry were conducted over the period of December 2013 to July 2014. During this period, there was a major reconfiguration in one of the pharmaceutical companies with a portfolio in mental health. After initially declining to participate in the study, the author approached the company in question for a second time to determine if they would be interested in participating. Following the second contact, the company agreed to participate. The interviews with the industry representatives ranged from 46 to 78 minutes in length and were conducted in a variety of settings including NHS, industry, and a hotel location.

All interview participants from the pharmaceutical industry had a national or international role and included a Chief Executive Officer, Strategic Lead for Europe and Canada, UK CNS Business Head, Healthcare Marketing Manager and Head of Market Access for the UK. Interviews were conducted with senior industrial representatives to gain a more strategic perspective on the working relationship with the NHS and the potential for joint working. Industry representatives 1 and 5 had a prior history of working in the NHS. Using Framework analysis, three main themes, and several sub-themes were identified. These are presented in Figure 5.1
Figure 5.1 Pharmaceutical Industry Interviews: Main themes and subthemes

A discussion of these themes and subthemes generated from the data will now be presented which will include the identification of any relevant interrelationships between these. The identified themes are as follows:

- Philosophy of Care
- NHS Infrastructure
- NHS-Industry Relationship

The first theme, ‘Philosophy of Care’, incorporated the idea of tensions between the ideology of providing evidence-based care and the practicalities of delivering it in a ‘real world’ setting.

The second theme, ‘NHS infrastructure’, identified the pharmaceutical industry’s response to the reform of the NHS in England through the Health and Social Care Act 2012. This theme focuses on the implication for commissioning of services and its potential impact on drug utilisation. The theme also explores the relationship between primary care and mental health services.

The third theme focuses on the ‘NHS-Industry relationship’ and includes the historical context to this relationship. Market access is considered in the context of the pharmaceutical industry’s
need to understand and integrate with the changing NHS landscape. Finally, the theme takes into consideration new ways of working between the pharmaceutical industry and the NHS.

5.3 Philosophy of care
The first theme ‘Philosophy of Care’ incorporated the idea of tension between the ideal and reality of providing evidence-based care. The theme includes the subthemes of prescribing guidelines and their role in clinical practice as well as their implementation and limitations. The theme also includes the limitation of pharmacological clinical trial evidence in mental health and the potential impact on pharmaceutical sales in the context of the austerity measures facing the NHS.

5.3.1 Role of prescribing guidelines
In this study, as in other studies, representatives from the pharmaceutical industry identified the clear rationale for the role of prescribing guidelines in clinical practice (Charani et al., 2013, p. 193; Bauer, 2002, p. 139). The role of guidelines was viewed as embodying evidence to support medicines optimisation for the individual as illustrated by industry representative 2:

_Industry Representative 2 Para 15, p 2: “Prescribing guidelines should inform clinical best practice, they should be research-based, evidence-based guidelines, and they should give the opportunity for the patient as well as the clinicians to understand what the best treatments may be for their individual circumstances.”_

The notion of guidelines in the role of empowering and informing patients is also articulated in the literature. Woolf et al. (1999, p. 527) recommend the use of ‘consumer’ versions of guidelines, embracing a range of communication media and technologies. It is argued, that such guidelines can empower patients to make more informed healthcare choices and to consider their personal needs and preferences in selecting the best treatment option.

In the response from Industry Representative 5, the use of prescribing guidelines was set in the context of expert opinion and clinician freedom, however there was also an acknowledgement of the role of guidelines in the promotion of prescribing efficiencies.

_Industry Representative 5 Para 4, p.24 “I do think that guidelines are important still. I think it’s nice to have a unified opinion on what is the right algorithm, where you start because there’s efficiency in it.”_
The role of prescribing guidelines as a mechanism for cost containment was also identified in the following response:

**Industry Representative 2.** Para 2, p. 3: “Standardisation is needed to a degree to help control finance, the NHS at the moment isn’t an endless pit of money.”

The above comment identifies a potential concern for the wider pharmaceutical industry that might be looking to launch new drugs in the UK. In mental health the lack of significant developments in innovative drug treatments is likely to lead to fewer drugs being approved for use as NHS organisations will be looking to maximise cost-effective prescribing.

The use of guidelines in terms of organisational expectations was expressed by one industry representative.

**Industry Representative 4.** Para 11, p.5. “I think guidelines are very good at, or can be very good at saying you know we expect our prescribers to follow the guideline perhaps for eighty ninety percent of the time.”

This view contrasts with that expressed by consultant colleagues who were interviewed (see section 5.25.1), as organisational expectations were not considered of primary importance when prescribing for an individual patient.

Prescribing guidelines were identified as a needed resource for junior doctors due to their lack of clinical expertise.

**Industry Representative 5.** Para 12, p.24. “So I guess for junior doctors when people build on the expertise, that’s probably where guidelines make most value.”

The study by Pulcini et al. (2011, p. 85) demonstrated that the availability of prescribing guidelines was judged by junior doctors to be the single biggest intervention to improve prescribing practice, closely followed by educational interventions.
5.3.1.1 The limitations of prescribing guidelines

Representatives from the pharmaceutical industry made a clear distinction between the role of prescribing guidelines for GPs and consultant psychiatrists. Consultant psychiatrists were perceived as operating outside of the framework of prescribing guidelines, largely based on their knowledge and experience. GPs were perceived as being more amenable to the use of prescribing guidelines, perhaps because of their wider clinical prescribing remit.

*Industry Representative 2.* “I think GPs – in certain areas, it depends, it varies up and down the country – but in certain areas GPs welcome the guideline and the government’s approach around a reassurance they’re doing the right thing.”

“I think specialists tend to be more experimental, understandably, because it’s more individualised in their care.”

The limitation of prescribing guidelines in the treatment of the individual patient was further highlighted and set in a context of the need for individualised care.

In contrast to the view that GPs are more likely to adhere to prescribing guidelines, there was an acknowledgement that they are independent contractors and therefore in one sense freer to prescribe outside of organisation constraints.

*Industry Representative 4 Para 8, p.10.* “Whereas with GPs they you know; they are independent contractors who contract with the NHS.”

One of the identified limitations of prescribing guidelines was the lack of technological infrastructure and the implications this had for wider patient physical health monitoring, which was considered in the context of prescribing practice.

*Industry Representative 3 Para 2, p.13.* “You know erm, because its paper based maybe the physical health checks aren’t as regular as they should be.”

This is in keeping with the findings of Mitchell, Lord, & Malone (2012, p. 437) who in their meta-analysis concluded that patients were less likely to be prescribed cardiovascular medicines than their counterparts without enduring mental illness. Phelan, Stradins, & Morrison (2001, p. 444) noted that doctors who were uncomfortable with mental illness were reluctant to engage with patients about physical symptoms and unlikely to perform associated physical examinations.
A further limitation of the use of prescribing guidelines was that there were often assumptions that are inherent in their development with which the GPs may be unfamiliar.

Industry Representative 2. Para 8, p 13: “There’s a whole raft of questions sit behind what will get you to where, and there’s the assumption that everyone knows those questions.”

5.3.1.2 Implementation of prescribing guidelines

Industry Representative 4 outlined a proposed approach to marketing guidelines using a multidisciplinary educational outreach.

Industry Representative 4. Para 3, p.8. “Why would people buy into it you know, erm quite often if it’s a, if it’s a new product or it’s a specialist type of product that requires then transfer of responsibility to primary care then you know some degree of if I can use the word selling of the guideline by, by the people who are designing the guidelines so the, the GP prescribing lead that was involved, the consultant clinician who was involved, the pharmacist who was, so you know it’s almost a road show type of thing.”

The representative was formally a prescribing advisor for a PCT and therefore had first-hand experience of implementing prescribing guidelines in clinical practice.

Implementation was also considered from a national level in terms of either NICE or the Scottish Medicines Consortium (SMC). There was a concern expressed that despite national approval, a drug might not necessarily receive approval for use at a local level.

Industry Representative 1. Para 6, p.3. “I think one of the biggest issues, so even where you have a positive NICE or a positive SMC at a local level, sometimes that recommendation is poorly implemented.”

There are a variety of reasons why local implementation might not necessarily be readily adopted, and this can be related to the agreement of funding streams for the new medicine, or in some cases where the treatment should be initiated and the subsequent development of shared care protocols. Other factors that can impact on the uptake of a new medicine can also include the culture of the trust. A trust that is committed to implementing guidance is likely to be one that has an infrastructure for managing NICE guidance and governance arrangements for ensuring compliance.
One of the challenges from the industry to the wider NHS was set in the context of its methods of communication. In the extract below, the limitations of the NHS approach are outlined by Industry Representative 2.

_Industry Representative 2_ Para 2, p 12: “So there is an element of how are you communicating what information to whom and by which channel, so do you do channel management....”

Para 7, p 12: “Which is how the NHS communicates.”

Para 9, p 12: “They’ll communicate the message and think it’s landed, and then do no assessment of how it landed or what the issue was or what they could change to do something different. So they do it once and think it’s done, job done.”

With the changes to the NHS as a result of the Health and Social Care Act 2012, there is a need to review communication strategies both within the trust and across the local health economy to ensure that messages are delivered to the appropriate stakeholder. Channel management is a term which has its origins in marketing; it refers to the process of analysing, planning, organising, and controlling an organisation’s communication/marketing channels. Channel management involves the development of a strategy for communicating, agreeing the mechanism of communication, identifying the key stakeholders e.g. mental health commissioners, identifying the needs of the recipients of the messages (e.g. a simplified protocol for lithium management in primary care), coordination of a mechanism of communication and assessing performance by determining if the message has reached a target audience e.g. GPs in a particular locality and managing any potential conflicts that arise (Mehta, Dubinsky, & Anderson, 2002, p. 430).

The concept of channel management is particularly important to enable key messages to be targeted across the local health economy.

A limitation in the implementation of prescribing guidelines was linked to a poor technological infrastructure within trusts.

_Industry Representative 3_. Para 12, p.12. “I think it’s very hard if you don’t have; it’s classic things like the technology I mean if you look at psychiatrist’s paper based prescribing in the acute setting in trusts you don’t have electronic prescribing record.”

This limits the availability of prompts at the point of prescribing and, at present, an educational outreach approach is adopted across the trust to support the implementation of prescribing guidelines.
5.3.2 Patient centred care

The theme of patient centred care incorporates the subtheme of ‘Patient Understanding’. Industry Representative 4 identified the factors that are required from a patient perspective to support concordance. In particular, attention is paid to the importance of the medication fitting the lifestyle of the recipient.

*Industry Representative 4. Para 6, p.7* “that actually it is helpful, it fits your lifestyle, the patient knows that because the medicine is there, working on the chemistry of their brain, and the chances of them getting rebound symptoms or anything are minimised and therefore chances for them to go downhill.”

The review by Mitchell & Selmes (2007, p. 337) identified that medication regimens that cause disruption to lifestyle, or require special techniques are less welcome by patients and hence less likely to lead to compliance with treatment.

The concept of treatment was broadened beyond pharmacological intervention by Industry Representative 5 who identified treatment in the context of the patient’s best interest.

*Industry Representative 5. Para 2, p.2* “What based on their needs is the best treatment for them?” *Para 2, p.2* “And I say treatment, because we know it’s not just a pill.”

The idea of not limiting treatment of the service user to pharmacological interventions implies holistic care. In the interviews with service users, there are clear findings which support the need for a more holistic approach to treatment which is discussed in the context of the findings from the service user interviews (see section 5.9.4). The need for the holistic care of patients has been articulated by the RPS (2013, p. 5) as a partnership between healthcare professionals and the recipients of care. The desire to be considered in holistic terms was one of the findings of the Scottish Governments report into mental health recovery (Smith-Merry *et al.*, 2010, p. 130). The report also identified that service users wished to be provided with a range of treatment options extending beyond pharmacological interventions.
5.3.2.1 Service User understanding

The extract below highlights the importance of a service user’s understanding of the treatment they are prescribed.

**Industry Representative 4.** Para 7, p.6. “I’ve been a patient myself at one point, so when I take something I want to have belief that it’s going to make a difference to me.”

An important aspect of treatment in mental health is that the service user has an understanding of their diagnosis and the need for treatment. Such an understanding has been positively linked to adherence and satisfaction (Mitchell & Selmes, 2007, p. 339). Furthermore, service users understanding of the treatment they are prescribed has been related to the amount, type and timing of the information received (Ha & Longnecker, 2010, p. 42).

5.3.3 Evidence

The paucity of robust clinical trial data is widely acknowledged in psychiatry (Turner, 2013b, p. 457; Das, 2011, p. 17; Heres et al., 2006, p. 191; Jelinek & Neate, 2009, p. 218; Rafols et al., 2014, p. 35; Nierenberg, 2009, p. 529). Industry Representative 1 identified this issue in relation to other therapy areas she had previously worked in.

**Industry Representative 1.** Para 2, p.7. “There’s a few things I’ve noticed having worked in other therapy areas a lot is, one, is the data is poor in comparison with other clinical areas.”

There was also an acknowledgement that the pharmaceutical industry has a responsibility to produce more meaningful evidence for the NHS.

**Industry Representative 1.** Para 11, p.17. “It’s up to us as a pharma industry to show the NHS that our drugs drive the outcomes that they’re looking for, the efficiency outcomes that they’re looking for.”

Para 3, p.18. “it’s just that we need to show it, we need to stop doing clinical trials that don’t use outcomes that the NHS actually care about.”
The perspective of industry responsibility for clinical trial data was challenged by Industry Representative 2 with the following statement:

_Industry Representative 2. Para 7, p 9: “Because it’s not about, well, you improve your clinical trials, it’s about, well, how do we do it together.”_

This statement implies that there is a shared responsibility for the clinical trial data which would imply the idea of post-marketing evaluation.

While post-marketing evaluation of medicines is key to determine outcomes in a ‘real world setting’, it is often problematic to determine the benefits afforded by newer psychotropic medicines over above existing ones.

5.4  **NHS infrastructure**

One of the key concerns expressed by the pharmaceutical industry representatives was the implications for achieving market growth in the changing NHS landscape. There was an acknowledgement of the need to fully understand the commissioning infrastructure and key drivers at a local health economy level. This was also set in the context of the financial constraint facing the NHS and the need to demonstrate the value proposition of a medicine. This theme focuses on the commissioning of services, the interface between specialist services and primary care and the importance of the existing interrelationships.

5.4.1  **Commissioning**

Successive UK governments have promoted commissioning as the process through which the health service is planned and overseen (Miller & Rees, 2014, p. 145). Across the local health economy CCGs are responsible for the commissioning of the majority of clinical services. It is clear from the interviews that the pharmaceutical industry views the relationship with commissioners as key to its continued success. This was especially concerning for those who, at the time of the interviews, were looking to gain approval for new drugs.

_Industry Representative 3. Para 9, p.16. “You probably need as a pharma company to understand a lot about that local health economy and what goes on with commissioning, what are some of the key challenges they face.”_
The traditional block commissioning of mental health services was identified as a limiting factor in the care pathways that exist for service delivery. Payment by results in mental health is a relatively new concept, however, it has existed for at least a decade in acute physical care (Jacobs, 2014, p. 157). This was reflected in the comments by Industry Representative 1 below.

*Industry Representative 1*. Para 10, p.3 “I actually think mental health is probably 10 years behind even the physical health agenda with commissioning and making sure that there’s a joined up approach to commissioning.”

Industry Representative 1 identifies some of the potential reasons why commissioners might choose not to invest in mental health which is linked to the concept of investing to save and the delivery of the return on investment within the existing financial year.

*Industry Representative 1*. Para 3, p.5. “so for a commissioner, actually, I might be more tempted to go and spend on osteoporosis, so that I don’t get that falls rate, or whatever, and I get my in year money back, which is what it’s all about at the moment, isn’t it?”

The financial pressure on commissioning and provider organisations to achieve demanding financial in-year targets makes long-term investments unappealing in the current economic environment. The approach of dealing with the immediacy of the present financial demands can potentially lead to failure to achieve longer-term savings.

*Industry Representative 1*. Para 3, p.5. “It’s tough to make the decisions to invest heavily in mental health, I might not see that result for years to come.”

Furthermore, the failure to consider longer term investments is not limited to the NHS, but includes the pharmaceutical industry; which is reflected in a lack of mental health related research and limited psychopharmacological agents in development (Dix, 2015, p. 210).

Another factor that could contribute to the reticence to invest in mental health therapeutics is the paucity of evidence in mental health related clinical trials and outcome data that are understood by commissioners. Miller & Rees (2014, p. 152), in their study of mental health commissioning, concluded that there was insufficient knowledge and experience to bring about transformative changes in mental health service provision. This was further echoed by Gilburt, Edwards & Murray (2014, p. 33) who identified that there was limited focus and skills in the commissioning of mental health services.
5.4.2 Primary/Secondary Care

The continuity of care for a mental health service user is dependent on a number of factors including; accessibility to a range of services across a health economy, the provider of care, and the service user. Problems can occur when there are barriers at any of these levels, e.g. an appointment system that makes personal continuity difficult, or if the service user is not an effective negotiator or is disadvantaged; as is often the case in people with severe and enduring mental illness, e.g. patients suffering with bipolar disorder or schizophrenia (Reilly et al., 2012, p. 7). People with severe mental illness value continuity of care but the evidence suggests that it is poor for a substantial proportion of service users (Reilly et al., 2012, p. 10; BMA, 2014, p. 29).

The statement by Industry Representative 3 embodies the notion that GPs are not fully engaged in the treatment of mental health illness.

Industry Representative 3. Para 4, p. 17. “My view would be that general practitioners in primary care have left mental health services alone.”

There is an acknowledgement that GPs are not always willing to include mental health services in a primary care setting (Crawford, Carr, Knight, Chambers, & Nolan, 2001, p. 218). The reasons for a lack of engagement may be multifactorial, with studies showing that GPs lack expertise in treating service users with personality disorders, mental disorders associated with substance abuse, and serious disorders e.g. schizophrenia and bipolar disorder (Fleury, Imboua, Aubé, Farand, & Lambert, 2012, p. 2). In addition to a lack of expertise, inter-professional relationships with specialist services and their clinical caseload can also impact on the willingness of GPs to engage with mental health service users (Fleury, Bamvita, & Tremblay, 2009, p. 4).

The reluctance of GPs to engage with service users was identified by Industry Representative 1, who alluded to attitudinal issues underpinning the lack of engagement.

Industry Representative 1. Para 4, p.19. “GPs don’t like doing the mental health, so actually there’s a, kind of, hands off approach, they don’t want somebody with serious mental illness in their surgery, so quite happy to push them back.”
Traditionally, Community Psychiatric Nurses (CPNs) have been linked to mental health provider organisations and this is reflected in the comment by Industry Representative 1 who draws a comparison between the mental health, nursing delivery model and that of other therapy areas.

_Industry Representative 1. Para 6, p.19. “it is divided, you know, you look at other areas where community teams operate from out of the GP practice, you know, CPN teams don’t, why not?”_

A recent project in London has led to the deployment of CPNs in GP surgeries for service users who wish to receive care in a GP practice setting. The CPNs have been responsible for monitoring the physical and mental health of service users who have been assessed as clinically stable. The initiative in Newham has demonstrated a 90% retention of service users in primary care (Lind, 2015, para 2).

5.5 **NHS – Industry Interface**

The theme of the NHS-interface focuses on the relationship between the pharmaceutical industry and the NHS. This theme explores the issues of market access and new ways of working that is mutually beneficial to the pharmaceutical industry and the NHS.

5.5.1 **Access**

The issue of market access was discussed by industry representatives in the context of the changing NHS landscape and the austerity measures impacting on healthcare provision. This is set against a government report which identified that uptake of new medicines approved by NICE is just 11% of the average of other developed countries after one year, less than a third of the average after two years, and only half the average after four years (DBIS, 2015, p. 35). Industry Representative 3 identified the differing NHS tiers that have to be overcome by the pharmaceutical industry to gain market access.

_Industry Representative 3. Para 8, p.5. “I think when you get below that hurdle to local market access. I think the same term becomes very blurred and I think that’s dependent on the characteristics of the trust in the area that you are working in.”_

A source of frustration as expressed by the pharmaceutical industry was the various hurdles; national, regional and local infrastructures that exist for drug approval. Furthermore, the approval process was considered to be difficult to circumvent with conflicting opinions based on differing healthcare settings.
An example is given below of the variable approaches to drug approval by differing NHS organisations.

**Industry Representative 3. Para 5, p.6.** “There are certain trusts that adopted paliperidone and said it’s an unmet need therefore we recognise that this is a me too atypical without huge differentiation but because all patients respond differently we prefer to have it on our formulary.”

At present, across the West Midlands Mental Health Trusts, there is no uniformity of new psychotropic drug approval, and in effect, a post-code lottery exists which could justifiably be challenged by service user groups. The fact that this variability exists is often due to the financial constraints facing mental health trusts, which is often compounded by the need to demonstrate year on year efficiency savings on drug budgets.

In some cases, an investment in pharmacy services can often be expected to be offset by an efficiency saving in prescribing, for example an investment in an electronic prescribing system might be tied to the expectation of a reduction in some aspect of prescribing costs which might impact the uptake of newer medicines.

Industry Representative 3 demonstrated in his response a degree of understanding of the drivers of prescribing uptake that was not fully appreciated by fellow Industry Representative 5.

**Industry Representative 3. Para 9, p.6.** “While in certain other trusts that’s not gonna get on their clinical guidance for love nor money and it is seen as a cynical ploy by pharma.”

**Para 11, p.6.** “It’s just beyond NICE large degrees of variance.”

There was an acknowledgment by Industry Representative 5 that there was a need to understand in greater detail the role of CCGs and the issues at the local level and this prompted the following statement:

**Industry Representative 5. Para 4, p.12.** “It seems a bit ridiculous, because once the medicine has been approved... So there is service in place, it’s been approved, it shows the benefit.”
5.5.2 New ways of working

All representatives from the pharmaceutical industry expressed the need for joint working and in particular, new ways of working which in part was linked to the financial pressures faced by the NHS. The language used in the interviews was focused on demonstrating the value proposition of new medicines and targeting the unmet need in psychiatric therapeutics.

Industry Representative 1 expressed her vision for the restructuring of the existing pharmaceutical industry workforce model of regional managers, key account holders and representatives.

The revised model would work alongside the local health economy as an implementation team which would be multidisciplinary in nature.

A variant on the implementation team was outlined by Industry Representative 2 who proposed a model based on financial target setting between the industry and the local health economy.

Industry Representative 2. Para 5, p 6: “I actually think the way that we should do it is that we should come and sit down with the organisation, we should lay out all the evidence, we should talk through where we think the medication would fit, and then we would agree together how we would market it as an organisation.”

Para 7, p 6: “So there needs to be a little bit more agreement between the industry and the organisation.”

Such an approach is likely to identify the local needs and cost pressures and could adopt tailor made solutions for identifying the unmet clinical needs across a local health economy.

The proposal as outlined is consistent with the Department of Health who have recently published the ‘Accelerated Access Review’ in response to pressure from the pharmaceutical industry (DBIS, 2015, p. 35). The report outlines plans for speeding up the access to new drugs in the UK but recognises the financial pressure facing the NHS and proposes a model of incentivisation to adopt “new innovations.” Thus, the UK government is balancing the
financial constraints of the NHS with the need for income generation from the pharmaceutical industry which has, over the past decade, consistently generated a large trade surplus in the UK of £1.1 billion per annum (ABPI websitehttp://www.abpi.org.uk).

Industry Representative 4 was a previous NHS employee with a background in medicines management. His response to the existing mode of pharmaceutical industry sales at a local level was balanced with the need for a new patient-centred approach. As a former prescribing support pharmacist, Industry Representative 4 demonstrated an understanding of the cost pressures and the ease with which a prescribing budget could targeted for delivering financial efficiencies.

Industry Representative 4. Para 5, p.15. “I’m happy to sit with your finance director and see what his, what his efficiency targets might look like, I’m happy to bring my finance man with me to say you know, to be honest for this population in the West Midlands.”
5.6 Summary

The main themes that emerged from the interviews with the pharmaceutical industry representatives were philosophy of care, NHS infrastructure and NHS-Industry interface. The theme of philosophy of care incorporated the role of guidance in clinical practice and this was discussed in the context of its benefits, limitations and implementation and in particular, Industry Representative 2 identified poor communication practice within the NHS.

The changing NHS and the implications for commissioning was discussed by all industry representatives who considered this a challenge in view of their existing limited workforce.

It was acknowledged that new relationships would need to be developed across health economies, to strategically convey value proposition messages about new pharmacological treatments. There was a view amongst industry representatives that GPs were reluctant to engage in the treatment of service users with enduring mental illness and that communication between them and mental health services was poor.

Finally, the NHS-Pharmaceutical industry interface was considered in terms of access, which included market access and the need to engage with the new NHS. There was a concern expressed that local uptake of medicines by provider organisations was variable and that approval processes for new medicines was inefficient.

The pharmaceutical industry representatives recognised the need for new ways of engaging with the NHS which is typified by the quote below:

*Industry 4. Para 9, p. 17. “I’m trying to get us to go into partnership working and that for me, that is the way forward.”*
5.7 Service Users

Interviews with service users were conducted between December 2013 and February 2014. Service user 1 was a former NHS professional, Service User 2 was at the time of the interviews, a health care professional working in private practice; Service User 3 had experience of working as a counselor in mental health services and Service Users 4 and 5 had no experience of working for the NHS. Service User 5 however, was actively engaged in a mental health self-help group. Interviews with the service users ranged from 39 to 69 minutes and were conducted at NHS locations with the exception of one interview which conducted at a local charity setting.

Using Framework analysis, four main themes and several sub-themes were identified (see Figure 5.2).

![Figure 5.2 Service User Interviews: Main Themes and Subthemes](image)
The emergent themes are as follows:

- Choice and medication
- Response to medication
- Patient centred care
- Communication

The theme of choice and medication explored the extent to which service users felt involved in making treatment decisions about prescribed medication. This theme also explored the service user's medication taking behaviour and the factors that influence their decision making.

The second theme, response to treatment, explored the impact of medication on the individual and the benefits and limitations of treatment. The third theme, patient centred care, related to the support systems in place for the individual and the desire for holistic interventions as part of mental health treatment. The final theme, communication, explored the relationships between healthcare professionals and service users and the impact of the relationship on medicines optimisation.

A discussion of the themes and sub-themes generated from the data will be presented using Framework analysis, which will include the identification of any relevant interrelationships between them.
5.8 Choice and Medication

Service users had negative perceptions about the choices offered to them. They all recognised the difficulties that they faced and the lack of choice that was made available. It was apparent that the lack of treatment options was a concern for Service User 1.

Service User 1. Para 12, p.19. “You’re not presented with, well, there’s A, B, C. The side effects of A are…the side effects of B are…the side effects of C are.”

Service User 5 indicated a historical background to prescribing practice which was set against a context of not being offered treatment options.

Service User 5. Para 3, p.2. “I’ve been put on so many different medications for my eating, and I guess in the early days I wasn’t really given much choice.”

The lack of choice in prescribed medication was echoed by Service User 1. Despite the lack of available treatment options, the service user was the final arbiter of the decision to take the medication or not.

Service User 1. Para 1, p.20. “I mean, in my last lot of meds there wasn’t any discussion; it was like, I think you should take these, and that’s it.”

The deliberate decision not to take medicines is often termed ‘intentional non-adherence’ in the literature and is predicted by the balance of an individual’s reasons for and against taking medication (Mitchell & Selmes, 2007, p. 338). Intentional non-adherence is a common reason not to start a course of medication and is embodied in the response by Service User 5 below.

Service User 5. Para 2, p.4. “He prescribed this medication, gave me the form, and I knew when I was sitting in the room, I’m not taking it so what’s.”

The service user desire for more information is consistent with the findings of numerous studies in psychiatry which indicate that in addition to the need for greater information, service users want to be involved in decision-making (Gray, Rofail, Allen, & Newey, 2005, p. 36; Olofinjana & Taylor, 2005, p. 371; Duncan, Best, & Hagen, 2010, p. 12).
Service User 5 was clear in her role as the final arbiter of the decision to take medicines throughout the interview, and her responses, indicated that the doctor’s therapeutic goal was for her to achieve symptom remission.

Service User 5. Para 12, p.8. “But that’s only because I will make sure if I take it or not. They’re not going to physically come out and make me take the tablet.”

The fear of non-compliance was expressed by Service User 2 and considered in the context of compulsory hospitalisation under the Mental Health Act.

Service User 2. Para 7, p.4. “What I want you to take, because if you don’t take them, they say you’re non-compliant and then you get frightened that if you’re non-compliant, they’re going to put you in the hospital.”

5.8.1 Concordance

The concept of concordance is not synonymous with either compliance or adherence. Concordance does not refer to a patient’s medication-taking behaviour, but rather the nature of the interaction between healthcare professional and patient. Concordance involves mutual respect and understanding in pursuit of an ideal therapeutic alliance. The issue of concordance was discussed by all participants and it was clear that there was a challenge to achieve a concordant relationship with their healthcare practitioner. Furthermore, there was a stigma associated with non-compliance, which was discussed in the context of a response to a breakdown or non-existence of a concordant relationship.

In the following extract, Service User 2 indicated that she had made an informed decision not to take medication based on an aversion to the side-effects. Later in the interview, Service User 2 articulated the beneficial impact of medicines on her well-being which was linked to the absence of adverse effects (see Section 5.32.12).

Service User 2. Para 5, p.4. “I’ve got to admit, I’ve been known not to take my medication, because I start to panic about the side effects, you know, it’s, like, the liver and whatever else, you know, and you think, do I need it?”
Service user engagement in medication use has been identified as a way of improving outcomes, as well as minimising waste (RPS, 2013, p. 15).

A concordant approach to medication taking was detailed by service user 3 who led the process of exploring treatment options as a series of trials with medicines.

Service User 3 Para 5, p.4. “..then olanzapine, I tried some olanzapine. It didn’t stop the paranoia and I just put on a lot of weight, I was worried about diabetes, and all that...on reflection, I decided the Modecate would be better”

Para 5, p.4. “Second time I went to Dr xxxxxx and he was very fed up with me in a sense, for messing him around, because I changed my mind, but he did after a time, after about three weeks, let me go back on the Modecate.”

Para 5, p.4. “as I say, I’ve been extremely well ever since and able to function.”

This notion of trial and error in determining how the medication will impact on the individual is in keeping with the view of a concordant relationship as articulated by Deegan and Drake (2006, p. 1638).

5.8.2 Shared decision making
A preference for a cooperative relationship involving shared decision-making, choices that reflected the service users wishes, negotiated agreements and a sense of partnership, was alluded to by Service User 2.

Service User 2. Para 7, p.20. “It’s a bit pointless giving me a load of medication that I know I’m not going to take, I can sit there and I can agree with you and I’ll say, yeah, I’ll take them.”

As part of an ongoing discussion with psychiatrists, service users expressed the importance of considering alternative therapies which included: prayer, mindfulness, acupuncture and reflexology.
Service User 5 explained that over the years, she had become more vocal in her treatment options and this was typified by the extract below.

Service User 5. Para 2, p.3. “But, if you are more vocal and say, right, can we try this and this before the tablets, and then if...really tablets should be the last resort...then you can actually work with the consultants.”

The desire for a discussion about the rationale for prescribing and the proposed benefits of treatment was discussed in the context of what would be considered the ideal consultation by Service User 2.

Service User 2. Para 7, p.4. “Then a joint talk about why they’re going to suggest that I take this medication and why it’s going to be beneficial for me.”

5.9 Response to medication
The second of the four themes ‘response to medication’ will be discussed in the context of the perceived impact of medication on quality of life and activities of daily living. In particular, this theme examines the impact of the adverse effects of medication as well as the benefits in terms of well-being.

5.9.1 Adverse effects
When confronted with a range of possible adverse effects, it can be challenging for a service user to retain a sense of proportion about them. They are a reality for the service user that has to be confronted and managed, and discrepancies have been found between psychiatrists and service users in estimating the degree to which psychotropic medicines exert their adverse effects (Rettenbacher, Burns, Kemmler & Fleischhacker, 2004, p. 2871). At the same time, explaining a medication’s full side effect profile can prove difficult to achieve in clinical practice and may be regarded by doctors as impractical (Seale et al., 2006, p. 2866). The findings from a National Service User Survey for inpatients across DWMHT indicated that 33% of respondents reported that they had received comprehensive information about the side effects of prescribed medication. This figure was higher than the national average and indicated the limited information given to service users on the side effects of prescribed medication.
All participants in this study discussed the adverse effects of medication and the impact on their quality of life.

Weight gain was associated with the use of medicines in all interviewees. The potential for weight gain with medication was associated with decisions to not take medicines.

This finding is consistent with that of other studies which have identified that body mass index (BMI) status and distress over weight gain served as indicators for noncompliance with treatment (Weiden, Mackell, & McDonnell, 2004, p. 56; Fakhouri, 1999, p. S285; Seale et al., 2006, p. 2866; Oehl, Hummer, & Fleischhacker, 2000, p. 84).

Service User 5 discussed the impact of medication on suicidal ideation. In particular, she described how her depression was worsened by the prescribed medication.

The association of antidepressants with suicidal ideation and completed suicides has been increasingly documented (Doshi, 2013, p. 1; Lenzer & Brownlee, 2008, p. 533; Eyding et al., 2010, p. 8). In addition to the reports in the literature, patient information leaflets also outline the increased risk of suicidal ideation in young adults with comorbid psychiatric diseases.
The interview extract below identifies the lack of awareness of the service user regarding the suicidal ideation associated with the prescribed antidepressant.

*Service User 5.* Para 4, p.2. “So, I did take an overdose, because I couldn’t cope with it…….

So, I did it again. Because I didn’t realise it was the medication.”

Para 4, p.2. “A consultant there that actually treated me, and he was on that ward then, and he looked at the actual medication I was on, and he says, no wonder, he said, this may be the cause why you’re having these suicidal thoughts.”

Previously in the interview, it became clear that the service user had become more assertive with regards to prescribed medication (see Section 5.8.2) and viewed herself as the expert of her wellbeing, with the prescriber acting as her support, helping to provide information, to discuss options, to clarify understanding and preferences, and to ultimately support her autonomy. This model of consultation is consistent with the model as outlined by Deegan & Drake (2006, p. 87).

The physical health impact of prescribing for mental health conditions is outlined by Service User 4 who explained in greater detail, the specific physical health complications associated with the long-term use of lithium and the lack of focus of the mental health doctor in terms of modifying her treatment regime to account for the adverse physical health effects.

*Service User 4.* Para 14, p.2. “I took lithium for a long time, but I started having some nasty side effects from that.”

The extract from Service User 4 reinforces the notion of clinician-centric decision making with the best interest of the service user seen as resident in the healthcare professional.

*Service User 4.* Para 1, p.5. “Well, I’ve already got an impaired thyroid because of it, but then I started getting this psoriasis in lots of places on my body.”

Para 3, p.5. “I went to see a skin consultant, and he said, well, when he found out that I was taking lithium, that I really shouldn’t be taking it, because it was aggravating for the psoriasis.”

Para 3, p.5. “So, it took a letter from him to the psychiatrist before he started, sort of, taking me seriously, and trying to find an alternative.”
The best interest of individual should be holistic in nature, taking into consideration potentially distressing side effects of their intervention. There is a clear need to ensure that pharmacological treatment is tailored to the needs of the service user, taking into consideration the individual preference, lifestyle, supporting evidence, tolerability and ease of administration as well as cost. The pharmacy profession is key to the delivery of patient centred care, which takes into consideration the optimisation of medicines in the treatment of the physical and mental wellbeing of the individual (Jimmy & Jose, 2011, p. 157; RPS, 2013, p. 3).

5.9.2 Medication and wellbeing

Wellbeing for service users has been linked to choice and autonomy (Read, 2009, p. 156). Although service users desire freedom from the debilitating symptoms of mental illness, they typically place as much emphasis on a good quality of life (Perkins, 2001, p. 9).

Wellbeing was considered by service users in the context of their individual functioning and quality of life. This was described in terms of accessing mainstream facilities, activities and gaining a social identity following integration into mainstream leisure and employment activities.

Service User 1. Para 10, p.21. “Being well is being able to function; you know, being able to go out, being able to enjoy things.”

Service user 3 identified wellbeing in terms of symptom remission which is more in keeping with the medical model and reflects the goals of healthcare professionals (Sajatovic & Ross, 2009, p. 28).

Service User 3. Para 11, p.5. “Basically, the ability to rationalise things and to not have painful thoughts.”
The interviews explored what wellbeing meant to the individuals and how this was attributed, if at all, to the medication they were prescribed. Service User 3 articulated the benefits achieved from prescribed medication.

**Service User 3** Para 3, p.3. “It acts like an oil, to oil the cogs of my mind and it keeps me thinking straight."

Para 5, p.4. “As I say, I’ve been extremely well ever since and able to function.”

Para 3, p.9. “The deliverance has helped me in that way, but the Modecate I still need, because I know if I start to, my mind would crash and I would lose confidence and I would basically not be able to treat my patients and do my writing and things like that.”

The impact of medication on wellbeing was linked to compliance for Service User 3, who was a healthcare professional. By contrast Service User 1 acknowledged the benefits of medication but had decided to discontinue medication through fear of weight gain.

**Service User 1.** Para 4, p.9. “Because I’m not taking my medication, my mental health is shot.”

Para 4, p.10. “It’s irrational for the fact that mentally at the moment, I’m absolutely screwed up, but I don’t want to take the medication.”

Some service users discontinue treatment because they perceive treatment to not be as effective as they expect or that it is not required in the absence of presenting symptoms (Oehl *et al.*, 2000, p. 84). In this particular scenario, the respondent was a former healthcare professional and had an understanding of the role of medication in wellbeing. She exercised her right to discontinue treatment, fully aware of the potential impact on her mental state.

The impact of bipolar disorder was summarised by Service User 4, who explained during the interview that there was a family history of mental illness. Wellbeing was linked to both physical and mental health functioning.

**Service User 4.** Para 7, p.9. “Because having a manic episode is dreadful mental and physically dreadful, and, you know, I want to avoid that at all costs.”
The use of medicines was linked to an improved quality of life by Service User 4, who acknowledged the advances in drug treatment and the potential advantage this conferred on her compared with the previous generation suffering with similar illnesses.

_Service User 4_ Para 2, p.16. “Well, I’m a bit of an optimist so I would hope that they have enabled me to live a fairly normal life, or, at least, make my life less problematic.”

Para 2, p.16. “My life has been more...more...well, less challenging than it was for my grandmother, put it that way around.”

The impact of medication on wellbeing was also echoed by Service User 3.

_Service User 3_. Para 4, p.12. “Oh, absolutely enormous, I couldn’t…I think two generations ago, I’d probably be a long time patient in a psychiatric hospital, it’s set me free, It’s given me back a normal life.”

5.10 Patient centred care

The theme of ‘patient centred care’ will be discussed in the context of the identified patient support mechanisms and the need for holistic care which transcends pharmacological interventions.

5.10.1 Support system

The underpinning support mechanisms for service users varied and were linked to a number of variables, including a family network that was encouraging and non-judgemental, links to voluntary and third sector organisations and finally, links with healthcare professionals.

_Service User 4_. Para 9, p.9. “I have in the past anyway, managed the depressive episodes while I’m at home with support from care coordinators, et cetera.”

When service users described support services that worked for them in their recovery, they did not describe complex support systems of care, but personal, flexible, joined-up or coordinated responses that offered choices. Service users discussed the accessibility of treatment in terms of where it was delivered. They saw clear benefits in being able to receive the treatment within the setting of their own home; this finding is consistent with that of a Scottish study which looked at recovery from long-term mental illness, in which a key determinant of successful outcomes for service users was linked to the support received from healthcare professionals, voluntary organisations and peers (Smith-Merry _et al._, 2010, p. 92).
Service User 3, detailed an account in which he had made numerous requests for administration of his depot injection via the deltoïd muscle rather than gluteal; this would mean receiving an injection in the arm rather than the buttock.

_Service User 3_. Para 1, p. 7. “and I found a card from the patient care and liaison service, which deals with patient complaints and I got in touch with them and they got it sorted for me.”

He was able to access support via the trust patient liaison service which led to concordance with his wishes. This raises an important issue of service user awareness and the role of advocacy. If the wellbeing of service users is a primary concern, then healthcare professionals have to try and find a balance between their provision of, and advocacy for, immediate treatment needs on the one hand and their longer-term relationships with service users. Thus a simple enquiry might have mitigated a long-standing battle to enable the service user to receive his depot injection via the deltoïd muscle.

Service User 5 lived in isolation and had limited family support; she was therefore mindful of the impact of medicines on her ability to undertake her daily tasks.

_Service User 5_. Para 6, p. 4. “I can’t afford to have all these things going on, if there’s nobody there to support me and help me.”

5.10.2 Holistic care
Service users described how they wanted psychiatrists to take a more holistic view of them. Although they did want them to explore their symptoms, they required to be seen as more than a set of symptoms.

_Service User 5_. Para 6, p. 17. “So, I think, you’ve got to look at the person, not just the physical person, the, sort of, emotional person, look at their intellect, look at their whole being.”
Service users perceived a lack of empathy and understanding of their history and the circumstances related to their ill health and life situation. Psychiatrists were urged to listen to the needs of the service users and to respond holistically as typified by the following response from service user 1:

**Service User 1.** Para 4, p.24. “I think medicines play a part, but I think you’ve got to look at the bigger picture.”

Para 8, p.13. “Things like exercise and things like that, I think, are important. I think talking therapies are very important as well.”

This view was echoed in the Scottish review of mental health service users (Smith-Merry et al., 2010, p. 131); furthermore Ha & Longnecker (2010, p. 42) conclude in their review of doctor patient communication that doctors with better communication and interpersonal skills are able to detect problems earlier, prevent medical crises, and provide better support to their patients.

Medication was viewed in the context of a more holistic spectrum of interventions aimed at improving wellbeing.

**Service User 1.** Para 5, p.24. “I just think we need more information, we need more discussion, we need a more holistic approach to psychiatric medication.”

Interviewees indicated that non-medical forms of treatment or therapy (religious practice, talking therapies, counselling, and support groups) had been important factors in supporting their recovery.

**Service User 3.** Para 2, p.8. “I’ve been through a lot of prayer counselling and deliverance.”

These findings are consistent with that of Smith-Merry et al (2010, p. 130) who identified that service users were accepting of combining conventional and alternative therapies. In a more recent Scottish survey, respondents indicated that in addition to medication, family support and alternative therapies were considered as the most important factors supporting recovery (Reid, Hinchcliffe, & Waterton, 2014, p. 3).
Service users found non-pharmacological interventions useful in providing strategies and techniques to limit stressful states, however some of these processes were quite demanding emotionally.

*Service User 1. Para 1, p.13. “I’m doing a mindfulness course at the moment, which I’ve actually just been asked if I want to come off it, because I’m finding that quite difficult.”*

### 5.11 Communication

Service users discussed the impact of communication on their relationship with healthcare professionals, in particular nurses and psychiatrists. There was less focus on relationships with GPs and their interaction with them was based primarily on the management of physical healthcare. This finding is in keeping with the perspective of representatives from the pharmaceutical industry, who expressed opinions that mental health services are largely neglected by GPs (see Section 5.4.2).

Service users also expressed the need for relevant and timely information about prescribed medicines. There was a desire for information to be provided in a variety of ways and at differing stages throughout the recovery period.

It was clear from the interviews that service users thought that trusting relationships was an important aspect in their care and they spoke of the positive and negative experiences of the healthcare professionals they had worked with. The quality of the clinician–service user relationship has been demonstrated to be of great importance to service users and has been shown to influence attitudes and understanding of prescribed medicines (Coulter, 2002, p. 669; Laugharne, Priebe, McCabe, Garland, & Clifford, 2012, p. 82; Bolster & Manias, 2010, p. 163).

The discussion that follows will detail the key findings in relation to the communication with healthcare professionals and the information needs of the service users.
5.11.1 Healthcare professionals

Service User 1 was distrustful of doctors and at the time of the interview had been given the option to change consultant by her existing psychiatrist. In her interview, she discussed her history of mistrust of doctors which was based on her professional experience of working with them.

Service User 1. Para 11, p.4. “Well, he thinks I think we’ve got conflict, and that’s why he’s offered me a change of consultant.”

The issue of trust was one of the important elements in the relationship with health professionals and has been identified as a key aspect of the recovery process for service users (Bezreh, Laws, Taubin, Rifkin, & Wilson, 2012, p. 17; Borg & Kristiansen, 2004, p. 496; Ha & Longnecker, 2010, p. 42; Topor, Borg, Di Girolamo, & Davidson, 2011, p. 3).

Service User 5. Para 2, p.3. “Some consultants and doctors you can trust, and some health people are very, very good.”

Service User 5 went on to discuss some aspects of her relationship with her doctors that characterised a good relationship; these were demonstrable acts of compassion and concern.

Service User 5. Para 4, p.5. “My doctor, would come out of hours to me, if he was popping by he would just make sure, are you okay.”

Para 4, p.5. “Everything I asked for, they really tried their best to sort it out.”

The need for compassionate care was echoed in the findings of a review, Rethink (2006, p. 10), in which service users identified the need for healthcare professionals to be more caring and empathetic. Similarly, Borg & Kristiansen (2004, p. 502) found that service users were open regarding the diversity in what helps, and were willing to stretch the boundaries of what was considered the ‘professional’ role of clinicians. Thus compassionate care can be viewed as respectful and empathetic in nature and appreciating the strengths and difficulties faced by the individual (Cleary, Horsfall, & Escott, 2015, p. 563). However, compassionate care should enable the service user to make sense of their dilemmas and harness their strength to engender hope and develop confidence and a sense of self-efficacy.
By contrast Service Users 3 and 4 considered empathy inappropriate under certain circumstances which were related to the presentation of their illness.

**Service User 3.** Para 1, p.4. "I think if you’re psychotic, they have to be detached, because they can’t empathise completely, because they can’t agree with what you’re saying."

**Service User 4.** Para 7, p.3. "Too kind in a way as to be, like, very forgiving about some of my behaviours, if you like."

Para 7, p.3. "You know, some people are, sort of, too understanding about it whereas I’ve set myself up to behave as normally as possible."

This finding is contrasted by the findings of Ha & Longnecker (2010, p. 40), who identified empathy as one of the most important ways of providing support to reduce service users’ feelings of isolation and validating their feelings or thoughts as normal and to be expected.

The variability in the expectations of healthcare professionals would suggest the need to understand the individual service user’s beliefs about health and health care provision; furthermore, the clinician should understand that empathy can be misplaced under certain circumstances.

The relationships with nursing staff were discussed in the context of an initial point of contact and support. Service User 4 described the characteristics of her relationship with her CPN with whom she was close.

**Service User 4.** Para 1, p.11. “Because...well, he’s just so down to earth, and he just says it how it is.”

The role of the CPN was viewed as a service user advocate and supportive in a more immediate sense than that of psychiatrists. CPNs appear to be centrally involved in care and health education of any of the service users, which is consistent with the findings of Reilly et al (2012, p. 5) in which the primary contact for service users with enduring mental health illnesses was CPNs.

**Service User 3.** Para 5, p.9. “I’d first of all have a word with my CPN and I’d go and see Dr xxxxxx.”
The role of the GP in the care of service users was minimal and in one case, a service user was unable to be discharged from mental health services because of the refusal of the GP practice to accept him. This refusal occurred, despite the mental stability of the individual who was in full-time employment. The reason that the service user was not accepted by the practice was because the individual was receiving treatment with an antipsychotic depot injection and the practice claimed not to have the skills to manage the individual and the administration of his medication.

Service User 5 highlighted the time-constraints in communication with her GP and the impact this had in terms of holistic care.

**Service User 5. Para 8, p.6.** “When you do actually go in, you feel a bit guilty that you’re going to be taking a bit more time and they’re going to be waiting even longer, so it’s, like, you know, you feel like you can’t take up all their time.”

Service User 1 outlined her relationship with her GP in terms of her mental health status. It was clear from the interviews that service users did not view GPs as central to their care; this is consistent with the views expressed by representatives from the pharmaceutical industry (see Section 5.4.2).

**Service User 1. Para 2, p.14.** “My GP has categorically said that he will not discuss my mental health issues with me, but he also doesn’t discuss any issues that could be possibly related to bariatric surgery.”

The role of GPs was viewed as limited to annual reviews and involvement with physical healthcare. Service User 4 outlined the role of her GP in her annual review of her physical healthcare medication.

**Service User 4. Para 5, p.4.** “And they go through all my medication, because I have to take some for blood pressure.”

The care of service users with enduring mental illness is set against a review in the quality framework against which GPs are measured. In 2014/15, the national review saw the removal of the requirement of GPs to undertake annual monitoring of weight, cholesterol and glycaemic levels in patients with severe mental illness. This decision was fiercely criticised by GPs with a specialist interest in mental health and conflicted with the government attempt to redress the
disparity of physical healthcare in services users with enduring mental illness (Price, 2013, para 4).

5.11.2 Information
Service users discussed medicines information in the context of their needs and the sources from which information was obtained.

Service User 5 used the internet to obtain written information on prescribed medicines but expressed concerns about the veracity of the published information on the various websites and the potential industry influence which was concerning for her.

Service User 5. Para 4, p.3. “I read studies that have been done by people, probably like yourself, on the internet.”

The observation by Service User 5 is consistent with the finding of Read & Cain (2013, p. 429) who concluded in their review that drug company–funded websites were biased and could not be considered an objective source of mental health information, for the public or practitioner.

Service User 5 went on to explain that she adopted an approach of double checking the information received from one psychiatrist with a second opinion from another as a means of verification.

Service User 5. Para 8, p.3. “I will ask the psychiatrist, but I do like to ask more than one psychiatrist.”
Para 12, p.3. “Because you get completely different responses from different ones. Like, I have recently.”

O’Neill (2002, p. 9) identified that in an age of consumerism, service users may choose to scrutinise their doctors more closely and call the traditional trust afforded them into question. This is balanced against an acknowledgement by doctors that deception can be employed as part of a communication strategy in the best interests of service users. Explanation of adverse effects of medication, or specifying a diagnosis, presented particular difficulties, leading to delays in the disclosure of such information (Seale et al., 2006, p. 2867).
The need for timely information was expressed by Service User 3 and was set in a historical context of his early diagnosis.

*Service User 3. Para 14, p.10. “I think I would have liked more information at an earlier stage I think.”*

The need for more information, especially on the side effects of medication, was expressed by all service users and is consistent with the results of the national survey by Rethink, in which 45% (total n=2222) of service users believed that they did not have any choice in the type of medications they were prescribed, with 54% claiming to have received no written information about the side-effects of their psychotropic medicines (Rethink, 2006, p. 9).

The need for written and verbal information was expressed by all service users and it was acknowledged that there was a lack of consistency in this practice.

*Service User 1. Para 6, p.21. “I think you need the written that you can actually...you know, the one to...the face-to-face, but the written that you can actually go and read it in your own time.”*

This finding is consistent with the study by Olofinjana & Taylor (2005, p. 371) in which the majority of the participants felt that they were not given sufficient or, in some cases, any information about prescribed antipsychotic medication.

*Service User 4. Para 5, p.4. “My GP just said I think we need to change your medication, end of, there was no talking and I find that even with my consultant, they never explain to you the side effects that there could be so that you can make an informed choice.”*
5.12 Summary

Four main themes emerged from the interviews with service users; they were choice and medication, response to treatment, patient centred care and communication.

The theme of choice and medication explored the extent to which service users felt involved in the decisions about the medication that they were prescribed. The findings from this study indicate that service users did not feel fully engaged in making decisions about their prescribed medicines and this is consistent with the findings from other studies (Gray, Rofail, Allen, & Newey, 2005, p. 36; Olofinjana & Taylor, 2005, p. 371; Duncan, Best, & Hagen, 2010, p. 12).

The development of a helping and supportive relationship with professionals was often a pivotal turning point in service users' journeys. Overall, service users regarded demonstrations of empathy, trust, collaboration, shared power, respect, personal investment and kind gestures as most helpful in their therapeutic relationship with mental health professionals. However, the findings of this study differ from that of Borg and Kristiansen (2004, p. 502), in that limitations to an empathic relationship with doctors were also identified.

Service users obtained information from a variety of sources and were mindful of the need for continuous information on prescribed medication as part of their recovery process. There was a need for information to be provided in a variety of ways and a clear desire to understand the potential side effects of prescribed medicines.

Perhaps most importantly, service users desired a more holistic approach to their treatment than was provided by healthcare professionals. Which was echoed in the findings from other studies (Reid, Hinchliffe, & Waterton, 2014, p. 3; Smith-Merry et al., 2010, p. 130).
5.13 Pharmacists

Interviews were conducted with pharmacists involved in formulary and/or guideline development across the local health economy during January and February 2014. All interviews were conducted at NHS locations and ranged from 40 to 67 minutes. The interviewees included specialist mental health and non-specialist pharmacists. The aim of the interviews was to develop an understanding of the perceived factors that influence the implementation of prescribing guidelines in a mental health setting and to explore the factors that impact on prescribing. Non-specialist pharmacists were included to give a comparative context from outside the field of psychiatry.

The interviews with the pharmacists identified three key themes which are presented in Figure 5.3.

The themes identified from the study were:

- Philosophy of care
- Prescribing practice
- Working practice

The first theme, philosophy of care, explored the meaning of efficacy, from both the healthcare professional perspective, and what it might mean for a service user. The philosophy of care theme also explored the concept of patient centred care and shared decision-making and linked these ideals with the reality of the current service delivery model.

The second theme to emerge from the interviews with pharmacists was prescribing practice. This theme explored the drivers for clinician behaviour and the influences on prescribing across the health economy. This theme also explored the role of prescribing guidelines in clinical practice, their implementation and factors that govern the use of guidelines.

The final theme, working practice, explored prescribing across primary and secondary care and the communication issues that are inherent in current healthcare infrastructure. The theme also explored the potential or otherwise, of working with the pharmaceutical industry and the drivers influencing this.

A discussion of the emergent themes and subthemes from the interview transcripts will be presented using Framework analysis and will include any interrelationships between themes.
5.14 Philosophy of care

The philosophy of care theme took into consideration the meaning of efficacy from the healthcare professional perspective and what efficacy might mean to the individual as the recipient of care. The theme also included the importance of patient centred care and the role of healthcare professionals in a patient-centric service.
5.14.1 Efficacy - Service user perception

Efficacy was considered in the context of the healthcare professional perspective, the individual as the recipient of care and the organisational ideal by Pharmacist 1.

**Pharmacist 1.** Para 4, p.69. “And efficacy to me also means that you know...from a patient, it’s got to be quality of life...you got...you’ve got to have quality of life measures...you know...and I think from an organisation point of view, efficacy is then much broader because then you’re looking at population level.”

Efficacy was deemed to relate to the impact on the quality of life if considered from the service user perspective. This link between achieving normality without debilitating physical health related consequences is echoed in a number of studies (De Boer, et al., 2015, p. 681; Lester, Tait, England, & Tritter, 2006, p. 418; Olfson et al., 2000, p. 221).

This notion of efficacy was contrasted with Pharmacist 2 who considered service users to be idealistic in their expectation of therapeutic outcomes.

**Pharmacist 2.** Para 9, p.5. “Patients would just think about the effectiveness of it so they would like a consultation, a magic drug to end their problem.”

This finding is inconsistent with that of other studies which identified that service users expected some benefits from pharmacological treatment, but did not view it as curative (Lang, 2005, p. 584).

In the public campaign, Defeat Depression, many people were wary of taking antidepressants and in addition to the perceived limitation of pharmacological interventions, more than three-quarters of those who were surveyed believed that the medications were addictive (Paykel et al, 1998, p. 520).

Pharmacist 2 was employed by a neighbouring CCG and was not directly involved in patient care; whereas Pharmacist 3, was at the time of the interviews, an active non-medical prescriber and therefore engaged in direct patient care.

**Pharmacist 3.** Para 3, p.8 “Can it allow me to return to as much a normal life as possible without having any other er physical or mental consequences for my health?”
The differences in response between Pharmacists 3 and 2 may reflect the health economic perspective of prescribing practice in which the individual needs are not foremost in the day to day activities of Pharmacist 2.

Pharmacist 5 identified the balance between perceived efficacy and the burden of adverse effects.

**Pharmacist 5.** Para 1, p.2. “The big thing was that you won’t put on weight and you know we had some great patients, wonderfully controlled on clozapine erm but you know massive 20, 22 stone....

So it’s in their view was the clozapine efficacious. Well yes on one hand but on the other hand it came with some pretty heavy baggage.”

The impact of weight gain from psychotropic medication has been shown to be the most distressing adverse effect experienced by service users in the treatment of mental illness (Fakhouri, 1999, p. S285). Furthermore, the issue of weight gain with psychotropic medication was identified as a concern by service users in this study (see Section 5.9.1).

### 5.14.2 Efficacy - Healthcare professional perspective

Pharmacist 4 identified efficacy in terms of symptom control and stabilisation, but also made the distinction between symptom attenuation versus improved quality of life for the individual. Thus, the traditional healthcare professional perspective could be viewed in the context of service user control and the management of presenting symptomatology.

**Pharmacist 4.** Para 5, p.7. “but what was traditionally experienced of control...and stability of the patient verses quality for that individual patient concerned.”

Para 9, p.7. “so there might be a perception by the outsider that’s become an efficacious treatment because it’s taken away the pressures of that patient.”

This is contrasted with the service user perspective of efficacy, which was viewed in a wider context of wellbeing (see Section 5.9.2). Some service users have considered that the side effects associated with medication were so debilitating that they were not worth enduring and in addition, the only reason medications were used was to make individuals ‘fit in’ to society (Smith-Merry *et al.*, 2010, p. 145).
5.14.3 Patient centred care

The theme patient centred care includes the role of patient choice and the impact that this has on the therapeutic alliance with healthcare professionals as well as the implications for the wider health economy. The theme of patient centred care also included patient understanding of the medication that they are prescribed and the implication this has on healthcare professional communication in both the timing and format of information given to the individual. Finally, the theme of patient centred care takes into consideration concordance with treatment and the factors that impact on this.

5.14.4 Choice and medication

At the time of the interviews Pharmacist 1 worked for a CCG and had minimal direct patient contact.

Pharmacist 1. Para 5, p.2. “And you know a patient might think, actually I’ve looked on the internet, I want that drug (laughs) what they may not understand is actually there is a lot of caveats before we can have that drug so I think.”

As part of his role he was charged with ensuring that the prescribing budget for the health economy was managed. This role facilitates a health economic view of healthcare linked with distributive justice, which is concerned with the allocation of resources. Thus, in response to a question relating to the importance of patient choice, his answer focused on the limitations of choice and the potential lack of understanding of the factors that govern the available options. This response does not consider the role of the service user as a consumer but can be viewed as a provider-centric response in which prescribing costs are seen in isolation. There is a potential concern for such a restricted view as it may pigeon-hole prescribing costs as a stand-alone measure of cost effectiveness; while cheaper treatments in some circumstances may enable delivery of an ‘in-year’ financial target, they may lead to longer term hidden costs associated with the management of adverse effects.

Pharmacist 2, who was employed by a local CCG, describes the ideal scenario for a consumer based model of healthcare provision in which choice is fundamental.

Pharmacist 2. Para 5, p.6. “If there is a divergence of opinion, then the patient obviously has the opportunity to go and get a second opinion if they’re lucky.”
In practice, a consumer based model of care is not routinely achieved for several reasons which can include fear, especially during the early phase of mental illness.

Often service users will link their ability to make choices based on the prior experience of their illness with the effectiveness or otherwise of past treatments. Interviews with service users in this study (see Section 5.9.3) have confirmed that service users grow in confidence as a result of their experience with mental health services which is consistent with the findings of other studies (Adams & Drake, 2006, p. 91; Deegan & Drake, 2006, p. 1636; Laugharne et al., 2012, p. 502).

Service users considered a trusting relationship with clinicians a vital aspect of their care and the therapeutic alliance between clinician and service user is identified by Pharmacist 4.

Pharmacist 4. Para 6, p.3. “It becomes this relationship their prescriber and the patient ... and how much scope that prescriber through their discussion gives them that opportunity to express their desires and wants.”

Service users in this study recognised that the nature of their illness itself could undermine the relationship with their clinician and identified that continuity of care was also an important factor in developing a therapeutic relationship.

5.14.5 Patient understanding

Service users’ understanding of their diagnosis and the need for treatment is related to concordance and in turn concordance, satisfaction and understanding are all related to the amount, type and timing of information given (Mitchell & Selmes, 2007, p. 336).

The relationship between understanding and concordance was highlighted by Pharmacist 1.

Pharmacist 1. Para 7, p.6. “You see a lot of people who have been given medication who are not taking it for one reason or another, quite often they don’t quite understand what it was for in the first place.”

Studies have shown that service users can typically leave a consultation with a limited understanding of the rationale for therapy (Weiden et al., 2004, p. 52). Poor service user understanding of the rationale for prescribed medicines has been linked with non-compliance, and in particular, service users with low literacy may have difficulty understanding instructions (Praska, Kripalani, Seright, & Jacobson, 2005, p. 1441; Kochevar & Yano, 2006, p. S27).
This is particularly concerning because Dudley and Walsall have literacy rates below the national average, with the number of adults between 16-64 without any formal qualifications ranging from 21.6% in Walsall North to a low of 16.0% in Dudley south compared with a national average of 11.1% (Sedghi, 2011, para. 2).

Pharmacist 4 identified the need for patient understanding of the treatment they receive and the potential benefits of the intervention.

Pharmacist 4. Para 7, p.5. “The idea is that the patient understands why it is they’re taking the medication…or the need to take the medication…or what it’s going to help and benefit to the…”

5.15 Prescribing practice

The theme of prescribing practice incorporated the role of guidelines and their limitation in a ‘real world’ setting. The theme also explored the barriers and facilitators for guideline use.

5.15.1 The role of prescribing guidelines

The role of prescribing guidelines was viewed as a mechanism for facilitating consistency of prescribing across the local health economy. Thus, standardisation was deemed as an important mechanism for identifying individuals who were prescribing outside of evidence-based standards; a view which was also echoed by GP 4 (see Section 5.21.2).

Pharmacist 1. Para 10, p.1. “Having some sort of consistency with clinicians…it’s how you might show that you’ve erm incorporated national guidance as well as local sort of agreement.”

Para 11, p.1 “but there is an educational element to it as well a sort of clinical practice hopefully across the broader group of erm clinicians across you know both primary secondary care sector”

Para 12, p.1. “safety is within there; cost effectiveness has got to be part of that as well”

In addition to acting as a governance framework for prescribing practice, guidelines were viewed in the context of facilitating cost-effective prescribing which is consistent with the findings of Grant (2006, p. 28) who identified the role of prescribing guidelines as promoting prescribing efficiencies.

These observations are consistent with those of Weinmann et al. (2007, p. 421) who articulated that guidelines should lead to improved quality of care by decreasing inappropriate variation in clinical practice, in addition to promoting a standardised approach to prescribing.
The educational role of prescribing guidelines was identified by Pharmacist 4.

**Pharmacist 4.** Para 7, p.1. “It’s to guide consistency and delivery of medication and to support those who aren’t familiar with those areas as to what they should be prescribing or direct them to further reading to enable them to then go onto making a prescribing decision.”

The finding is consistent with that of Rashidian, Eccles, & Russell (2008, p. 232) in their study of the willingness of specialists and GPs to use joint treatment guidelines. Both groups agreed that these were useful as an educational tool, which could facilitate communication and improve harmonisation between primary and secondary care.

The educational role of prescribing guidelines for junior doctors has also been established and is found to be of value to them as they often lack the knowledge in specific specialities (Pulcini et al., 2011, p. 84). Despite the lack of prescribing knowledge of junior doctors, they are often responsible for much of the prescribing in an in-patient setting. The recognised need to support junior medical staff was identified across the West Midlands and this has led to the development of a regional e-learning programme to support them in prescribing more effectively and safely.

### 5.15.2 Barriers to guideline implementation

In the development of prescribing guidelines there are a number of factors that act as facilitators or barriers to implementation (Bauer, 2002, p. 149; Weinmann, Janssen, & Gaebel, 2005, p. 22). Pharmacists detailed in their interviews an understanding of the potential facilitators and barriers to prescribing guideline implementation. Aspects of professional culture were identified that could facilitate or discourage compliance with evidence-based practice.

#### 5.15.2.1 Cultural barriers

Pharmacist 1 highlighted the reluctance of mental health clinicians to engage in the process of formulary/guideline development.

**Pharmacist 1.** Para 3, p. 26,…“but your probably always going to have certain barriers with clinicians as well…erm I can remember in my early days certainly round here if I mentioned the F word, the formulary word to psychiatrists it was sort of...”
This was set against a backdrop of the then, lack of trust employed pharmacists and hence a lack of strategic leadership in medicines management. The author was the first full-time trust employed pharmacist and within the first year in post, began the development of a series of prescribing guidelines which was supported by medical colleagues and subsequently disseminated across the local health economy.

Pharmacist 1 identified the importance of the relationship with the originator of the guidance and the inclusion in the process of development.

**Pharmacist 1.** Para 2, p.14. “I think the key factor with any formulary has got to be your clinical engagement. I think if you don’t have your clinical engagement, you won’t have….it doesn’t really matter how good your formulary is…”

The observation by Pharmacist 1 is based on the engagement of end users and this is consistent with the study by Rashidian, Eccles, & Russell (2008, p. 149) in which high representation of secondary care clinicians was seen to undermine the credibility of the guidelines themselves, as they were perceived as seeing ‘filtered’ patients and were associated with a lack of appreciation of the patient–doctor communication in general practice. This creates a potential problem for mental health engagement with GPs as there are over 120 practices across the Dudley and Walsall boroughs and engagement at an individual practice level would be difficult to achieve. Thus, the implementation process is dependent on the communication mechanisms in place across the local CCGs and the integration of pharmacy teams at the practice level to reinforce key messages.

### 5.15.2.2 Availability of guidelines

A further barrier to guideline implementation was the ready availability of prescribing guidelines. This finding has implications in the mental health setting as there is a limited technological infrastructure to support prescribing.

**Pharmacist 2.** Para 6, p.10. “Right, availability you know- can you put your hand to the guidance at a glance, you know almost at a glance.”

The review by Cabana *et al.* (1999, p. 1461), identified that clinicians only used guidelines if they were readily accessible; furthermore, the study by Connelly *et al.* (1990, p. 356) found that clinicians accessed guidelines if they felt they would achieve a beneficial outcome in a limited timeframe.
5.15.2.3 Comprehension of guidelines

Another barrier to guideline use was the time required to read and understand the prescribing guidelines.

*Pharmacist 2. Para 1, p.9. “I guess that is another one. You know, time to read the guidance and understand it erm.”*

Pharmacist 4 in his response to the issue of implementation, alluded to the role of the area prescribing committees in disseminating information on prescribing guidelines which includes a variety of clinical forums.

*Pharmacist 4. Para 9, p.8. “There needs to be a forum for discussion circle so we have an area medicines management committee which has a prescribing sub-committee where these ideas, or idea.”*

5.15.3 Facilitators for guideline implementation

The broad categories that represent the facilitators for implementing prescribing guidelines from this study include: presentational considerations, promotional strategies, implementation strategies, resources, individual-level factors, organisational-level factors, and factors external to the organisation.

5.15.3.1 Presentation

Pharmacist 2, who was instrumental in the design and presentation of CCG prescribing guidelines identified the practicality of the guidelines which was linked to the ease of use.

*Pharmacist 2. Para 2, p.3. “But they generally are practical so that helps with the implementation of driving them forward and is a key factor.”*

The prescribing guidelines across the Walsall CCG are based on a simple design which guides the prescriber via the use of icons and includes details such as diagnosis, drug treatment, monitoring requirements and when to refer to specialists.

The need for readily readable and understandable guidelines is consistent with the findings of other studies (Cabana *et al.*, 1999, p. 1463; Forsner *et al.*, 2010, p. 7; Addington, Kyle, Desai,
& Wang, 2010, p.1328). Despite the need for clear and available guidelines, over simplification has been shown to limit clinician uptake (Cabana et al., 1999, p. 1461).

5.15.3.2 Shared care agreements

One of the facilitators put forward by Pharmacist 1 was that shared care agreements encouraged generalists to prescribe a drug they may have been unfamiliar with.

Pharmacist 1. Para 12, p.15. “When you go at a point of prescribing, that’s an ideal opportunity…. Erm…plus also you have things like you know I would for new drugs, particularly in psychiatry you may be looking at a lot more shared care agreements…”

Despite the view expressed by Pharmacist 1, there is evidence to suggest that the GP concerns are not primarily related to the familiarity of prescribing a given medicine, but rather the cost implication and potential impact on practice drug budgets (Horne, Mailey, Frost, & Lea, 2001, p. 192). The issue of cost containment is further compounded by the role of the practice based pharmacists who have a remit for delivering prescribing efficiencies.

In a review of shared care arrangements, Smith, Allwright, & O'Dowd (2007, p. 15) indicated improvements in mental health outcomes; for example, the proportion of patients recovering from depression and improvements in prescribing practice because of their use.

5.15.3.3 Clinical engagement

Pharmacist 2 identified the importance of a key opinion leader as part of an implementation strategy across the health economy. This idea was also considered by pharmaceutical Industry Representative 4 (see Section 5.3.12).

Pharmacist 2. Para 2, p.3. “made the adoption of guidelines easier if they were signed off by a clinician erm a clinician in secondary care for instance that was well thought of in primary care.”

Pharmacist 4 also identified the potential role of psychiatric specialists in championing guideline promotion across the local health economy.

Pharmacist 4. Para 13, p.2. “So if its medicine that was used in the older adults psychiatry, you’ll be then looking for an older aged psychiatrist to take a lead and evaluate that, and to really guide his peers or her peers, in adopting those guidelines.”
The use of peer-led championing of guidelines is reflected in the findings of the review by Flodgren et al. (2011, p. 14) in which the potential role of opinion leaders, alone or in combination with other interventions, was identified as potentially beneficial in promoting evidence-based practice. This conflicts with the findings of Rashidian, Eccles, & Russell (2008, p. 149) in which specialists were seen to undermine guideline credibility.

At present, psychiatrists are not actively engaged in the education of GPs across the health economy and there is a clear role for their involvement in an education outreach programme to improve awareness in psychiatric therapeutics which could be used as a wider implementation strategy for improved prescribing practice.

In addition to recommending the use of a key opinion leader, Pharmaceutical Industry Representative 4 also detailed a multidisciplinary ‘road-show’ approach to improving guideline awareness and implementation (see Section 5.3.1.2). This idea was also echoed by Pharmacist 3 who advocated the use of a similar approach.

**Pharmacist 3.** Para 5, p.7. “So how you roll it out to the end users and its almost erm you need to put in some leg work to allay any fears address any concerns.”

Forsner et al. (2010a, p. 6) in their study of facilitators and barriers to guideline implementation, identified the need for a baseline understanding of clinical practice. Regular audits of patient care delivered by the clinicians were reported to be of help in identifying ongoing important gaps between current care and guideline recommendations.

The role of mental health pharmacists in implementing and engaging clinicians was identified and outlined by Pharmacist 1.

**Pharmacist 1.** Para 5, p.28. “Erm, getting them engaged and working through medicines committees or subgroups etcetera...I think is really important...and probably...having the advent of mental health pharmacists....”
5.15.3.4 Access

One of the facilitators for guideline adoption was identified as access, which was dependent on the existing technological infrastructure. Pharmacist 1 identified the importance of technology as a means embedding evidence-based prescribing practice.

Pharmacist 1. Para 4, p.15. “but the whole point of formularies is that you’ve got to get that across to your person on the ground and this is where things like IT comes in.”

5.16 Working practice

Pharmacists discussed the working relationship between primary and secondary care and identified ways in which communication could be improved to deliver better patient care. The theme of working practice also considers the historical and potential future working relationship with the pharmaceutical industry and its relevance in the new NHS.

A key issue that was identified from this study was the communication between primary and secondary care; there were two main issues that were identified; first the speed at which information was disseminated from mental health services to primary care and secondly the quality of the information that is communicated. Pharmacist 4 summarised the issues of communication below:

Pharmacist 4. Para 3, p.13. “communication of the...the care plan...particularly around the prescribing.”

Para 3, p.13. “they’re not always a connect between the two in terms of immediacy of the information...so you have situations where patients have been sent for lithium blood checks in the community, because they can’t find the latest result they had from the hospital.”

While GPs are involved in the care of people with serious mental illness there is evidence to suggest that for service users in contact with secondary mental health services, the relational and cross boundary continuity of care are poor (Reilly et al., 2012, p. 1).
At present in the Walsall borough of the trust, prescribers have access to any blood monitoring results undertaken in primary care; but due to the limitations of the technological infrastructure, there is limited access in Dudley. The issue of transferring information between healthcare settings is identified in the following extract:

**Pharmacist 2. Para 1, p.4.** “So this transfer of information is still an issue and it has been for years, and you know we’re not going to solve it overnight erm obviously, the electronic transfer of information would be preferable in that situation to make sure that everyone has access to the full patient’s notes.”

With the current technological infrastructure, it is possible that service users will receive duplicate therapeutic drug monitoring, as well as biochemical monitoring, or potentially not receive appropriate monitoring. The problem of inappropriate monitoring has been identified by national audits such as the National Audit of Schizophrenia (NAS) and the Prescribing Observatory for Mental Health (POMH) audit findings (Patel et al., 2014, p. 507; Barnes & Paton, 2011, p. 330).

As part of a national move to improve the continuity of care for patients, changes to the 2015/16 NHS standard contract for NHS Trusts were introduced in October 2015. One of the changes required NHS providers to send discharge summaries within 24 hours of discharge to GP practices. These discharge summaries include information on prescribed medicines, which supports the timely supply of information to primary care colleagues, and the process of medicines reconciliation across the health economy.

### 5.16.1 Engagement with the pharmaceutical industry

All the interviewed pharmacists were suspicious of the pharmaceutical industry. They believed that the industry’s sole agenda was to increase its profit margins. Despite these views there was an acknowledgement of the inevitability of joint working with them.

Pharmacist 1 was particularly cynical of the pharmaceutical industry and at times had refused to engage with them.

**Pharmacist 1. Para 10, p.32.** “Well my stock answer on this with industry is that I don’t think the industry understand (laughs) the NHS that well at the moment…erm…”
The approach of the industry in identifying and using key opinion leaders is highlighted below in the comment by Pharmacist 4 and links with the idea of engaging with a senior clinician.

**Pharmacist 4.** Para 2, p.18. “What industry can be very good at, or maybe very bad at is picking off the people that they think are going to support them...the loudest voices, the biggest players who then put an extra pressure on committees to see things going through.”

### 5.16.2 Joint Working with the Pharmaceutical Industry

The inevitability of working with the pharmaceutical industry was expressed by Pharmacist 3, who linked the idea of trying to implement services with the resources available from the industry.

**Pharmacist 3.** Para 3, p.12. “I think in some way that we’ve got to go because... they’re the people who’ve got the money and can help you implement certain things so.”

Para 3, p.13. “I do think that you wouldn’t progress if you didn’t have them working with you so you know sometimes.”

One way in which the industry could support service users with enduring mental illness is to facilitate education to enable individuals to understand and manage their own health care, which has been demonstrated to be problematic for them (Mitchell *et al.*, 2012, p. 437; Weiden *et al.*, 2004, p. 55).

The potential support in achieving improved physical health was identified by Pharmacist 3.

**Pharmacist 3.** “I think there are things that...they can support if you want...some of the physical health monitoring stuff they can give you some sort of steerage...you will have to use the pharm industry to pay for some of the initiatives that you want to do.”

In a broader context, Pharmacist 5 identified the need to collaborate with the pharmaceutical industry to enable the UK to continue to access new drugs.

**Pharmacist 5.** Para 1, p.13. “If we don’t collaborate and don’t work with them and don’t start to develop things such as value based pricing, the UK in terms of sales, doesn’t matter. You know, it’s smaller than Florida, much smaller. So you know, why do we matter in the global scale of things? So if we don’t start to engage, I think there is a risk.”
Despite these concerns there is an acknowledgment that new drug therapies are not particularly innovative (Barral, 1995, p. 21; La Revue Prescrire, 2005, p. 73), and that there is a paucity of mental health research (Dix, 2015, p. 210) coupled with significant publication bias in psychiatric clinical trials (Abraham, 2009, p. 105; Read & Cain, 2013, p. 432; Turner, 2013b, p. 465).
5.17 Summary

The main themes that emerged from interviews with pharmacists were philosophy of care, prescribing practice and working practice. The philosophy of care theme incorporated patient choice and understanding and explored the idea of efficacy from the perspective of the pharmacist and their interpretation of what efficacy means for a service user. While there was a general acceptance of the need for patient engagement, this was set in a context of containing prescribing costs; thus, choice was viewed within the context of NHS affordability. There was an acknowledgement that service users needed appropriate and timely information about their prescribed medication and that this should be tailored to the individual’s needs.

Pharmacists had differing expectations of the role of guidelines in practice. The identified roles for prescribing guidelines were linked to, clinician support for decision-making, reducing variation in clinical practice and the promotion of cost-effective prescribing. Implementation of guidelines was also considered and barriers to implementation were linked to communication and underpinning technological infrastructures. Facilitators for use included the use of shared care protocols to support GP prescribing; ease of access to guidelines was considered an important aspect of implementation which was linked to the available technological infrastructure. The final theme of working practice explored working relationship between primary care and mental health services and considered the ways in which communication could be improved. This theme also explored the relationship with the pharmaceutical industry and the NHS and although pharmacists were somewhat cautious about engagement, there was some acknowledgement of the inevitability of a working relationship based on the financial constraints facing the NHS.
5.18 General practitioners

The interviews with GPs were conducted over the period of December 2013 to November 2014. Gaining access to interview GPs proved to be difficult and in one case the interview had to be scheduled six months in advance of the proposed interview date. All interviewees were participants in area prescribing committees and of the five, two were involved in the commissioning of mental health services in Dudley and Walsall respectively and had a specialist interest in mental health.

All interviews were conducted in the respective GP practices and interviews ranged from 33 to 81 minutes in duration.

Using Framework analysis three main themes and numerous sub-themes were identified which are presented in Figure 5.4.

![Figure 5.4 General Practitioner Interviews: Main themes and subthemes](image-url)
A discussion on the main themes and subthemes which was generated from the data will be presented which will include: interrelationships between themes and relationships with the findings from previous stakeholder group interviews.

The main themes to emerge from the interviews with GPs were:

- Philosophy of Care
- Prescribing practice
- Working practice

The first theme ‘Philosophy of Care’ incorporated the subthemes of efficacy and its relevance in clinical practice. This was related to the subtheme of patient centred prescribing practice which explored the patient related factors that impact on prescribing. Finally, the subtheme of shared-decision making was explored in relation to current prescribing practice.

The second theme of prescribing practice explored the role of prescribing guidelines in clinical practice in relation to evidence-based practice and medicines optimisation. The theme also explored the influences on prescribing practice.

The third and final theme of working practice explored the working relationship between primary care and mental health services. This theme explored the potential ways in which communication could be improved to deliver improved patient care.
5.19 Philosophy of care

The theme of philosophy of care explored the tension between the ideal and the reality of the impact of drug therapy on the individual and the intended outcomes of treatment from the perspective of the GP and patient; this was linked to patient-centred practice and treatments which reflected the individual as the recipient of care. The role of the patient in terms of the choice of treatment was explored in the context of current practice.

5.19.1 Efficacy

In this study efficacy, as defined by GP 3, was considered to be time-dependent and broader in context than symptom remission. The long-term efficacy of pharmacological interventions in chronic mental illness was called into question by GP 3 who had a specialist interest in mental health.

Her statement implies a time dependence, which is consistent with the observations of Moncrieff (2009, p. 151) who has called into question the long-term efficacy of psychotropic medication. Furthermore, some studies of antidepressants have failed to demonstrate the long-term impact on suicide rates compared with controls (Khan et al., 2001, p. 113; Mann et al., 2005, p. 2071). In a study of relapse rates for patients with schizophrenia following discontinuation of antipsychotic medication, only 13% (n=6 out of 45) of participants required hospitalisation; which has led some to call into question the long-term efficacy of antipsychotics (Gitlin et al., 2004, p. 1839). Efficacy was considered in terms of specific, agreed outcomes by GP 4.

GP 3. Para 5, p.5. “But really, for me I think efficacy would be to use everything effectively for the time being.”

GP 4. Para 3, p 7. “Well, any drug, efficacy for me, it comes down to what the problem is and what you're trying to get, and anything that brings you closer to your end point

So when you're looking at antidepressants per se, if somebody's depressed, I'm looking if they're less depressed.”

Para 4, p 7. “If they're bipolar I'm looking for them to have smaller swings and extremes of...well, it's mainly depression, their mood. And mostly it comes back from the patient's perspective in most drugs of what they feel.”

Para 5, p.7. “With other things whereby three weeks down the line somebody comes back and they feel a bit happier, it's very difficult to know that is the antidepressant. We assume it is in many cases. But often I think there's much more to it than just the antidepressant, the things that have affected their mood.”
Agreeing treatment strategies has been identified as an important aspect of creating a successful therapeutic relationship. Furthermore, on initiating treatment in primary care, treatment goals should be agreed and subject to periodic review (Ha & Longnecker, 2010, p. 42). Coulter, Roberts & Dixon (2013, p. 14) in their report on long-term conditions recommend that patients receive copies of their care plans as part of the consultation process.

A more recent onset of change in personal circumstances, employment, family support and education status have all been demonstrated as good prognostic indicators for remission of depression (Smith-Merry et al., 2010, p. 147) hence pharmacological treatments are part of a spectrum of interventions that can impact on the course of a depressive episode. Thus, the observation by GP 4, in not attributing the improvement in mood solely to an antidepressant is consistent with the evidence.

Patient centred care has been promoted as a way of engaging with the individual to optimise outcomes with the use of medicines (Royal Pharmaceutical Society, 2013, p. 3). This coupled with the rise in consumerism and the expectation by service users that their needs will be met, (Gabe & Monaghan, 2013, p. 203), should be balanced against the limitations of pharmacological interventions.

Thus, GP 3, who has a specialist interest in mental health, views the use of medicines as ‘limited’ in the treatment of mental health disorders, and articulates efficacy in terms of the mitigation of unwanted symptoms as determined by the patient and not the prescriber.

GP 3. Para 8, p.5. “And, I think the balance in the efficacy of a tablet is to reduce unwanted, by the patient not by the psychiatrist, unwanted symptoms.”

5.19.2 Patient centred prescribing

The limitations of prescribing guidelines in the context of the individual is highlighted by GP 2 and is related to the complexities of clinical practice; thus, the GP is required to individualise treatment based on the patient while at the same time being mindful of the implications for non-guideline based prescribing practice.

GP 2. Para 5, p.5. “and that when you’ve got a patient sitting in front of you there are all sorts of other things that may have to be taken into account.”
As previously identified in this discussion (see Section 5.4.1), in psychiatry the generalisation of research findings is often limited by poor supporting data and therefore harder to translate into clinical practice (Nierenberg, 2009, p.529).

The issue of individualised versus guideline driven practice is also identified by the consultant psychiatrists and will be discussed later in the psychiatrist section of the results and discussion (see Section 5.24.1).

The importance of information that is tailored to the individual and the quality of communication between the doctor and service user have been demonstrated to contribute to improved understanding and adherence to treatment (Ha & Longnecker, 2010, p. 42; Mitchell & Selmes, 2007, p. 339).

GP 4 identifies the importance of communication with the patient to support their decision-making process.

**GP 4. Para 7, p.20.** “You’ve got to always explain to a person what it's for, what the drug does and how it benefits them and it's got to be their choice to use it.”

**Para 2, p.21.** “But the drugs aren't a punishment for you, the drugs are a gift.”

The review by Sajatovic et al. (2004, p. 901), found that effective therapies in bipolar disorder occur in the context of long-term management, which incorporates a clear understanding of medications their risks and benefits, as well as education about illness awareness and self-management by the recipients of care. Thus, there is a need for GPs to understand the diagnoses and treatments so that there is continuity in the messages given to service users from specialist mental health services and primary care. This would also suggest the need for clear written communication from specialist services, which supports the role of the GP, in addition to shared-care arrangements.
GP 3 posits a scenario in which a service user is intentionally non-adherent with medication and which incorporates the utility theory, in which the individual has made a conscious decision not to take medication. This then leads to an exploration with the individual to understand why they have decided not to take the medication.

Distinguishing intentional non-adherence (missing or altering doses to suit one’s individual needs) from unintentional non-adherence (e.g. forgetting to take medication) is a critical step in determining pharmacological treatment success or otherwise (Mitchell & Selmes, 2007, p. 338). Intentional non-adherence is predicted by the balance of an individual’s reasons for and against taking medication. The predictors of non-adherence include: lack of efficacy, intolerable adverse effects, the desire to manage independently of medical intervention (self-efficacy) and disagreement with or mistrust of healthcare professionals (Crowe, Wilson, & Inder, 2011, p. 900; Mitchell & Selmes, 2007, p. 339; NICE, 2009, p. 7).

Seale et al. (2006, p. 2868), in their study of psychiatrists, reported that patients were, at times, dishonest about their medication taking behaviour; however, there was equally an acknowledgement by psychiatrists of strategic withholding of information about the side effects of medication, thus departing from the ideal of a therapeutic alliance.

The communication and interpersonal skills of doctors are linked with early detection of potential problems which, in turn, can lead to the avoidance of a costly hospital admission and provide better support to service users.

GP 5. “but then having a consultation with a patient and another 20/30 percent of the people the problems have been resolved talking to the doctor.”

This may lead to higher-quality outcomes and better satisfaction, lower costs of care, greater patient understanding of health issues, and better adherence to the treatment process (Ha & Longnecker, 2010, p. 42). The provision of a patient centric consultation is also set in the context of a limited timeframe for engagement with the individual and this was a concern that
was expressed by service user 5, who acknowledged that she would feel guilty to ‘take up the doctors time’ (see Section 5.10.1).

5.20 Prescribing practice

The theme of prescribing practice explores the role of prescribing guidelines and their impact on clinical practice as well as the factors driving their use. The theme also explored the factors that influence prescribing practice in primary care.

5.20.1 The Role of prescribing guidelines

The role of prescribing guidelines as decision support tools for practitioners was identified by GPs and was viewed as a mechanism for promoting evidence-based practice. They were viewed as part of a mechanism to improve the quality of care and identifying outlying prescribing practice.

\textit{GP 1. Para 4, p.2. “I think prescribing guidelines basically will help a GP to improve the quality of prescribing, based on up to date current medical knowledge, which has been tried and tested, in general, and the GP will adhere to good practice.”}

Field & Lohr (1990, p. 58) cite the role of guidelines in supporting patient decisions about appropriate health care; however, despite this notion, none of the GPs identified the role of prescribing guidelines in the context of patient support.

There was an inherent expectation that specialists had reviewed the evidence and that the prescribing guidelines represented the distillation of that evidence.

The theme of consistency in prescribing practice was also identified by GP 2.

\textit{GP 2. Para 3, p.2. “I think it provides a consistency throughout the borough and the practice and obviously, the clusters of practices.”}

\textit{Para 3, p.2. Enables us to hopefully manage people just in primary care as well, often without perhaps needing to make secondary care referrals.”}

\textit{Para 3, p.2. “but I suppose in the remit of drugs and psychiatry in particular it’s useful to have a sort of framework of regular review.”}

The use of prescribing guidelines was viewed as a mechanism for review of patients with enduring mental illness in a primary care setting. This is particularly important for primary care clinicians who are responsible for treating individuals with enduring mental illness.
Despite the use of prescribing guidelines; continuity of care across health economies, remains poor for a substantial proportion of service users (Reilly et al., 2012, p. 5). Thus, guidelines were viewed as a mechanism to facilitate communication between mental health services and primary care.

GP 3 detailed the tension between her own experiences and the guideline recommendations which was alluded to by GP 1, who also had a specialist interest in mental health.

**GP 3. Para 2, p.2.** “and I think really guidelines are there to assist specifically those who may not be experienced in the field.”

GPs viewed consultations with patients as more complicated than their portrayal in guidelines; which is consistent with the findings of Carlsen, Glenton, & Pope, (2007, p. 973), in which guidelines were viewed as lacking flexibility to take into account the complexity of individual circumstances, such as multiple diagnoses, adverse effects, and individual preferences.

GP 4 identified prescribing guidelines as a governance framework for prescribing practice, which would imply that objectively, arrangements are in place to monitor prescribing practice; however, while this is important there is an inherent problem of trying to identify objective quality indicators to demonstrate clinical improvement in mental health.

**GP 4. Para 4, p.2.** “the chance of us going down and looking at the direct literature which tells us about the studies that promote these drugs in the first place are going to be really, really difficult for us to get access.”

### 5.20.2 Prescribing influences

**Patient pressure**

GP 3 reflected in her comment that patients were overly optimistic about the benefits of pharmacological interventions. This statement is similar to that of Pharmacist 2 in which patients were considered to expect a ‘magic drug’ (see Section 5.14.1).

**GP 3. Para 7, p.7.** I think patients for them, you know, can place too much optimism in a medication.”
Despite these perspectives of the perceived overt optimism in pharmacological treatment, there is contrasting evidence to suggest that GPs can misinterpret patients’ expectations with regard to prescribing, and where consultations are conducted in a paternalistic manner, there can be a tendency to fail to elicit patients’ expectations or unvoiced agendas; which can subsequently result in unnecessary prescribing and poor adherence (Little et al., 2004, p. 3).

The findings contrast with that of the study by Lewis & Tully, (2011, p. 8) in which hospital doctors reported pressure to prescribe from patients, relatives, or carers and in some cases gave in to demands to maintain good relations with patients. The complexity of experiencing pressure to prescribe also stemmed from circumstances particularly relevant to secondary care, such as prescribing to avoid conflict in the multidisciplinary team.

**Key Opinion Leaders**

Adoption of guideline recommendations by specialists have been shown to be positively influenced by key opinion leaders (Tansella & Thornicroft, 2009, p. 284). Although Rashidian et al. (2008, p. 149) identified a limitation to this approach as specialists were viewed as seeing ‘filtered patients’ from the GP perspective. The idea of specialist promotion of guidelines reflects the comments made by Pharmacist 4, who advocated a role for guideline champions in specialist clinical areas as a means of promoting good prescribing practice (see Section 15.14.3.3). GP 2 identifies the role of peer to peer support for prescribing of a new drug.

**GP 2. Para 9, p.2.** Yes. Yes, I think peer to peer is quite useful. You sort of naturally talk to other doctors that might have more experience with a particular drug and, you know – oh, this has been quite good.”

GP 3 identifies the practice of strategic industry influence on senior clinicians in the CCG with a view to facilitating increased market access for their products.

**GP 3. Para 9, p. 16.** “I wonder really if there’s a sneaky thing about it, because if you’ve formed a relationship with, say, the prescribing leads for the CCG, then when it comes to arguing about which antidepressant, whether subconsciously they’re all affected.”
A further influence on prescribing was identified via the role of the practice pharmacist by GP 2.

**GP 2. Para 10, p.4.** “And also possibly a number on that where, if we’re unsure about something we can go for advice, so the pharmacy advisers…”

The pharmacist was viewed as having specialist knowledge and providing relevant medicines information. GP 4 identified the role of the pharmacist in reviewing the clinical trial data and distilling it for use in a care-pathway.

**GP 4. Para 4, p.2.** “Big pharmacy team in Walsall and they’ll actually look at the research, they’ll review it, they’ll come up with a sensible pathway and that gives us a bit of security that if we’re within that pathway we’re safe.”

It was clear that the advice received played a major part in influencing prescriber decision making; prescribers directly acted on the advice provided, and in many instances, complied explicitly with the advice given.

The extract from GP 5 indicates the supporting role of the pharmacist and their potential to influence prescribing practice.

**GP 5. Para 2, p.9.** “I am doing it jointly with the help of my pharmacist in the practice. If he wasn’t there I won’t be prescribing anything.”

This finding is consistent with other studies that have identified the role of pharmacists in influencing prescribing patterns in primary care (Rutter, Fitzpatrick, & Rutter, 2015, p. 311; Lowrie, Lloyd, Mcconnachie, & Morrison, 2014, p. 7).

### 5.21 Working practice

The theme of working practice explored the relationship between primary care and mental health services and the role of specialists in sharing information and education of primary care colleagues.

#### 5.21.1 Interface working

GPs indicated that communication with mental health services was poor and that there was a lack of responsiveness to resolve emergency needs that might circumvent hospital
admissions. Furthermore, GPs described a ‘disconnect’ from mental health services and highlighted the need for meaningful engagement that would embrace numerous ways of communication.

The comments from GP 1, who is responsible for commissioning mental health services, highlighted these concerns.

**GP 1.** Para 2, p.9. “And I think the communication between secondary and primary care has to improve.”

Para 2, p.9. “It has to be fast, it has to be relevant, it has to be evidence based, and it has to be more often, more frequent.”

Para 2, p.9. “I personally think we should use all forms of communication, telephone, email, fax...personal face-to-face talk, with the secondary, primary care clinicians, like a consultant, GP forum for example.”

In a study by Horne et al. (2001, p. 190), similar concerns were expressed by GPs regarding the communication of shared care arrangements and, in particular, the delay in receiving communication from specialised services which was perceived to have serious implications for patient care.

Given the prevalence of mental illness, GPs are increasingly called upon to provide appropriate treatment that psychiatric services cannot provide alone. GP 2 highlighted the issue of trying to contact the mental health services for individual patient-related and wider system-related issues.

**GP 2.** Para 9, p.7. “As a GP in Dudley I don’t feel at all connected to DWMH whatsoever.”

Para 5, p.8. “When we’ve had issues and we’ve tried to meet with our local primary care mental health manager we’ve been stonewalled.”

This finding is particularly concerning as the GP has a role of liaison with multiple agencies on behalf of patients, and typically, patients find engagement with primary care less stigmatising than mental health services and more comprehensive, since it manages physical ailments along with mental health disorders (Fleury et al., 2012, p. 2). It is therefore important that mental health services support GPs to maintain the wellbeing of patients in primary care and this was identified as an area for development by Consultant 2 (See Section 5.26.1).
5.21.2 Knowledge and skills transfer

GPs expressed differing degrees of knowledge about mental health pharmacological interventions. GPs 1 and 3 had a remit for mental health service commissioning and therefore claimed to be more knowledgeable in this regard.

A number of barriers have been identified in relation to diagnosis and treatment of psychiatric disorders in general practice which includes a lack of knowledge, skills, and interest, and negative attitudes to mental health (Cook & Wang, 2010, p. 7; Fleury et al., 2009, p. 9; Jorm et al., 2012, p. 1036).

GP 5 identified his lack of knowledge with respect to psychopharmacological treatments.

**GP 5.** Para 8, p.13. “I am open to you; I don’t have too much knowledge about mental health medication.”

This lack of understanding was echoed in a study by Fleury et al. (2009, p. 6) in which only a minority of patients were managed primarily by their GP; which was attributed to their lack of expertise in treating such patients.

Siriwardena et al. (2010, p. 731) identified a lack of knowledge in hypnotic use and GPs were found to believe incorrectly that z-hypnotics were safer to prescribe than their older benzodiazepine counterparts, despite the lack of evidence to the contrary. The study also identified that GPs had poor knowledge of psychological therapies for insomnia or their possible clinical benefits.

GP 4 discussed the use of audit as a mechanism for measuring compliance with prescribing guidelines.

**GP 4.** Para 1, p.15. “I'm not saying at a punishment level, but I'm saying at a level just for education to say you prescribe this all the time for this condition, wouldn't you be better trying this one.”

This could be used as a mechanism for delivering education on prescribing practice. Grimshaw et al. (2004, p. 33) in their review of guideline implementation strategies, concluded that audit and educational input were shown to have modest effects on implementation on practice; however, there are two important factors that were not taken into consideration by
this review. The first is the omission of implementation studies in mental health and the second is the financial constraints on the NHS which can also act as a catalyst for changing prescribing practice.

In a more recent study comparing interventions to enhance prescribing efficiencies, Godman et al. (2010, p. 718) demonstrated that audit, in combination with other interventions, impacted on prescribing practice.

GP 3 recommended that routine correspondence be adapted to include an education tool to empower GPs’ understanding of diagnosis and treatment. Such an approach is a variant of educational outreach. This links with the idea of GP 3 to retain more patients in primary care rather than referring into mental health services.

GP 3. Para 5, p.2. “And, that’s what’s needed, and when specialists take time out to actually write educationally within a patient’s notes.”

Para 5, p.3. “In this practice, we are now going down the line quite heavily because of commissioning, is to actually seek advice rather than to refer.”

This view was unique to her and reflects a new way of thinking amongst those interviewed; it is consistent with a tariff based model of payment for mental health providers in which it is likely to be more cost effective to treat patients closer to home.
5.22 Summary

One of the main themes that emerged from interviews with GPs was philosophy of care which explored efficacy from the perspective of the GP and the perceived patient expectations with respect to pharmacological interventions. Efficacy was considered in a broader context than pharmacological interventions and was considered as time dependent. Furthermore, the theme explored the tension between guideline-driven and personalised care. There were concerns for the individual patient’s needs coupled with the potential limitations of guideline-driven care for complex patients.

The second theme of prescribing practice incorporated the role of prescribing guidelines and influences on prescribing practice. Prescribing guidelines were viewed as a governance framework against which GPs could be assured that their prescribing practice was evidence-based. In addition, prescribing guidelines were considered as an educational intervention in which clinical trial data were distilled into a usable format to guide practice. There was an acknowledgement that guidelines were limited in certain patient groups and of variable benefit, dependent on the GPs’ knowledge-base. Influences on prescribing practice were driven by pharmacists who were viewed as specialists and advisors; in addition, peer recommendation was also considered as a potential influence on prescribing practice.

The final theme of working practice explored the relationship between GPs and the local mental health trust and the role of knowledge and skills transference between mental health services and primary care. There was a consensus that communication between primary care and mental health services was poor. The main factors contributing to this view were the lack of rapid access to mental health advice from within the trust and the perceived poor communication and integration with training and education.
5.23 Consultant psychiatrists

Interviews with consultant psychiatrists were conducted over the period of December 2013 to April 2014 and included a Medical Director, an Associate Medical Director, a Clinical Director and two general Adult Psychiatrists. All interviews were conducted on NHS sites at the request of participants. Interviews ranged from 46 minutes to 67 minutes.

Using Framework analysis, three main themes and several sub-themes were identified see Figure 5.5.

The emergent themes were as follows:

- Philosophy of care
- Prescribing practice
- Working practice

As with the GP group, the theme of ‘philosophy of care’ explored the tension between the ideal and the reality of the impact of drug therapy on the individual. The theme also incorporated the psychiatrist views on efficacy and their interpretation of the service user’s perspective in this regard. This theme also explored patient centred care and in particular, the role of shared decision-making as part of the consultation process.

The second theme, ‘prescribing practice’, explored the role of prescribing guidelines in clinical practice in relation to evidence-based medicine and the tension between guideline driven care, clinical expertise and clinician freedom. The theme also explored the influences on prescribing practice including the pharmaceutical industry, key opinion leaders and clinical experience.

The third and final theme of ‘working practice’ explored the working relationship with primary care services. This theme also explored joint working with the pharmaceutical industry and the impact of drug development on patient care.
5.24 Philosophy of care
The philosophy of care theme took into consideration efficacy from the perspective of the psychiatrist and what they thought efficacy might mean to the individual as the recipient of care. The theme also included the extent to which psychiatrists felt that shared decision-making was relevant in clinical practice.

5.24.1 Efficacy
Efficacy was described in holistic and patient focused terms by Consultant 2 and all respondents associated efficacy with tolerability for the individual. This is an important finding since the relationship between the clinician and the individual is one of the most important variables in the decision to take prescribed medication.

Consultant 2. Para 5, p.18. “Feeling better and their lives being better, I guess. An awful lot of people, that’s what matters. It doesn’t matter how they rate on a scale, it matters what their relationships are with the family, at work, whether they’re able to do things that they enjoy doing, that they’re able to enjoy life, whether they’re able to go out on their own and this sort of...goals that are about how they’re functioning.”
Oehl et al. (2000, p. 84) identified the importance of the clinician’s understanding of the service user experience in terms of their needs, fears and experiences around medication taking.

Consultant 4 identified the limitation of symptom remission in terms of the recipient of care. This observation is consistent with the findings from the service user interviews, in which symptom remission was considered only a part of personal wellbeing (see Section 5.9.4).

Consistent with the findings from the service user interviews, in which symptom remission was considered only a part of personal wellbeing (see Section 5.9.4).

An appreciation of the individual’s lifestyle is important in understanding the difference between poor symptom control due to lack of efficacy rather than non-compliance or a comorbid problem (e.g., substance misuse), which might deter the clinician from seeking a more effective treatment option. An understanding of the service user’s perspective on efficacy or well-being is part of a wider engagement which can lead to the implementation of support mechanisms to help a service user with limited understanding of the role of medication in wellbeing (Adams & Drake, 2006, p. 94).

5.24.2 Patient-centred care

The role of shared decision-making was discussed in the context of the relationship with service users. The response from Consultant 1, typifies a paternalistic approach to engagement in which the individual is dependent on the clinician or is reluctant to engage.

The paternalistic view of the role of the clinician has been a dominant model in healthcare and one of the factors that has been identified as promoting patient involvement in decision-making is the ability to access information via the internet (Tambuyzer, Pieters, & Van Audenhove, 2014, p. 139). The use of the internet was also alluded to by Consultant 1 (see Section 5.32.3).

At the time of the interview, Consultant 1 was close to retirement and it is possible that this view reflects an historical approach to consultations with service users. This view of the historical, authoritarian approach of doctors was identified by Service Users 3 and 5, who in
their interviews, identify the lack of treatment choice that were offered to them and the reluctance of doctors to engage in their treatment preferences (see Sections 5.8).

Consultant 2, in her response, identifies the importance of goal-setting and varying the approach of the consultation to meet the needs of the individual.

**Consultant 2.** Para 9, p. 7. “I do think that it’s quite worthwhile exploring with the patient expectations they have from medication and almost in some way it mirrors, I think, some old interpersonal relationship in their life.”

Para 2, p. 8. “I don’t think that one size fits all and that it’s quite individual thing how people…it’s important for them to be allowed to engage in a way they want to engage, but really, it varies.”

This approach is consistent with that of Adams & Drake (2006, p. 90) who note that in shared decision-making, “the practitioner becomes a consultant to the client, helping to provide information, to discuss options, to clarify values and preferences, and to support the client's autonomy.”

Consultant 5 identifies the importance of trust as part of the therapeutic relationship. In this context, Hall, Dugan, Zheng, & Mishra (2001, p. 615) define trust as “the optimistic acceptance of a vulnerable situation in which the individual believes the clinician will care for their best interests.”

**Consultant 5.** Para 9, p. 11. “Yes, definitely. It’s all about trust, it’s all about people will take medication from people that they like, that they trust, and that they share the decision with.”

Para 9, p. 11. “… nearly all mental health problems are associated with fear, so the more information you give somebody, the more you empower them to be in the driving seat of their own recovery, the better the outcome generally.”

Bezreh, Laws, Taubin, Rifkin & Wilson (2012, p. 17) in their review concluded that, distrust of doctors’ recommendations about medications may be more widespread than doctors perceive, but that this distrust is not always expressed. This is consistent with the findings from this study in which service users have chosen for a variety of reasons not to express their concerns regarding prescribed medication to their psychiatrist (see Section 5.8).

The review recommends that doctors encourage their patients to express dissent and even mistrust about medications and medical practice. This is an important recommendation and one that challenges the paternal model of the doctor-patient consultation.
5.25 Prescribing practice

The theme of prescribing practice considers the role of prescribing guidelines on clinical practice for psychiatrists and the influences on prescribing practice.

5.25.1 Role of prescribing guidelines

While the pharmaceutical industry representatives, pharmacists and GPs considered prescribing guidelines primarily in the context of promoting evidenced-based prescribing (see Sections 5.31, 5.14.1 and 5.20.1), this view was not reflected by the consultant psychiatrists who acknowledged the role of prescribing guidelines in terms of promoting evidenced-based practice but considered guidelines primarily as an educational tool. In addition, guidelines were also considered to be a support mechanism to assist the prescriber in specialist patient groups.

Consultant 1. Para 3, p.7. “I think most people will use it as an aid memoir for themselves and for helping and training people who don’t have the knowledge so forth new doctors who are new to psychiatry...”

Para 3, p.7. “The guidance I think is particularly useful for people who have got no previous experience of medication prescribing practices.”

Para 3, p.7. “I think it is also useful to have because some of the things change like prescribing guidance for pregnancy are always those are always useful to have because they keep changing and it’s something commonly GPs ring up and ask you.”

The idea of prescribing guidelines as an educational tool is consistent with the findings in this study in which both pharmacists and GPs identify the importance of adherence to evidence-based practice and the role of guidelines in its promotion (see Sections 6.14.1 and 6.21.2). This has also been demonstrated by other studies (Bauer, 2002, p. 139; Pulcini et al., 2011, p. 85; Rashidian et al., 2008, p. 232).

The role of prescribing guidelines in reducing irrational prescribing practice was articulated by Consultant 2 and is consistent with existing recommendations (Bauer, 2002, p. 139).

Consultant 2. Para 7, p.7. “The risk of not having any guidance is people prescribing based on their idiosyncratic clinical experience that sometimes can be quite harmful, so I do think that in terms of risk and benefits guidelines, they’re good.”
5.25.2 Influences on prescribing

Evidence was cited as the most important driving factor for influencing prescribing practice and, in addition, the pharmaceutical industry was cited as a determinant of prescribing practice which is consistent with the findings of Spurling et al, (2010, p. 22) and (Jelinek & Neate, 2009, p. 220). Unlike GPs, there was no reference to patient pressure or pharmacists as influencing prescribing (see Section 5.20.2).

Consultant 4. Para 4, p.2. “Personally think that the greatest influence is my own views about the medication and the research behind and evidence behind, and also the papers or any other sort of work which is done by other people.”

Para 4, p.2. “Drug companies or the pharmaceutical industry’s influence is there as well. But I consider that what information and support they provide I consider it helpful rather than influencing me to prescribe.”

As previously acknowledged, the evidence-base for pharmacological interventions in psychiatry is often limited; which has led to the recommendation that clinicians lobby their drug regulatory agencies to be more transparent (Turner, 2013b, p. 465). Despite this recommendation, it is difficult to envisage this happening as there is often a mutually beneficial relationship that exists between psychiatrists and the pharmaceutical industry. Psychiatrists often benefit from industry sponsored education events and payments for acting as advisors. The industry values relationships with psychiatrists, especially those in a strategic role to help promote their products as was identified by GP 3 (see Section 5.20.2).

Consultant 1 identified the role of peer support as a potential driver for influencing prescribing practice; this was consistent with the findings from the GP 2 who identified the role of peer-to-peer support for prescribing of a new drug (see Section 5.20.2).

Consultant 1. Para 5, p.3. “We have one of issues about people having been tried on a variety of treatment and then there is a discussion about what colleagues would think be a good thing, what have colleagues found to be useful.”
5.26 Working practice

The theme of working practice incorporated the role of psychiatrists in communication across the interface between specialist services and primary care and their role in supporting GPs. The theme of working practice also included the innovation in mental health therapeutics. Finally, this theme of working practice included the role of the pharmaceutical industry and the potential for joint working.

5.26.1 Interface

Consultant 2 identified the role of psychiatrists in providing specialist advice to GPs and the potential for prevention of referrals to specialist care. This reflects the perspective of GP 3, who is responsible for the commissioning of mental health services and is consistent with the idea of providing 'care closer to home' which has now become enshrined in the new model of healthcare delivery (vanguard sites), which is intended to help single organisations to provide GP, hospital, community and mental health services (See Section 5.21.2).

Consultant 2. Para 3, p.15. “I think maybe we can work on that and really...them and us getting...yeah, having some framework where we can...both of us can comfortably feel that we can give some prescribing advice even without referring a patient. I think prevent referrals to secondary care. It can also, I guess, make people, make GPs more empowered that they are able to manage...”

The tension between the need for support and its provision was also identified by GP 2 who explained the difficulties he had encountered in obtaining advice from mental health services (see Section 5.21.1).

The empowerment of GPs to manage patients with enduring mental illness is in part dependent on support from specialists. In the study by Horne et al. (2001, p. 192) GPs expressed their concerns about their lack of knowledge in relation to prescribing in specialist groups which was reflected in this study by GP 5 who identified his lack of knowledge of prescribing in mental health (see Section 5.21.2).
Consultant 5 identified prescribing costs as a concern for primary care clinicians.

**Consultant 5.** Para 1, p.17. “I was going to say prescribing costs, but the worry for primary care colleagues is why are you asking me to prescribe this really expensive drug for a condition where you can prescribe something cheaper. So, there’s the costs, prescribing the right drugs, the monitoring around certain medications, discharging people into primary care and how often they need to be reviewed, where the responsibility lies, shared care protocols.”

All GPs in this study reported compliance with prescribing guidelines which they claimed was based on promoting rational and cost-effective prescribing; this is consistent with the findings of a GP study of attitudes to joint treatment guidelines (Kasje et al., 2004, p. 232).

### 5.26.2 Innovation

The lack of innovation in pharmacological treatments is widely acknowledged in mental health (Light & Lexchin 2012, p. 2; Dix, 2015, para 2; Barral, 1995, p. 21; La Revue Prescrire, 2005, p. 73). Consultant 1 identifies the lack of therapeutic advances in psychiatry.

**Consultant 1.** Para 2, p.11. “Because you know innovations in psychiatric drugs are very few and far between really, it’s not really as if we have a wonder drug even every 10 years really and I think there is a possibility you could just stagnate any pharmaceutical development if you are too fancy on the price.”

Despite the acknowledgement that there is a lack of innovative drugs in development for the treatment of mental illness, there was also an acknowledgement that prescribing guidelines could impact of freedom to prescribe.

**Consultant 4.** Para 3, p.4. “Yeah, prescribing guidelines can interfere with innovation. People can be quite restrictive with regard to really trying something out, if they blindly adhere to prescribing guidelines.”

The lack of innovative medicines in psychiatry was identified by Consultant 5 in the following statement:

**Consultant 5.** Para 3, p.5. “But, I think the last ten years have been notable by the fact that nothing’s really...apart from aripiprazole, no really ground breaking stuff.”
5.26.3 Joint working

There were mixed feelings about working with the pharmaceutical industry and an acknowledgement that the financial pressure facing the NHS would catalyse the need for joint-working. Despite this view there was deep distrust of the industry and its motives, which were closely related to the findings from the pharmacist interviews (see Section 5.16.1). The distrust of the pharmaceutical industry was echoed in a recent survey of doctors (n=300) in which 75% viewed the industry as looking to increase their profits, with 84% of respondents calling for greater transparency (Megget, 2015, p. 29).

The extract from Consultant 1 implied the notion of being used as a key opinion leader by the pharmaceutical industry to promote its product.

Consultant 1.

Para 5, p.13. “I stopped seeing them because the reps would tend to say to people I have spoken to Dr xxxxxx about this and either he uses this drug or that.”

Para 3, p.14. “Probably no. I mean the finance of the NHS is going to shrink and the feeling currently is that outside partnerships with various voluntary, public sector, private organisations is the way to go.”

Consultant 2 has an interest in clinical trials and therefore has a working relationship with the pharmaceutical industry in this regard.

Consultant 2. Para 12, p.11. “I think we have to work with them but I’m on the other hand a bit suspicious, because they do have clear rein of wanting to promote their product.”

Her comments reflect the tension between the perceived inevitability of the working relationship and the distrust of the motives of the pharmaceutical industry.

Despite widespread mistrust of the pharmaceutical industry and paucity of clinical trial evidence, there are those that suggest that the NHS can learn from the quality assurance experience of the pharmaceutical industry (Nelson, 2007, p. 117).
The idea of learning from the pharmaceutical industry in terms of research and the potential for joint working in this regard was identified by Consultant 4.

**Consultant 4.**

*Para 12, p.13.* “I don’t see any reason why we can’t work with the pharmaceutical industry, as long as you’re not going to be completely influenced by what they tell you...So I think it’s about utilising them appropriately and keeping them at arm’s length....”

*Para 14, p.13.* “Their research facilities, that they utilise and these days anyway, you can’t do any research unless it’s a large-scale research, because of the absolute nightmare about ethics approval and things.”
5.27 Summary

The findings of the study with psychiatrists indicated that patient treatment was considered in terms of tolerability for the recipient of care; however, there seemed to be limited engagement with service users regarding the choice of medication that they are prescribed. The paternalistic approach to consultations was evident from one interview and the need to set treatment goals, coupled with the importance of trust in the psychiatrist was identified as factors for improved service user outcomes.

Prescribing guidelines were considered an important tool in the standardisation of treatment and of educational importance for less experienced prescribers. This view was echoed by GP 3 (see Section 5.20.1). Despite the merits of prescribing guidelines, psychiatrists were mindful that their use did not impinge on clinician freedom.

All psychiatrists acknowledged the role of the pharmaceutical industry in disseminating information regarding clinical trials but were reluctant to acknowledge any influence on prescribing practice. Key factors governing prescribing practice were identified as the robustness of the available clinical trial data and peer-to-peer recommendations.

The psychiatrists did not highlight the range of communication issues that were identified by their GP colleagues (see Section 5.21.1); however, there was an acknowledgement that they could provide specialist knowledge and support for GPs. This finding is similar to that of the study by Kasje et al. (2004, p. 235) in which GPs expressed the need for improved communication which was not reflected by specialists.

There was an acknowledgement by psychiatrists, of limited developments in pharmacological treatments for mental health conditions. Furthermore, psychiatrists expressed concerns that the use of guidelines could adversely impact on innovative prescribing practice.

Psychiatrists expressed similar reservations to other healthcare professionals about engagement with the pharmaceutical industry, however, there was an acknowledgement of the need for collaborative working which included support for NHS-based research.
5.28 Discussion

The findings from this study reveal several factors that impact on prescribing practice and the potential to optimise patient care. These involve service delivery models, healthcare professional attitudes, the influences on their practice and patient related factors.

The research aimed to explore the extent to which service users perceive they are involved in making treatment decisions about the medication that they are prescribed. The research also explored the factors that influence prescribing in mental health from a range of stakeholders. The discussion will consider those themes that directly relate to the study objectives and will set them in the context of the wider body of knowledge. The research objectives are listed below:

1. To explore the extent to which service users perceive they were involved in making treatment decisions about their prescribed medication. The research also explores the factors that influence the service user’s involvement in treatment decision making.

2. To explore the perceived factors that influence prescribing from the perspective of healthcare professionals; consultant psychiatrists, pharmacists involved in formulary/guideline development across the local health economy and GP/GP commissioners and representatives from the pharmaceutical industry with a national or international remit.

3. To develop an understanding of the perceived factors that influence the implementation of prescribing guidelines in a mental health setting from the perspective of consultant psychiatrists, pharmacists involved in formulary/guideline development across the local health economy, GP/GP commissioners and senior representatives from the pharmaceutical industry.

4. To provide a framework of recommendations for optimising the use of medicines across the health economy.
5.28.1 Communication

The study explored how service users obtained information about prescribed medicines and the extent of their engagement in the decision-making process. The findings of the study indicated that information was identified as a mechanism for individual empowerment and was viewed as underpinning person-centred care. This finding is consistent with that of Deegan & Drake, (2006, p. 87) who articulated a model in which the recipient of care was considered the expert of their own wellbeing.

The service users identified various challenges in their journey towards recovery and highlighted growing confidence in terms of decision making and navigating their way around the complexities of the compartmentalised healthcare system.

The need for more information, especially on the side effects of medication, was expressed by all service users and is consistent with the results of the national survey by Rethink, in which 45% of n=2222 service users believed that they did not have any choice in the type of medications they were prescribed, with 54% claiming to have received no written information about the side-effects of their psychotropic medicines (Rethink, 2006, p. 9).

Service users identified non-adherence with treatments which was based on their analysis of risks versus benefits; thus, the service users regarded their own judgement as pivotal in the decision to take prescribed medication. Furthermore, all service users acknowledged that they had experienced disagreements with their psychiatrist and that this was linked to their level of adherence with treatment. This finding is consistent with the review by Jimmy & Jose, (2011, p. 156) who concluded that poor clinician-patient communication and inadequate knowledge about medication and its use were factors that negatively impacted on adherence to treatment.

The findings from this study indicate that the decision by service users not to take medicines is often withheld from clinicians for a variety of reasons; including, not wanting to be perceived as non-adherent and conflict avoidance. The implications of non-disclosure would suggest the need for healthcare professionals to engage meaningfully and openly with service users about their medication taking behaviour. Such an approach to engagement would challenge the legitimacy of a paternalistic model of healthcare, in which the agenda for medication taking is set by the healthcare professional. Furthermore, such an approach would encourage patients to express disagreement and mistrust about medications and medical practice (Bezreh et al, 2012, p. 17).
Thus, it may be necessary to invite shared decision-making overtly into the consultation with individuals and to encourage disclosure of opinions that may be perceived as taboo or threatening to the healthcare professional.

The findings from this study suggested that individuals welcomed a collaborative communication style by the clinician which facilitates enhanced service user knowledge of the medication. Such an approach has been demonstrated to improved satisfaction with medication and improved reliability of medication use (Mitchell & Selmes, 2007, p. 340).

Service users identified psychiatrists as their primary point of contact for information on prescribed psychotropic medicines, however information was sought from alternative sources such as the internet or peers. The findings from the study suggest that psychiatrists were considered a more reliable source of information than either the internet or other service users; however, there was an acknowledgement of triangulating information obtained from psychiatrists which is reflective of consumeristic behaviour, rather than the trusting behaviour that often assumed by clinicians (Mather, Baker, & Laugharne, 2012, p. 166). This finding has important implications for service delivery as healthcare providers need to ensure that communication about medication is open, honest, informative, bidirectional and that there is consistency in messages between healthcare professionals and organisations providing healthcare (Bezreh et al., 2012, p. 17).

The limitations of the timeframe for engagement during a consultation was identified by service users and healthcare professionals alike and were viewed as negatively impacting on the delivery of key messages promoting the optimisation of medicines.

### 5.28.2 Choice and medication

Service users expressed dissatisfaction with the lack of choice that they were offered, which is consistent with the findings from other studies indicating that there is a substantial gap between service users’ preferences for information and their actual involvement in decision-making (Ford, Schofield, & Hope, 2003, p. 77; Read, 2009, p. 31; Fotaki et al., 2008, p. 182). The review by Entwistle, Sheldon, & Watt (1998, p. 220) identified that a substantial proportion of service users were insufficiently informed to be able to exercise treatment choice effectively. The implications of the findings from this study are that the service delivery model is not meeting the expectation of the service users. In an era of technological development where information is readily available, service users are well placed to obtain information on
prescribed medicines, despite concerns about the questionable quality of that information (De Freitas, Falls, Haque, & Bursztajn, 2014, p. 222; Read & Cain, 2013, p. 424).

Service users articulated their autonomy in a variety of ways including: silent dissent, lack of engagement and vocally challenging treatment recommendations proposed by healthcare professionals; thus suggesting the need for greater healthcare professional understanding of the complexities of medication taking behaviour associated with service users as suggested by the results of other studies (Ha & Longnecker, 2010, p. 38; Mitchell & Selmes, 2007, p. 337).

The autonomy of the service user as the final arbiter of the decision to take medicines is consistent with the study by Woltmann & Whitley (2010, p. 33) who found that service users regarded their own autonomy as central to any decision-making process and therefore central to any shared decision-making. Their study also highlighted that when service users believed a clinician was making decisions for them in a paternalistic fashion, they verbally acceded to the clinician and did not voice their own preferences, which is consistent with the findings from this study.

At present, there is minimal incentivisation for mental healthcare providers to offer service users treatment choice and while the NHS constitution affirms the individual's right to treatment choice, the options are based on two caveats: NICE approval and confirmation by the doctor that these are appropriate for the individual. This is particularly concerning in a mental health context as most drugs do not have NICE approval and in effect, the NHS constitution affirms the role of the healthcare professional as the final arbiter of the decision making process, which is in conflict with the concept of shared decision-making (Deegan & Drake, 2006, p. 87). A further factor which is impacting on patient choice is the increasing financial pressure on NHS providers to minimise prescribing costs which, is further likely to impede patient choice as healthcare providers focus on providing the cheapest treatment options.

There was an acknowledgement by some psychiatrists of the need to have a dynamic flexibility in their engagement with service users, taking into account their mental state and experience. Despite this acknowledgement there was no explicit recognition of the importance of engagement of service users in shared decision-making. The autonomy for shared decision making thus remains the domain of the clinician and the status quo of a lack of meaningful engagement continues. This is consistent with the findings of Hamann et al. (2009, p. 1111)
where psychiatrists expressed reservations about shared decision-making with pharmacological treatment.

5.28.3 Patient-centred care
Service users identified the importance of supportive networks which they relied on at times of need. Primarily family and healthcare professionals were identified as supporting the wellbeing of the individual. The importance of supportive networks for individuals with enduring mental illness has been well documented. Braunholtz et al. (2006, p. 6) found that mental wellbeing was associated with positive family and friend relationships. The findings from the study by Fisher (2003, p. 3) suggest that individuals should be supported to increase family members’ understanding of their mental health problem. At present, the trust pharmacy team is actively engaged in the delivery of education sessions for service users and their carers to reinforce understanding about medication and the wider services available to support medication use, such as medication reviews by community pharmacists and medicines information services provided by the clinical pharmacy team. As carers often act as advocates, lay therapists, and confidants, in addition to early detectors of relapse signs, it is logical to support their understanding of medicines and the available support networks (Smith-Merry et al., 2010, p. 112).

In keeping with other studies, service users expressed the desire to be offered alternatives to pharmacological interventions (Smith-Merry, Sturdy, & Freeman, 2010, p. 130; Gray, Rofail, Allen, & Newey, 2005, p. 36). The identification of alternative interventions to support wellbeing reinforces the need for healthcare professionals to be able to signpost service users to a range of services offering support. The findings from this study indicate that service users view their wellbeing in the context of a wider spectrum of interventions than is currently delivered by mainstream mental health services.

5.28.4 Response to medication
Several issues were identified from the study in terms of how service users identified medication and wellbeing. Individuals identified troubling side effects as challenging in terms of the impact on their quality of life. Weight gain was identified as problematic with all service users and was linked with discontinuation of treatment by some. This is consistent with findings from the literature (Oehl, Hummer, & Fleischhacker, 2000, p. 84; Weiden, Mackell, & McDonnell, 2004, p. 56). This is particularly concerning as the associated physical healthcare of service users with mental or intellectual disabilities has been shown to be inferior to that of patients with purely physical health diagnoses (BMA, 2014, p. 33). The psychiatrists who were interviewed in this study expressed concerns about the potential impact of adverse effects on
In turn, the therapeutic relationship with themselves. Thus, the therapeutic alliance was in part attributed to minimising the potential harm associated with pharmacological treatment. This has important implications as there is evidence to suggest that there are discrepancies between psychiatrists and service users in estimating the degree to which psychotropic medicines exert their adverse effects (Rettenbacher, Burns, Kemmler & Fleischhacker, 2004, p. 2871). Furthermore, explaining a medication's full side effect profile can prove difficult to achieve in clinical practice and may be regarded by doctors as impractical (Seale et al., 2006, p. 2866). Despite the challenge of disclosure, service users need to be supported and healthcare professionals should facilitate an environment in which empowerment is more likely to occur, thus enabling individuals to optimise the use of medicines and recognising their expertise in “their own lives” (Williamson, 2014, p. 5).

A complication of mental health pharmacological treatment is that there is a substantial gap between the efficacy of known treatments and treatment effectiveness in real-world settings (Sajatovic et al., 2004, p. 264; Turner, 2013b, p. 458). Thus, as was highlighted in the CATIE study which compared atypical antipsychotics; many participants discontinued treatment because of lack of efficacy (Lieberman & Stroup, 2011, p. 770).

### 5.28.5 Prescribing practice

The findings from this study identified that prescribing practice was influenced by the complexities of the individuals that were encountered in clinical practice. It was argued by GPs and psychiatrists that guidelines often posed difficulties when the individual nature of patients’ problems did not fit with guidelines and that these standardised approaches conflict with the idea of patient-centred care. These findings are consistent with the meta-synthesis by Carlsen, Glenton, & Pope, (2007, p. 973) in which GPs described the tension between their own experiences and the guideline recommendations. This finding has implications for guideline adoption as it is unlikely that clinicians will engage with treatment protocols that are not contextualised for use in a real-world setting. Thus, prescribing guidelines will require a review to incorporate commonly encountered comorbid disease states to support prescribing practice in more complex individuals.

In primary care, pharmacists were identified has having a role in Influencing prescribing practice. This can be understood in the context of practice based pharmacists who are responsible for monitoring prescribing practice, which can include formulary adherence and expenditure as well as providing a medicines information service for GPs. This finding is consistent with other studies that have identified the role of pharmacists in influencing

With the implementation of vanguard models of care, it is possible that there will be a move towards treating more patients with enduring mental illness in primary care; therefore, there will be a greater need for expertise in mental health therapeutics across health economies.

Psychiatrists identified evidence as the most important factor influencing prescribing practice; however, when this was explored in greater detail, the source of the evidence was linked to information imparted by the pharmaceutical industry from whom most psychiatrists obtained their updates on drug developments. Thus, the influence of pharmaceutical industry is experienced through the dissemination of largely industry sponsored research findings, which in turn impacts on prescribing practice (Jelinek & Neate, 2009, p. 220; Spurling et al., 2010, p. 22).

5.28.6 Guideline implementation

Several barriers were identified in implementing prescribing guidelines based on historical practice. The cultural barriers were linked to the process of clinical engagement during the development of the prescribing guideline. The findings from this study suggest the need for a balance between specialist and primary care input into guideline development. The need for wider health economy engagement in guideline development is consistent with the findings of the study by Rashidian, Eccles, & Russell (2008, p. 149) in which high representation of secondary care clinicians was seen to undermine the credibility of the guidelines themselves, as they were perceived as seeing ‘filtered’ patients and were associated with a lack of appreciation for the patient–doctor communication in general practice. In the author’s practice, this creates a potential problem for mental health engagement with GPs as there are over 120 practices across the Dudley and Walsall boroughs and engagement at an individual practice level would be difficult to achieve. Thus, the implementation process is dependent on the communication mechanisms in place across the local CCGs and the integration of pharmacy teams at the practice level to reinforce key messages.

Another factor that was identified as a potential barrier to guideline implementation was the accessibility of guidelines; this is of particular concern for mental health prescribers as there is no electronic prescribing support to promote safe and effective practice. The use of electronic prescribing reminders has been demonstrated to improved adherence to protocol driven algorithms for a range of mental health conditions (Milner et al., 2009, p. 1011; Forsner
et al., 2010a p. 5). This has important implications for service users as the physical monitoring associated with psychotropic use remains poorly managed in mental health and the use of electronic reminders could be used to support the care of patients in this regard (Patel et al., 2014, p. 507; Barnes & Paton, 2011, p. 330).

The findings from this study reinforce the need for guideline development to strike a balance between being readily understood and accessible on the one hand and comprehensive enough to support clinical practice on the other, as oversimplification has been demonstrated to impede implementation (Addington, Kyle, Desai, & Wang, 2010, p. 1328; Milner et al., 2009, p. 1012; Cabana et al., 1999, p. 1461; Kasje, Denig, & Haaijer-Ruskamp, 2002, p. 514).

The findings from this study suggests that GPs are more inclined to adopt prescribing guidelines than their specialist counterparts (Kasje et al., 2004, p. 235). It is possible that it will become increasing difficult in the current economic climate for mental health services to adopt the use of new medicines with negligible benefits over cheaper existing ones.

Clinical engagement was identified as a way of promoting improved prescribing practice. This approach has been adopted across DWMHT and as part of a wider strategy to improve prescribing practice. The mental health pharmacy team is engaged in prescribing audits which are fed back to prescribers at various clinical forums. In addition to audits, a six-monthly review of prescribing practice is undertaken with each consultant team across the trust. This feedback includes a breakdown of findings with recommendations for change as well as feedback on compliance with guideline standards such as generic prescribing. Action plans are agreed with the consultants and progress is determined at follow-up meetings. Thus, the pharmacy team is actively engaged in the implementation of recommended prescribing standards across the trust; however, despite the educational interventions employed by the trust pharmacy team, in isolation there is evidence to suggest that the effectiveness of such approaches is limited (Bauer, 2002, p. 149).

The use of key opinion leaders was identified by pharmacists and GPs’ as a potential way of promoting evidence-based prescribing practice across the local health economy. While such an approach may have merits as highlighted in the editorial by Tansella & Thornicroft, (2009, p. 283), there are others that consider the use of key opinion leaders of variable effectiveness (Grimshaw et al., 2004, p. 64; Rashidian, Eccles, & Russell, 2008, p.149).
5.28.7 Medicines optimisation

A pharmaceutical company has been approached to engage in a risk share scheme that would promote payment for patient outcomes. The company was asked to agree on outcome measures that would be used to determine a payment tariff. If service users were maintained in line with the agreed outcomes, then the trust would continue to pay for the medicine; however, if the service user failed to respond to, or was intolerant of the medicine, then the trust would receive a refund from the company. Unfortunately, an agreement could not be met with the company in question as it stipulated that the drug should be used as a first-line agent, despite a lack of evidence to suggest that it was superior to existing cheaper alternatives.

The findings from the interviews with GPs indicated that there was scope for improved communication with the trust. This led the author to develop a joint medicines management CQUIN in conjunction with commissioners. The CQUIN is designed to improve communication between the trust, CCG and community pharmacies for service users who are treated under the care of the trust Crisis Resolution and Home Treatment Team. The CQUIN has led to an increased focus on identifying service users who are experiencing difficulties with their prescribed medication and relaying these issues across the health economy so that appropriate, supportive interventions can be made.

Service user engagement in prescribing guideline development and review has become a routine part of policy review. In addition to this, an education programme has been developed with service user groups to help them understand the medicines optimisation support that is available across the trust and the wider health economy.
5.28.8 Summary

In summary, a gap was identified between the service user expectation of shared decision-making and its delivery in clinical practice. In trying to overcome some of the difficulties encountered as part of the recovery process, service users adopted a range of strategies to manage the relationship with their psychiatrist, including: negotiation, verbal acquiescence, and triangulation of information received. Service users obtained information about prescribed medicines from a variety of sources including other service users, the internet and healthcare professionals.

Central to the concerns faced by healthcare professionals was the quality of the supporting infrastructure to deliver patient-centred care. Protocol driven care was perceived to be at variance with patient-centred care in more complex patients. All healthcare professionals acknowledged the importance of contextualising prescribing guidelines to facilitate their use in patients with comorbid disease states.

There was a general recognition that prescribing guidelines had more of an influence on prescribing practice in primary care which is attributable to two factors: the non-specialist nature of general practice and the technological infrastructure to support prescribing practice. The lack of an electronic prescribing system in the mental health trust limits the integration of guidelines across the organisation.

The current prescribing practice across the local health economy could be improved by the sharing of timely information between healthcare settings and by psychiatrists sharing their expertise with GPs to help support the care of service users in primary care. It is possible that this might be achieved by the implementation of new models of care in which there is greater integration between healthcare providers.

If the full realisation of the benefits of medicines in mental health is to be realised, there is a need for a step change in which service users are empowered to make informed decisions about their treatment, taking into consideration their lifestyle and the impact of medicines. This will require a focus on providing relevant information on medicines to service users coupled with ongoing engagement with them to address any concerns they might have. Furthermore, to fully optimise the use of medicines, healthcare professionals will need to consider the evaluation of adherence to treatment as part of routine care.
5.29 Thematic map

The research themes have been incorporated in Figure 5.28 which identifies the main themes for each stakeholder group based on Framework analysis. The diagram also identifies convergent and divergent themes across the stakeholder groups.

![Thematic Map of the Research Themes](image)

**Figure 5.6 Thematic Map of the Research Themes**
5.30 Synthesis of findings

This research sought to explore different perspectives on prescribing practice and the potential for optimising care. The study therefore explored the views of:

- Service users
- Healthcare professionals
- Representatives from the pharmaceutical industry

This final sub-section of Chapter 5, presents the synthesis of the key findings, and is structured as follows:

- Summary of the findings
- Synthesis of the key findings
- Strengths and weaknesses of the study
5.31 Summary of findings

This section summarises the findings from the stakeholder groups.

5.31.1 Pharmaceutical industry

Engagement with the changing NHS landscape was a key theme that emerged from the interviews with representatives from the pharmaceutical industry. There was also an acknowledgement of a need for a paradigm shift in the current relationship, which would place greater emphasis on the value proposition of new products. This sentiment was expressed by Pharmaceutical Industry representative 3.

*Industry Representative 3. Para 9, p.8. “There should be less room for me too’s and that less drugs should get funding but that the good drugs should get funding.”*

5.31.2 Service users

Service users expressed concerns regarding the lack of treatment choice, and low levels of satisfaction with timely information on prescribed medication. Furthermore, divergence between their treatment aspirations and those of the service providers were apparent. The statement from Service User 5 reveals a perspective of healthcare that is at odds with patient-centred care.

*Service User 5. Para 12, p.10. “That basically the services are not services for people, it’s a business. So, it’s mainly run on a business level.”*

5.31.3 General practitioners

GPs described the tensions between resource limitations and the delivery of patient-centred care, which was described as complex, and existing outside of guideline-driven care. GPs also expressed concerns over poor communication with the local mental health provider. GPs considered the mental health provider to be a repository of information and support. GP 4 identified the need for close working with the local mental health trust.

*GP 4. Para 4, p.30. “But when it comes to specialist drugs I think specialist should remain involved and I think at least we should have more community CPNs that patients have direct access to if they need help, quick access.”*
5.31.4 Pharmacists

Pharmacists considered guidelines as a means of promoting medicines optimisation. Guidelines were considered to have a role in supporting clinicians with decision-making, and reducing variation in clinical practice. Facilitators for the use of guidelines included, perceived benefit for the clinician and ease of access. Shared decision-making was thought to improve the patient-clinician relationship and increase medicine adherence. Pharmacist 4 identified a link between the acceptance of a diagnosis and the subsequent need for treatment.

Pharmacist 4. Para 3, p.4. “it’s about they have condition X, and it’s about them and how do they feel about that…and these are some of the options that they can take with the pros and cons of doing that and they are within…sit within a prescribing guideline.”

5.31.5 Consultant psychiatrists

Consultant psychiatrists acknowledged the importance of guidelines, however there were concerns raised about their potential impact on freedom to prescribe. Choice was considered primarily in terms of clinicians’ access to newer medicines; however, there was very little discussion about patient-centred choice. Consultant Psychiatrist 1 outlined the following approach to shared-decision making:

Consultant Psychiatrist 1. Para 3, p.9. “if you are very worried I would say go away and think about it. 99% of people told to go away and think about it come back and say actually yeah, I’ll give it a go.”

Overall, psychiatrists did not perceive a problem in communication with primary care, unlike GPs. In keeping with other healthcare professional groups, psychiatrists acknowledged the inevitably of joint working with the pharmaceutical industry, despite their reservations about the industries motives for collaboration (see Sections 5.16.1, 5.20.2 and 5.26.3).
5.32 Emergent themes from the study

A total of 9 themes emerged from the analysis of the interviews across the stakeholder groups. As the emergent themes from pharmacists, GPs and consultants were the same: working practice, prescribing practice and philosophy of care; these professional groups have been amalgamated for diagrammatical representation. The colour coding denotes the stakeholder group from which the theme emerged. Where spheres within the diagram have more than one colour this denotes an emergent theme which occurred across more than one of the identified groups, however this does not imply convergence or divergence. The relationships between the emergent themes from the stakeholder groups are shown in Figure 5.7.

![Diagram of emergent themes from the study](image-url)

**Figure 5.7** Emergent themes from the study
5.33 Synthesis of findings

The author considered an evaluation of convergent and divergent themes to explore the tensions and concord between the stakeholder groups, and where possible, to identify potential recommendations to optimise the use of medicines in keeping with the research aims and objectives.

From the synthesis of the study four core tensions and three areas of concord arose (see Figures 5.8 & 5.9).

The areas of tension were:

- Joint working between the pharmaceutical industry and the NHS
- Guideline versus individual driven care
- Patient-centred care versus the realities of its delivery in a resource limited system
- Rhetoric of service user choice versus the realities of shared decision-making in practice

The areas of concord were:

- Communication and its importance in medicines optimisation
- The role of guidelines
- Wellbeing and its meaning for service users

The following section of this chapter will discuss the divergent and convergent findings from this study which will be supported with verbatim quotes from participants.
Figure 5.8 The Core tensions identified from the study
5.33.1 Joint working

Joint working between the pharmaceutical industry and the NHS is set against a context in which the NHS faces unprecedented pressure to achieve improved quality and productivity under severe economic pressure (Ousey & Bielby, 2011, p. 153).

A key tension that emerged from the study was collaborative working between the NHS and the pharmaceutical industry. Representatives from the pharmaceutical industry were keen to explore joint working and more specifically, new ways of working, especially the development of care-pathways, which they considered a strategic way of identifying unmet clinical needs within the NHS (see Section 5.5.2).

Industry 1. Para 1, p.29. “Have a focus group, get people from primary care, the commissioners, maybe chief pharmacists, people like that, bring them all together and just try and brainstorm what are the opportunities for joint working in mental health?”

The obvious implications of this proposed way of working is that the industry could be seen to be driving clinical needs based on their pharmacological portfolio.

Healthcare-professionals, while acknowledging the inevitability of joint working, were cautious about working with the pharmaceutical industry, whom they perceived to have differing motives for engagement (see Sections 5.16.1, 5.20.2 and 5.26.3).

Suspicions about joint working with the pharmaceutical industry have been identified based on conflicting priorities with the NHS (Moynihan, 2011, p. 1). While the pharmaceutical industry aims to maximise profits based on increasing sales of their products; the NHS aims to maximise population health. Furthermore, the NHS has a remit to deliver cost-effective prescribing which includes the use of cheaper treatments to achieve desired patient outcomes.

Pharmacist 2 expressed strong reservations about joint working with the pharmaceutical industry and considered the agendas of both organisations to be in conflict; a view which is shared by Moynihan (2011, p. 1).

Pharmacist 2. “I gonna put it up front...and I don’t trust them at all. Erm their agenda is not the NHS agenda, it’s not the patient agenda. It is separate thing, the shareholder agenda. The sooner the NHS realises that and works away from them the better.”
Consultant 5 also expressed reservations about engagement with the pharmaceutical industry which was reflected in his comment below.

**Consultant 5.** Para 5, p.14. “I mean, obviously, the bottom line is these companies are there to make money, and in many cases to make lots of money, so there’s a slightly uncomfortable feel about getting too close, getting into bed with companies.”

Despite the acknowledgement of the industry agenda, consultant psychiatrists and GPs identified the potential for training and educational support from the industry (see Sections 5.26.3 and 5.32.1).

Nationally, concerns have been raised about the role of the pharmaceutical industry in medical education, which have been linked to the potential bias in doctors’ professional development (Spurgeon, 2008, p. 743).

GP 3 outlined a pragmatic approach in which the NHS would engage with the pharmaceutical industry to their advantage.

**GP 3.** Para 8, p.16. “and I’ve seen their shift and focus change from trying to get lead and champions, to prescribing their drugs into more of working with organisation.”

Para 1, p.17. “But, we should actually play the game too, so if they’re offering loads of support, loads of money, loads of other things to help the organisation, our organisation, develop better protocols, do workshops, offer training, well don’t knock it, use it.”

The observation by GP 3 is particularly relevant for GPs, who as generalists, are perhaps, more open to influence from the pharmaceutical industry as was demonstrated in the study by Muijrers, Grol, Sijbrandij, Janknegt, & Knottnerus (2005, p. 627) who identified a negative correlation between evidence-based prescribing and frequency of visits by pharmaceutical industry representatives.

Pharmacists, differed from their medical colleagues, in that they did not see a key role for the pharmaceutical industry to support healthcare professional education. However, despite their deep suspicions of the industry, they did see a potential role for joint working, in which the industry would commit to risk-sharing schemes based on joint agreements of clinical outcomes with commissioners and healthcare providers (see Section 5.16).
Furthermore, pharmacists identified the potential for schemes that would lead to improvements in cost-effective prescribing. Thus, the pharmacists considered the contribution of the pharmaceutical industry to joint working in terms of direct financial benefit to the NHS (see Section 5.16.1). The statement from Pharmacist 1 summarised the potential financial gain from collaboration with the pharmaceutical industry.

**Pharmacist 1.** Para 9, p.36 “...a kickback back to the commissioners in terms of rebates...yeah it would be interesting to see if mental health companies are looking at rebates...”

### 5.33.2 Guideline versus individual driven care
A key finding from the study was the tension between individualisation and standardisation of care based on prescribing guidance. Healthcare professionals identified the difficulties associated with meeting the needs of individuals, whilst trying to adhere to guideline-driven care. Some psychiatrists acknowledged the limitations of using outcome measures that did not necessarily reflect important aspects of the patient experience. This point was reinforced by service users during their interviews (see Section 5.9.2).

There was also an acknowledgement by psychiatrists in particular, that prescribing guidelines were of limited clinical value in difficult-to-treat patient groups which is consistent with the findings of Forsner *et al.* (2010b, p. 7).

**Consultant 1.** Para 3, p.4. “I think I take it as guidance not as you have to do it and I think if you speak to most of my colleagues they would do the same...”

“They would be aware of the guidance but they would also know that isn’t going to be for 100% of the patients.”

Para 3, p.4. “You’ve done the first four things and actually nothing’s happened and then you are into stuff where there is not a lot an awful lot of evidence.”

In the absence of evidence, a psychiatrist is likely to rely on clinical experience and guidelines may be of limited clinical relevance. In the study by Rashidian *et al.* (2008, p. 153), a lack of contextualisation of prescribing guidelines led some clinicians to conclude that their use was of minimal value.

The delivery of patient-centred care is further complicated by several factors including; postgraduate medical education as it is estimated that the pharmaceutical industry sponsors about 60% of training (Spurgeon, 2008, p. 743). Thus, in addition to the paucity of robust evidence in psychiatry and industry influenced postgraduate medical education, the ability to
deliver patient-centred care in a mental health setting is impaired. Furthermore, existing guidelines that do not take account of all evidence can result in suboptimal, ineffective, or harmful practices for service users (Woolf et al., 1999, p. 529).

Pharmacist 5 identified the limitations of prescribing guidelines and acknowledged the importance of clinical decision making for the individual.

Pharmacist 5. Para 2, p.1. “I think we take ourselves into very dangerous territory if we say it mandates what they will do because obviously, we’re dealing with a patient at the end of this and so for me, what human beings are very good at is (particularly healthcare professionals) is making decisions.”

The limitations of prescribing guidelines were further highlighted by Pharmacist 2 who identified the importance of considering the individual’s co-morbid disease state.

Pharmacist 2. Para 4, p.1. “They’re not really there to be followed to a letter, because patients come with more than one problem and you have to account for the comorbidities.”

The observation by Pharmacist 2 is consistent with the findings of Davis & Taylor-Vaisey (1997, p. 412) who identified co-morbid diseases as a contributory factor for non-compliance with clinical guidelines.

GP 4 highlighted the limitation of prescribing guidelines, in a context of personal-goal setting between the GP and patient. The case identified a long-term benzodiazepine user in which an agreement was made with the patient to reduce rather than discontinue treatment.

GP 4. Para 1, p.9. “To me that’s success for him, it’s success for me. From a guidance point of view we failed because we’re still prescribing something that we shouldn’t be.”

The scenario highlights the importance of adopting a patient-centred approach to prescribing which can be at variance with protocol-driven care. Furthermore, under certain circumstances, there is evidence to suggest that clinicians do not consider clinical guidance as relevant to the individual recipients of care (Cabana et al., 1999, p.1463).
Despite the reluctance to acknowledge the impact of the pharmaceutical industry influence on prescribing by psychiatrists; Service User 3, a former counsellor, identified prescribing trends in her previous professional capacity.

**Service User 3.** Para 7, p.11. “Oh we’ve got a new drug now, because then you would see the referrals with this new drug.”

Para 7, p.11. “And everybody would be on it. Everybody would be on it. Then, later down the line we’d have another new drug, and everybody would be on that.”

The influence of the pharmaceutical industry on prescribing practice is well documented and is not limited to marketing alone but also includes the reporting of favourable clinical trial data (De Freitas, Falls, Haque, & Bursztajn, 2014, p. 219; Moynihan, 2011, p. 2; Muijrers et al., 2005, p. 627 Turner, 2013b, p. 465; Fischer et al. 2009, p. 795). As the pharmaceutical industry are forbidden from direct marketing of prescription only medicines to patients in the UK, it is hard to correlate prescribing trends with patient preferences.

### 5.33.3 Patient centred care

In this study, service users have expressed a desire to be involved in treatment decision-making and to be considered holistically in terms of the care that they receive. This is similar to findings of the study by Smith-Merry et al. (2010, p. 130) in which patients considered holistic care a key factor in their recovery from acute mental illness. Service users identified the importance of treatment which met their needs and which was characterised as being non-judgmental, empowering and pragmatic which is similar to the model of care as outlined by Cleary et al. (2015, p. 564).

**Service User 4.** Para 6, p.17. “So, I think, you’ve got to look at the person, not just the physical person, the, sort of, emotional person, look at their intellect, look at their.”

In this study, psychiatrists, GPs and pharmacists discussed the importance of identifying and recognising individual patient needs (see Sections 5.14.5 and 5.19.2). In particular, psychiatrists focused their attention on individualised treatments, drawing on their clinical expertise and experience. Pharmacists and GPs also recognised the importance of the individual needs, but also considered the wider health-economics of prescribing practice (see Sections 5.19.2 and 5.20.1).
Representatives from the pharmaceutical industry recognised the limitations of protocol-driven care, and all healthcare professionals consistently discussed the limitations of guidelines in clinical practice (see Sections 5.3.1.1, 5.19.2 and 5.25.1). In the case of psychiatrists, whilst their treatment decisions were reported as individualised, in the sense that decisions were bespoke for each patient, it did not necessarily reflect patient preferences. It is possible that healthcare professionals do not view patient preferences as a fundamental issue, either because they do not think it is relevant, or possibly, because it may be perceived as impossible to engage patients who have a variety of treatment preferences.

The observation from Consultant 1 would seem to suggest that most service users are ill-equipped to make informed decisions about prescribed medication.

**Consultant 1.** Para 3. p.9. “There are a minority at the moment although that may change, that are very interested and have done a lot of looking on the internet and stuff but mostly people are very badly informed and are worried they are going to zombies and that they are going to be completely changed and medication is going to do terrible things to them.”

A further finding from this study was that healthcare professionals discussed patient-centred care in the context of the time allocation for a consultation, communication and the relationship with the healthcare provider. However, despite the acknowledgement of the limitations of the existing system, it was not clear that this necessarily led to explicit attempts to understand the preferences and/or needs of individuals.

Service User 2 describes an impersonal consultation in which she feels that she is not the focus of attention.

**Service User 2.** Para 7, p.4. “Talking to me for a start, you know, because sometimes they sit there and they’re typing away on their laptops as if you’re the second.”

Para 7, p.4. “for them to get to know me, a bit about my life, so they can…if they’ve got a better picture of me.”

Service User 2 identified the importance of establishing a relationship with her doctor. This implies the notion of a relationship which is built over time, and in which there is a shared knowledge that transcends the clinical presentation of the individual. The constraints of time on engagement with healthcare professionals was also identified by Service User 5 (see Section 5.10.1).
Furthermore, the issue of the consultation timeframe was identified by Consultant 2 and Pharmacist 4.

**Consultant 2.** Para 5, p.9. “I wonder whether we don’t allow enough time to discuss which things are serious but which are happen really rarely, and I do think it helps people a lot.”

Pharmacist 4 identifies a connection between the consultation time and the impact on meaningful engagement with the individual.

**Pharmacist 4.** Para 3, p.5. “I think sometimes there’s a pressure within prescribing: I mean with contact time that you have with the patient that you’ve got to do it all there and then because they might not come back.”

As mental illness is often associated with stigma, there is a need to consider the potential impact on the individual and the importance of achieving a concordant relationship between the service user and healthcare professional. The potential stigma associated with a mental illness is perhaps one causal factor in the caution of healthcare professionals to formally diagnosing individuals. (Lampe *et al.*, 2012, p. 377).

GP 3 alludes to a provider-centric model of care in which the effectiveness of treatments is based on standardised outcome metrics, which differs from the views of the individuals as the recipients of care.

**GP 3.** Para 10, p.4. “So really, it’s like what is wellbeing for the psychiatrist, it’s that there’re not actively psychotic, they’re nicely sedate, they’re not jumping off the bridge.”

Para 10, p.4. “But actually, the fact that they may be not doing anything, not going out, not happy, for them is not a sign of poor wellbeing.”
5.33.4 Choice and medication

Health professionals recognised the role of choice in the treatment of the individual but differed in the extent to which they believed that treatment choice should be a routine part of care (see Sections 5.14.4, 5.19.2 and 5.24.2). Pharmacists considered treatment choice as secondary to the financial capacity of the NHS to offer such options, and as such, choice was set in the context of distributive justice rather than patient-centred care. This view of healthcare provision was linked to the roles of the pharmacists, who were involved in budgetary analysis and or management of drug expenditure.

Pharmacist 1. Para 14, p. 64. “I think there has to be a balance between freedom of choice and the needs of...well obviously, you got to balance the needs of the patient against the needs of the NHS, even the needs of perhaps the commissioner...”

Psychiatrists identified the importance of involving patients in decision-making but acknowledged that the extent to which individuals can be involved, was impacted upon by their desire to and capacity for engagement (see Section 5.24.2).

Consultant 3. Para 8, p.11. “When they become acutely unwell and psychotic, and particularly when they are detained under the Mental Health Act, that is the more difficult and tricky time for people to understand about their treatment plan and care plan and consent - give informed consent about any treatment options or interventions.”

GPs did not consider treatment choice a primary consideration in the treatment of individuals with enduring mental illness.

GP 4. Para 3, p.17. “When you're looking at it from a commissioning point of view or a practical point of view, from the other side, you can't give the best straight off. You've got to give what is the most cost effective, sensible...”

There are several reasons for this; it is possible that GPs are not routinely responsible for initiation of treatment and therefore are not able to have an initial discussion about treatment options. It is also possible that financial concerns are a contributory factor in limiting treatment choice, as GPs are expected to manage prescribing costs. A further factor impacting on the GPs consideration of choice may be linked to the knowledge of the GP with respect to the potential treatment options and their suitability for the individual.
Service users stressed that they were dissatisfied with the extent to which healthcare professionals involved them in decisions about their prescribed medication (see Section 5.8). In particular, service users felt that they were provided with insufficient treatment options.

**Service User 4.** Para 16, p.7. “I would have been happier if I’d been given a few options.”
**Para 16, p.7.** “Say somebody had said, well, you could take that, but the side effects might be that.”
**Para 5, p.8.** “it wouldn’t take long just to give, say, four options to a service user.”

Unlike the findings from the study by Laugharne et al. (2012, p. 500) in which service users described a loss of confidence in their own judgement, which negated the potential for treatment choice during the acute phase of their illness, the findings of this study suggest that service users considered choice and information as integral to their recovery (see Section 5.8.2).

Patient choice and empowerment are interlinked and complex concepts that need to be considered carefully, and individuals require different approaches to their involvement in care. The response from Service User 1, identifies the shortcomings in the existing system in which the recipient of care is ill-informed about her prescribed treatment.

**Service User 1.** Para 3, p.20. “But when you’re prescribed something as an inpatient, you don’t get the list to read, so you don’t know what the side effects are.”
**Para 3, p.20.** You don’t know how they’re supposed to work, you know, so you’re just prescribed, this is what you’ve to take, and, you know, end of story.”

The findings from this study indicate that a universal approach to engagement with service users in terms of treatment choice is unlikely to be satisfactory. Treatment choice should therefore be explored with service users and consultations should be adopted to meet the needs of the individual.
5.33.5 Summary of the core tensions
This study identified a tension between guideline driven, and patient centred care. These
tensions exist in the context of delivering pharmaceutical care across a health economy which
contrasts with a focus on a patient-centred agenda in which patients are engaged in decision-
making and choice.

5.33.6 Patient versus guideline centred care
Healthcare professionals, in attempting to adopt a patient-centred approach by developing an
understanding of a patient’s problem, from their own and the patient’s perspective, is
contrasted by the health economy focus of prescribing guidelines which, standardises
decision-making, rather than individualising it. This presents a large challenge to health
professionals who are responsible for balancing these competing tensions between adopting
an individualised patient-centred care whilst adhering to the culture of evidence-based
prescribing.

Prescribing guidelines are currently designed to take into consideration the pharmacological
management of a single disease state (Coulter, 2013, p. 21). The findings from this study
suggests that this does not always facilitate patient-centred prescribing practice. This occurs
for a number of reasons which include:

- The complexity of presenting disease states that are often encountered in clinical
  practice which are not reflected in guidelines.
- The service user desire for consideration of alternative therapies which are often
  excluded from protocol driven care because of the lack of supporting evidence.
- The need for achieving distributive justice which focuses on a health economy based
  prescribing practice.
**Comorbidities**

The complexities of prescribing in individuals with physical health conditions have been identified in this study (see Sections 5.9.1 & 5.19.2).

The need to treat individuals with comorbid diseases is common, and will become more so as the population ages and survival from acute disease improves. Therefore, the management of people with comorbid diseases is a key challenge for healthcare providers. Prescribing guidelines have an important role to play in meeting this challenge, but are constrained by the evidence on which recommendations are based and by their current design.

The use of polypharmacy is not intrinsically inappropriate, but where patients have strong preferences about limiting their pharmacological treatment burden, or the impact of treatment on wellbeing, then prescribing guidelines should be part of a support mechanism help to facilitate shared decision-making.

The use of prescribing guidelines may be inappropriate for individuals, and blanket recommendations, rather than a menu of options or recommendations for shared decision-making can lead to treatment that excludes patients' preferences. Thus, consistent practice patterns and reduced variation may come at the expense of reducing individualised care for patients with specific needs (Woolf et al., 1999, p. 529).

Patient education and empowerment have important implications for medication optimisation and the very nature of engagement with healthcare professionals (RPS, 2013, p. 35). Furthermore, if service users are encouraged to be more open and ‘active’, this will have implications for the nature of engagement with healthcare professionals who not only have to be able to listen but also have to be able to deal constructively with challenges. A collaborative approach is outlined by Consultant 5 below.

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**Consultant 5.** Para 4, p.11. “I think once you’ve connected with patient, once you’ve earned that trust, and that’s tricky because the thing to do when somebody is vulnerable is don’t hurt them by prescribing decisions or behaviour.”

Para 4, p.11. “It is a journey, that sounds like a cliché, but the most effective prescribing is prescribing that’s signed up to on both sides of the relationship.”

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The attitudes and skills that relate to one person ‘acting upon’ another are different from the attitudes and skills that are appropriate when two people are properly ‘inter-acting’
**Complementary therapies**

All service users expressed the desire to be treated holistically and the use of medication was considered as part of a spectrum of interventions that impacted on wellbeing (see Section 5.9.4). The comments from Service User 1 identifies the role of supporting therapies.

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*Service User 1. Para 2. *p.13. “But normally I find talking therapies are really quite beneficial, and I think just to have somebody to talk to actually helps a lot.”*

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Service users have developed alternative approaches to mental health that can complement existing services such as self-help groups (Tait & Lester, 2005, p. 171). Complementary and alternative therapies and approaches have been an element of people’s recovery (Smith-Merry et al. 2010, p. 130). One way in which prescribing guidelines could support access to wider services is by inclusion of references to available support services.

5.33.7 Distributive justice versus individual choice

This study identified a tension between individual choice and distributive justice. Healthcare providers with a responsibility for managing prescribing budgets or formulary adherence were more focused on optimising the use of medicines across a health economy or healthcare setting within the context of an allocated prescribing budget (see Sections 5.14.4 and 5.19.2). Service users on the other hand, highlighted the importance of choice and consideration of personal factors (see Section 5.8).

Pharmacists are often charged with responsibility for deciding whether pharmacological interventions are clinically appropriate and cost-effective. Across the local health economy, the accountability for the management of the CCG prescribing budget is the responsibility of the Head of Medicines Management. At a provider level, responsibility for management of the prescribing budget is entrusted to the Chief Pharmacist. Thus, patient choice is set against a context in which those charged with managing the prescribing budgets are facing increasing pressure to curb prescribing costs.
5.33.8 Joint working vs professional independence

A key tension that was identified from this study was the drive for collaborative working between the NHS and the pharmaceutical industry. Representatives from the pharmaceutical industry were keen to explore new ways of working with the NHS (see Section 5.5.2), however, pharmacists expressed concerns about engagement with the pharmaceutical industry, who they felt did not appreciate the financial constraints on prescribing budgets (see Section 5.16).

The role of the pharmaceutical industry in education was acknowledged by all psychiatrists despite their acceptance of the financial motives behind the industry’s desire for collaboration (see Section 5.26.3). This view contrasted with that expressed by pharmacists who identified the potential for Joint working with the industry in terms of facilitating stakeholder engagement for guideline implementation and improving cost-effective prescribing.
5.33.9 Concordant findings

The analysis of the findings from the study identified the following areas of concord:

- Communication and its importance in medicines optimisation.
- The role of guidelines in clinical practice.
- Wellbeing and what it means for service users.

Figure 5.9 outlines the key findings in which there was broad agreement across the relevant stakeholder groups.
5.33.10 Communication

There was an acknowledgement by healthcare professionals and the pharmaceutical industry of the need to communicate effectively with service users as the recipients of care. Furthermore, there was an acceptance of the need to engage with the individual and to promote their understanding of the role of medication in their wellbeing (see Sections 5.3.2, 5.14.5, 5.19.2 and 5.24.2). The extract from the interview with Pharmacist 3 emphasises the need for patient engagement and understanding.

Pharmacist 3. Para 5, p.5. “I mean why would I start all this new stuff that I don’t really understand.”

Para 7, p.5. the idea is that the patient understands why it is they’re taking the medication…or the need to take the medication…or what it’s going to help and benefit to the…”

The response from Pharmacist 3 implies a patient led assessment of the risks and benefits associated with treatment, as suggested by utility theory (Mitchell & Selmes, 2007, p. 338). The need for patient engagement was articulated by Service User 3 in the following extract:

Service User 3. Para 16, p.12. “I sit there and I go, can we go through it and make sure, what are my options, how is this going to benefit me? And sometimes I will go and see them three or four times before I literally take a medication.”

Service User 3 exercised her right to reflect on her treatment options and assumed control over the decision-making process which is consistent with the findings from Woltmann & Whitley (2010, p. 33).

The findings from this study indicated that service users viewed communication with healthcare professionals and psychiatrists as fundamental to their care. Effective communication was viewed in the context of understanding the particular needs and historical context of the individual.
In response to a question in which service users were asked to identify key recommendations for healthcare professionals, Service Users 1 & 3 gave the following response:

**Service User 1.**
Para 15, p.22. “Listen to your patient.”
Para 1, p.23. “Don’t dismiss what they’re saying offhand because it’s not toeing the party line.”

**Service User 3.**
Para 15, p.16. “Listening. Listening to service users.”
Para 1, p.17. “So I do honestly think, listening, working together with service users.”

The responses identified the importance of being understood. Hence personalisation was considered an essential component of patient-centred care.

The need for consistency in conveying information to service users was highlighted in the following extract from Consultant Psychiatrist 3 who also identified the importance of continuity for the recipient of care.

**Consultant 3.** Para 7, p.11. “We have got a continuity model here, possibly only a few places in the country that the same team manages them in the community or as an inpatient as well…… “
Para 8, p.11. “When they become acutely unwell and psychotic, and particularly when they are detained under the Mental Health Act, that is the more difficult and tricky time for people to understand about their treatment plan and care plan and consent - give informed consent about any treatment options or interventions.”
Para 4, p.12. “But we still, we need to continue to pursue that sort of practice to say continue to inform them, continue to repeatedly give them some information.”

This finding is consistent with the findings from other studies in which continuity of care was deemed an important aspect of patient care (Laugharne, Priebe, McCabe, Garland, & Clifford, 2012, p. 499; NICE, 2014, p. 6).

GP 3 further emphasised the importance of service user engagement as part of a process for facilitating an understanding of the rationale for treatment, thus empowering the individual to review their treatment options.

**GP 3.** Para 5, p.15. “And at the centre of it all, we’re talking about…but the guidance, the patient should be able to follow it and understand it and understand why you’ve done something.”
5.33.11  The role of guidelines

Despite the acknowledged limited role of prescribing guidelines in certain patient groups, there was broad agreement from industry representatives, GPs and pharmacists that prescribing guidelines acted as governance framework for practice (see Sections 5.3.1, 5.14.1, 5.20.1 and 5.25.1). Furthermore, all professional stakeholder groups and industry representatives acknowledged the role of prescribing guidelines in promoting evidence-based practice and minimising risks to service users. Psychiatrists identified the need for prescribing guidance in specialist patient groups such as pregnancy (see Section 5.25.1).

Pharmacist 4 outlines his perspective on the applicability of prescribing guidelines in the following comment:

Pharmacist 4. Para 4, p.1. “It’s a set of rules that would apply to the majority of patients, not necessarily every single one.”

The comment by Pharmacist 4 reflects the limitations of prescribing guidelines under certain circumstances, e.g. in patients with comorbid disease states. This was reflected in the findings by Industry Representatives (see Section 5.3.3.1).

Industry Representative 2 identifies the role of guidelines in the context of an aide-mémoire for GPs.

Industry Representative 2. Para 4, p 11: “and you’re making a diagnosis, how can I hold every clinical guideline in my head.”

Para 6, p 11: “How can I even hold the questioning I need to ask to get me to the right diagnosis?”

The response from Industry Representative 2 identifies the role of guidelines in the education of the practitioner which is consistent with the findings from the pharmacist interviews (see Section 5.14.1) and consultant interviews in which prescribing guideline were considered as an educational support mechanism for less experienced doctors (see Section 5.25.1). Furthermore, GPs identified a role for guidelines as an educational tool and reinforcing expected standards of prescribing (see Section 5.21.2).
The notion of measuring the impact of prescribing guidelines was alluded to by Industry
Representative 4 who was a former prescribing advisor for a PCT.

**Industry Representative 4.** Para 4, p. 10. “I think it does have an impact, I think it should have an
impact and it does have an impact.”

It is possible that this view reflects his prior experience in which practice based pharmacists
were measured by achievement of prescribing efficiencies which directly relate to prescribing
guideline adherence. Measuring the impact of prescribing guidelines in clinical practice is
linked by Pharmacist 3 to corporate expectations of prescribing practice.
Corporate expectations of prescribing in a mental health setting is often linked to cost
containment, as the costs associated with prescribing are easily determined and are often
measured in isolation of clinical outcomes and associated secondary costs.

**Pharmacist 3.** Para 2, p.1. “Lays a parameter for the organisation as to what the organisation
expects a prescriber or their prescribing patterns to be.”

GP 2 outlines the role of a borough formulary, a platform against which prescribing can be
measured which gives an assurance to the practitioner. This is consistent with the perspective
from the pharmaceutical industry representatives (see Section 5.3.1.1) in which the role of
guidelines are articulated in terms of a governance structure and assurance for GPs.

**GP 2.** Para 9, p.3. “but I think sometimes having a locality formulary can be helpful because it
can give you an idea and you’ve got the backing of that in a way.”
The role of guidelines in assurance to the individual GP was further outlined by GP 5 who had expressed his lack of knowledge of mental health therapeutics (see Section 5.21.2) with the following statement:

**GP 5.** Para 4, p.2. “there's various things that will progress, but being in general practice you might not be the forefront of new introductions to things and new drugs coming out, et cetera.”

Para 4, p.2. “So we also are quite dependent on guidance, so usually guidelines as to what we can prescribe, how we follow things and what we do.”

Consultant 2 outlined the rationale for the use of prescribing guidelines in clinical practice in supporting clinical decision making.

**Consultant 2.** Para 2, p.2. “that they're a helpful tool to guide clinical decisions on starting treatment, and particularly in the situations where there is no specific reason or preference for only one then, just to summarise the best available evidence and, yeah, helping the decision making process.”

Constant 2 went on to rationalise the role of guidelines in mitigating poor prescribing practice with the following statement:

**Consultant 2.** Para 7, p.7. “The risk of not having any guidance is people prescribing based on their idiosyncratic clinical experience that sometimes can be quite harmful, so I do think that in terms of risk and benefits guidance they're good……”

“…it’s good to actually have to refer to guidance so that we are not allowed to prescribe anything out of our clinical experience.”

This observation by Consultant 2 regarding idiosyncratic prescribing is consistent with the findings of serval national audits in which prescribing practice has not reflected national guidance across a range of measures, including associated physical health checks and inappropriate polypharmacy (Patel et al., 2014, p. 507; Barnes & Paton, 2011, p. 330).

Consultant 3 summarises in the following statement the role of prescribing guidelines in the context of a governance framework and best practice model of care.

**Consultant 3.** Para 8, p.2. “I do think they’re relevant, yes, because I think the consistency, and the fact that the evidence base on which they’re generated is useful to all prescribers.”
Consultant 3 later outlines the inherent risk of prescribing outside of a governance framework. He also alludes to the role of prescribing guidelines in governing the physical wellbeing of the patient by outlining the appropriate physical healthcare of the recipient of care.

*Consultant 3. Para 3, p.9. “There’s no doubt about it, sometimes if there’s no guidance, there’s no reference point, there’s a risk….”

“And, at least it provides certain standards, not just standards of what you prescribe, but standards of how you manage the response, how you treat people physically, and what monitoring needs are required.”*
5.33.12 Wellbeing

Service users expressed varying ideas about wellbeing and the potential impact of medication (see Section 5.9.2). There was an acknowledgement of the positive impact of medicines on quality of life but this was balanced against the potentially debilitating adverse effects and the problem of weight gain (see Section 5.9.1). These views were also reflected in the interviews with healthcare professionals and representatives from the pharmaceutical industry who were asked to consider what efficacy might mean to the recipient of care (see Sections 5.3.2, 5.14.1, 5.19.1 and 5.24.1).

The following is an extract from Service User 2 with regards to medication and wellbeing. The extract captures both the quality of life for the individual and identifies the importance of tolerability.

Service User 2. Para 3, p.5. so, this medication was working for me, you know, I was quite getting on with my life, it didn’t make me feel doped up.”

The findings from the interviews with the consultant’s mirrors that of the service users themselves and is typified by the following quote from Consultant 5, in which he responds to a question probing him about what efficacy might mean to a service user.

Consultant 5. Para 4, p.17. “more concerned about the harm, how little this drug is going to have a negative impact on me, is it going to make me a zombie, over sedate. Is it going to cause me any other side effects, sexual dysfunction, agitation, is it going to cause me long term damage, is it going to cause my physical health”

In section 5.19.1, GP 3 identifies efficacy in terms of desirable symptom remission for the recipient of care and makes a distinction between their desires and that of the clinician. This observation has important implications for patient care and medicines optimisation because it focuses attention on treatment goals as defined by the recipient of care. Thus, the individual and the practitioner share their respective information and determine collaboratively the optimal treatment, which is consistent with the model of shared decision making as outlined by Deegan & Drake (2006, p. 1637).
The following extract from the interview with GP 2 outlines his perception of the patient perspective on wellbeing and reinforces the notion of quality of life which is linked to tolerability and stability for the individual.

**GP 2. Para 7, p.5.** “Some form of stabilisation, good improvement, it would be tolerable, enable them to enjoy a better quality of life compared to when they were premorbid.”

Section 5.14.1 details the findings from the pharmacist interviews in terms of what efficacy might mean to a service user. Pharmacists 3 and 5 considered that the service user would balance wellbeing with tolerability which is in keeping with the findings from the interviews with the service users (see Section 5.9.2).
5.33.13 Summary of concordant findings

The findings from this study suggest that communication with service users was fundamental to a concordant relationship which facilitates the optimal use of medicines. Service users expressed the need to be understood holistically reflecting their value systems and required healthcare professionals to provide reassurance, practical advice and support (see Sections 5.9.3 and 5.9.4).

Healthcare professionals expressed the importance of continuity in conveying information to individuals with enduring mental illness about their medication. Furthermore, there was an acknowledgement of the need to empower service users to optimise the outcomes from the medicines they are prescribed (see Sections 5.14.5, 5.19.2 and 5.24.2).

The use of prescribing guidelines was viewed in the context of promoting evidenced-based practice and education, especially with primary care clinicians and junior medical staff (see Sections 5.3.1, 5.14.1, 5.20.1 and 5.25.1). Consultants while affirming the need for prescribing autonomy, acknowledged the importance of guidelines in minimising poor prescribing practice. In particular, prescribing guidelines were considered to be of significant value in special patient groups where there is minimal evidence to support evidence-based prescribing (see Section 5.25.1).

The findings from this study indicated that healthcare professionals acknowledged the impact of adverse effects on patient perceptions of wellbeing associated with medication use (see Sections 5.14.1, 5.20.2 and 5.24.1). This is an interesting finding since both healthcare professionals and service users were aligned in the understanding that principally, recipients of treatment were primarily concerned with the side effect burden of the intervention and that the impact on symptom remission, while important, was not a primary concern. The finding is typified by the following quote from GP 4.

GP 4. Para 3, p.3. “the patient will want to know what we expect in terms of side effects, which will inform whether they are prepared to take a chance with side effects versus the efficacies of the treatment.”
5.34 Strengths and limitations of the study

The strength of this study is that it explored prescribing in mental health from a range of stakeholders; which has not been undertaken previously in a single study. The relatively small stakeholder sample size may be considered as a limitation of this study. However, the emergent data were rich enough to cover a wide range of views and there was a recurrence of several themes which provided sufficient data for analysis.

5.34.1 Healthcare professionals

The health professionals who took part in this study agreed to do so following a request from the researcher; therefore, those with a clear interest in medicines optimisation, who were willing to take the time to participate in this study may not have been representative of the wider workforce. It is not known if participants who declined the invitation to take part would have similar experiences to those who agreed to participate. In this sense, the participants are unlikely to be representative of the stakeholder groups as a whole.

5.34.2 Service users

Not all participants were satisfied with their pharmacological treatment; but they had engaged with treatment and may have been more positive than those who did not engage. Conversely, those who participated may represent a more negative cohort wishing to express their dissatisfaction with treatment.

The age of the expert by experience service user group involved in the study may also limit the findings. This is because all individuals in this group were below the age of 65. As mental health problems are present in individuals of all ages, it is possible that older participants might have added to the rich, descriptive data obtained from the study. It is also possible that expert by experience service users might not be representative of service users that are not strategically engaged with healthcare provision and might represent another limitation of this study.

The heterogeneity of mental health diagnoses across the service user group may have had an impact on the study findings with needs and expectations varying according to diagnosis.

5.34.3 Pharmaceutical industry

Representatives from the pharmaceutical industry were chosen because of their seniority and strategic remit within the organisation. All industry interviewees discussed the need for joint working, and the exploration of new ways of collaboration with the NHS. However, despite
these aspirations, industry representatives at a local level are primarily driven by sales-targets. Thus, the views expressed by interviewees contrast with the factors driving the activity of local sales representatives.

5.34.4 Researcher Characteristics/Identity

As a Chief Pharmacist, the author was directly involved in guideline development and strategic leadership for medicines management across the trust. It is therefore possible that this may have had some influence on the responses received from interviewees.

It is acknowledged that although the author may have held some preconceived ideas, these were not necessarily the same as those with direct experiences of prescribing, commissioning of mental health services or representation of the pharmaceutical industry. The author attempted to be as objective as possible throughout the data collection. It has been argued that only individuals that are directly engaged as members of a group can fully understand the experiences of those within that group and therefore the interpretations of an ‘outsider’ in this case the author, may diverge from those shared experiences (Hockey, 1999, p. 220).

5.34.5 Generalisability

The findings from this study cannot be generalised to all mental health services. This is consistent with the research methodology which aimed to explore participant’s views and experiences in detail. The author has provided a rich, transparent and contextualised account of participant’s views to enable the reader to determine the transferability of the findings to their healthcare setting.

5.34.6 Reflexivity

It is possible that the researcher in the role of a Chief Pharmacist could, unintentionally, exert pressure on healthcare professionals and service users to participate. To minimise the potential influence to participate, individuals were approached on a single occasion to participate and were informed that their involvement was optional.

It was also possible that participants felt obliged to answer in a particular manner. To try to elicit genuine responses, the researcher followed the interview in conversational manner which often meant that the interview questions were not asked in the order as outlined in the interview schedule. Iterative questioning, in which the participant was asked similar questions, enabled the interviewer to cross check prior responses and probe for detailed answers which would highlight potential falsehoods.
The author made every effort to ensure objectivity and was aware of the potential biases as articulated by Miles and Huberman (1994, p. 263):

- holistic fallacy: interpreting events as more patterned and congruent than they really are, lopping off the many loose ends of which life is made;
- elite bias: overweighting data from articulate, well-informed, usually high status informants and underrepresenting data from less articulate, lower-status ones;
- going native: losing your perspective or your “bracketing” ability, being co-opted into the perceptions and explanations of local informants.

In this study, the researcher repeatedly referred to the dataset when developing the themes during data analysis; this was subject to external scrutiny by project supervisors.

Elite bias was minimised by analysing each stakeholder group separately, thus giving a voice to each interviewed group. Furthermore, the focus of the analysis of the interviews was based in part on meeting the study aims and objectives which was not dependent on the seniority of the individual respondent.

The researcher remained aware of his perspective as a pharmacist and it is possible that he exercised attributional bias.
Chapter 6: Conclusions

The aim of this study was to explore prescribing practice in a mental health setting from a range of stakeholders using qualitative research methodology and in particular, the use of semi structured face-to-face interviews. Framework analysis was used to analyse the interview transcripts which facilitated a rich understanding of the comparisons between various stakeholder groups.

Despite the primary objectives of the study, the analysis of the findings led to rich descriptive data that, in addition to addressing the initial research aims and objectives identified key tensions and concord between stakeholder groups. The conclusion will detail the findings from the study in relation to the study aims and objectives and will summarise the core emergent tensions and concord based on the Framework analysis of the interviews; following this the conclusion will summarise the recommendations for future research and detail the actions for practice in relation to the research findings.

6.1 Authenticity of data

Lincoln and Denzin (2011, p. 366) cautioned that the involvement of the inquirer can influence the ability to speak authentically for the experience of others, which requires conscious attention to the influence of the inquirer. The author was mindful of the concerns as articulated by Lincoln and Denzin and this influenced the decision to use Framework analysis for the study data. The use of a variety of stakeholders is representative of the complexity of real life health care systems and the existence of multiple perspectives on health care. The use of the Framework analysis was chosen in an attempt to produce findings that were transparent and that could be directly linked to the study data set, in addition to meeting the research aims and objectives.

The study incorporated a variety of differing stakeholders to ensure that the research reflected not only the concerns of the providers but also the recipients of care. The research was designed to reflect the meaning, lived experiences and perceptions of the participants. This was reflected in the design of the questions. Participants were asked to respond to open descriptions of the subject under consideration which is supportive of establishing the trustworthiness and authenticity of the data (Streubert and Carpenter, 2011, p. 93).
For example, in this study service users were asked the following:

“Based on your experience, what is the most important thing that mental health professionals should know in order to be helpful to people using medications?”

This question gave an opportunity to compare and contrast data with healthcare professionals in terms of their role in communicating to service users.

The audit trail of how data were collected and analysed has been detailed in Chapter 4 of this thesis. The use of verbatim extracts from the data set also enable transparency from the raw data to interpreted meanings. The potential influence of the inquirer in authentically representing the views of others has been identified and addressed through the use of data extracts, thus highlighting the views of the various stakeholders.

6.2 Meeting the study objectives

The four key objectives from this study were as follows:

1. To explore with service users the extent of their involvement in treatment decisions about prescribed medication and the factors that influence this.
2. To explore the factors that influence the implementation of prescribing guidelines in a mental health setting from a range of stakeholders.
3. To explore the perceived factors that influence prescribing in a mental health setting.
4. To provide a framework of recommendations for optimising the use of medicines across the health economy.

Objective 1: Exploration of involvement in decision making and factors that influence this

The findings of the study suggest that service users did not consider their involvement central to the decision-making process and this was set within a historical context of engagement with their psychiatrist. The lack of engagement occurred for several reasons including; paternalism by the clinician, service user fear of the consequences of challenging clinician autonomy and a lack of awareness of their treatment options.

The paternalistic role of clinicians was reinforced by one consultant who was near retirement at the time of the interviews. His statements were linked to an historical approach to consultations in which the clinicians were regarded as experts and the recipients of care were not regarded as experts of their own wellbeing.
This finding is consistent with that of other reviews in which patients were regarded as passive recipients of care (Tambuyzer, Pieters, & Van Audenhove, 2014, p. 143; Ha & Longnecker, 2010, p. 38). There was an acceptance by other psychiatrists that patients have embraced a more active role in their care, however, despite this acknowledgement, treatment choice was discussed in the context of available options for the psychiatrist and not the service user. This has important implications for service users who expressed the need to have meaningful engagement in their treatment options. Thus, the findings from this study would suggest that the needs of service users are not currently being met within the context of treatment choices.

This study identified that service users were fearful of the consequences of being perceived as non-compliant with treatment and this was linked to reputational concerns for the individual as well as the potential for compulsory detention and treatment under the Mental Health Act. In contrast to the findings by Eliacin, Salyers, Kukla, & Matthias, (2014, p. 26), where service users expressed fear about their own competency to make an informed decision about their pharmaceutical care, participants in this study expressed a degree of confidence about making treatment decisions. In part, the confidence of participants in the study is related to two factors, the first is the length of their experience with mental health services and the second is their professional backgrounds as three of the service users were involved in healthcare delivery.

Objective 2: Factors that influence the implementation of prescribing guidelines

The study identified several factors that impacted on the implementation of prescribing guidelines in clinical practice, which included the technological infrastructure to facilitate timely reminders, which was present in primary care, but not in the mental health trust. Furthermore, GPs identified that prescribing guidelines could be used as part of a wider educational outreach programme which could incorporate clinical audit as part of a drive to improve prescribing standards. Comprehension of clinical guidelines was identified as a potential barrier to successful implementation by pharmacists who suggested that this could be addressed by an educational outreach programme as well as focusing on a practical design for prescribing guidelines. Shared care agreements were also regarded as a further mechanism to encourage GPs to prescribe psychotropic medicines with which they were unfamiliar.

GPs and pharmacists considered the use of peer support a suitable mechanism to facilitate the process of implementation as well as an educational programme detailing the rationale and background to the guideline development.
Objective 3: Factors that influence prescribing in a mental health setting

The complexity of individuals seen in clinical practice was identified as a key factor governing prescribing practice by all healthcare professional groups. Individuals with comorbid disease states were identified as a limiting factor in implementing protocol driven care by healthcare professionals. GPs viewed the role of guidelines as educational and instructive in prescribing practice, by contrast psychiatrists acknowledged the limited influence of guidelines on their prescribing practice, however there was an acknowledgement that prescribing guidelines would influence prescribing for more junior medical staff. Psychiatrists cited evidence as the most important factor driving their prescribing decisions and there was minimal acknowledgement of the role of the pharmaceutical industry on influencing practice. GPs unlike their specialist counterparts, cited patient pressure as a potential influence on prescribing practice, this view was linked to expectations by patients that GPs would use pharmacological interventions to manage their presenting symptoms.

Objective 4: A framework of recommendations for guideline development and practice

Service Users

The findings from the service user interviews indicated that they wanted to be engaged in decisions about the pharmacological treatments they receive; they felt that they were provided with inadequate information about prescribed medicines. As a result of these findings a number of steps have been taken or are in development to optimise the use of medicines for service users. These steps include: the use of service user groups in the revision of prescribing guidelines, the development of summary guidelines for service users, a continuous programme of educational meetings with service user/carer and voluntary sector organisations and the provision of counselling on medication for all inpatients prior to discharge from in-patient care.

GPs

During the interviews with GPs several concerns were raised which related to poor communication with mental health services and in particular, a lack of clarity regarding the monitoring associated with the prescribing of psychotropic medicines. In response to these findings, the pharmacy team is working with medical colleagues to develop an education programme for GPs in terms of physical healthcare of patients with enduring mental illness. Furthermore, internal newsletters that have been developed to inform, and educate healthcare professionals within the trust will now be made available to healthcare professionals across the local health economy.
**Psychiatrists**

The author will present the findings of the study to the Associate Medical Directors of the trust. Emphasis will be placed on the need for rapid access of information and support by GP colleagues in mental health therapeutics. The author has developed a Medicines Management CQUIN for 2016/17 which includes a measure of the evidence detailing the provision of information on prescribed medication to service users. The CQUIN has also led to improved identification and communication with primary care for individuals who experience difficulties with prescribed medication.

**Pharmaceutical Industry**

The desire for a closer working relationship with the NHS was expressed by all representatives from the pharmaceutical industry. There was also an acknowledgement of the importance of demonstrating the ‘value-proposition’ of new medicines to the NHS and risk sharing scheme has been adopted with a pharmaceutical company. The author is currently working with a pharmaceutical company to enable service users to have their depot injections administered in a non-psychiatric setting, via a community pharmacy.

As a result of discussions with the pharmaceutical representatives, all newly approved psychototropic medicines are subject to trust-wide evaluation to determine the impact on patient-care. This information will be fed-back to all prescribers across the trust and will also be conveyed to commissioners for wider discussions.

**Pharmacists**

Pharmacists have identified the importance of prescribing guidelines as an educational tool and as a means of supporting evidence-based prescribing. The author will support trust-employed pharmacists, to deliver education support and training for CCG and community pharmacists.

The pharmacy team have been actively involved in redesigning the discharge summary to make more explicit the rationale for prescribed medication and any changes in prescribing following admission to mental health services.

Trust-employed pharmacists will continue to support the evaluation of psychototropic medicines and will continue to work in conjunction with regional mental-health clinical pharmacists to support the regional work-streams aimed at improving prescribing practice. The work-streams will also incorporate undergraduates from regional schools of pharmacy to support practice.
research, but equally important, to promote and generate interest in mental health therapeutics.

6.3  **Key conclusions**

The findings from the study highlighted the complexity of decision making in prescribing practice. The success of patient centred care is dependent on several factors including; healthcare professional attitudes, healthcare provider models, patient empowerment, and resources such as electronic prescribing to support evidenced-based prescribing practice. The scarcity of timely prescribing reminders impacts heavily upon the decisions that are made which can have a substantial impact upon variability in treatment decisions and the ability to facilitate patient choice in a meaningful way.

6.4  **Areas of tensions**

The study identified a range of tensions between the differing stakeholder groups. These core tensions were:

- Joint working between the pharmaceutical industry and the NHS.
- Guideline versus individual driven care.
- Patient-centred care versus the realities of its delivery in a resource limited system.
- Rhetoric of service user choice versus the realities of shared-decision making in practice.

*Joint working between the pharmaceutical industry and the NHS*

This study identified the complexity of the relationship between the pharmaceutical industry and the NHS. Representatives from the pharmaceutical industry expressed the desire for more meaningful collaboration with the NHS. Furthermore, there was a focus on demonstrating the value proposition for pharmaceutical products and a need to be more closely aligned with the NHS infrastructure. It was acknowledged by healthcare professionals that there was a need for engagement with the industry but the nature and extent of the engagement was variable between the differing healthcare professional groups. All healthcare professionals considered the industry agenda to be linked directly to increasing sales, whilst that of the NHS focuses on maximising health outcomes by promoting cost-effective prescribing, in this sense healthcare professionals felt at odds with the industry agenda. These views are reflected in the critique of the pharmaceutical industry by Moynihan (2011, p. 1). Pharmacists were particularly distrustful of the pharmaceutical industry and viewed joint working in the context of efficiency gains for the NHS and the potential for facilitating stakeholder engagement. This view differed
from those of the GPs and psychiatrists who considered the industry to be a facilitator for continual professional development.

**Guideline versus individual driven care**
The findings from this study indicate that GPs and pharmacists recognised and accepted the primary role of prescribing guidelines in the context of promoting cost-effective prescribing. This view differed from that of psychiatrists who considered prescribing guidelines as primarily an educational tool for more junior medical staff. Psychiatrists noted that prescribing guidelines were restrictive and that they should retain autonomy to prescribe outside of the governance framework of guideline-driven care. These findings are consistent with that of other studies in which specialists were more reluctant than GPs to implement guidelines in clinical practice (Kasje et al., 2004, p. 235; Kasje et al., 2002, p. 514). A further finding from this study was that there was an acknowledgement of the importance of focusing on treating the individual rather than adhering to guideline driven care. A key consideration from this study is that prescribing guidelines should be explicit about the promotion of shared-decision making with service users which is consistent with the recommendations of (van der Weijden et al., 2013, p. 855).

**Patient-centred care versus the realities of its delivery in a resource limited system**
The delivery of patient-centred care was set against a context of delivering prescribing within a governance framework. The limitations of guideline driven care was acknowledged by all healthcare professionals who viewed guidelines as limited in the treatment of more complex individuals.

The nature of the healthcare professional’s interaction with the individual was a key issue for service users who expressed concerns that their views were not often accounted for as part of the consultation process. This finding is consistent with that of other studies in which individuals expressed concerns about not being engaged in the decision making process (Olofinjana, 2005, p. 370; Smith-Merry et al., 2010, p. 145). Furthermore, service users expressed concerns that consultants were focused on pharmacological interventions and that their care was not reviewed holistically. This was in part attributed to the limited consultation time and the lack of continuity in engagement with individual medical staff. Thus in essence, the three factors impacting on the delivery of patient centred care are:

- The style of communication by the healthcare professional, paternalistic versus a patient centred approach.
- The individual as the recipient of care incorporating their needs and expectation.
• The service delivery model which may conflict with the healthcare professionals’ ideology and which can include the prescribing infrastructure, continuity of staff and the time allocation for engagement with patients.

By addressing these tensions, the potential of pharmacological interventions to improve mental health well-being can be better realised.

**The rhetoric of service user choice versus the realities in practice**

The notion of a ‘patient’s best interest’ has often been provider led in mental health services, and the views of service users as experts in the understanding of their needs has often been overlooked. This is consistent with that of Curtis *et al.* (2010, p. 15), who identified in their review, that knowledge is seen as the domain of healthcare professionals who determine what treatments are in the best interest of recipients of care.

There was minimal acknowledgement from healthcare professionals about the importance of patient choice; there are potentially a number of reasons for this, first healthcare professionals have traditionally adopted a paternalistic role in treating individuals and the notion of the patient in the role of “consumer” is not culturally embedded in professional thinking.

A further limitation to offering individual choice is linked to distributive justice in which the primary focus of healthcare professionals is based on optimising the use of medicines across a given population. Another potential factor that impacts on choice is the limited timeframe during a consultation to engage with individuals to offer sufficient choice.

**6.5 Areas of concord**

In addition to identifying tensions the study also identified areas of concord, these were:

• Communication and its importance in medicines optimisation
• The role of guidelines
• Efficacy and its meaning for service users

**Communication**

The need for consistent and individualised communication was acknowledged by all healthcare professionals, representatives from the pharmaceutical industry and service users themselves. Service users expressed a desire for individualised care in which their concerns were addressed during consultation with healthcare professionals, they also noted that there were issues of continuity in inter-professional communication that impacted on their wellbeing.

This is consistent with the findings of the review by Reilly *et al.* (2012, p. 5) in which information
and health economy continuity was poor for individuals with severe mental illness. The findings from this study have important implications for medicines optimisation, as it is likely that if there is no clear agreement between the recipient of care and the healthcare professional then concordance will be less than ideal. Thus, the impact of medicines on wellbeing cannot be fully realised unless there is optimal communication with the recipients of care, furthermore information needs to be tailored to the individual, timely and consistent across healthcare settings.

**The role of prescribing guidelines**

All healthcare professionals considered prescribing guidelines a useful source of evidence for clinical practice. Furthermore, GPs considered prescribing guidelines essential to their educational development in mental health therapeutics. In addition to a role in educating doctors, pharmacist also linked the use of prescribing guidelines with the promotion of cost-effective prescribing; a view which was shared by GPs. Conversely, psychiatrists considered the use of prescribing guidelines more applicable to junior member of staff, however, they acknowledged the importance of guidelines in supporting the treatment of more complex individuals. Psychiatrists also noted a role of prescribing guidelines as a benchmarking tool which could be used to measure practice against defined standards, thus facilitating patient safety.

**Wellbeing and its meaning for the recipient of care**

Healthcare professionals and representatives from the pharmaceutical industry were asked to consider the service user perspective on the association between medication and wellbeing. The findings from the study indicated that service users, healthcare professionals and the pharmaceutical industry were in broad agreement that tolerability was a key issue for individuals and this had to be balanced against any perceived benefits of treatment. Service users assessed the impact of pharmacological treatment in terms of tolerability and quality of life improvements which enabled them to undertake their activities of daily living. The concord between healthcare professionals’ appreciation of the service user perspective on the impact of medication and well-being has important implications for agreeing outcomes and for shared decision-making. Understanding the individual’s perspective is important in facilitating a consultation that is more in keeping with the desires as expressed by service users. The empathy of healthcare professionals with the service user experience is important in promoting shared decision making and a sense of partnership working.
6.6 Recommendations for future research

The study has identified a number of tensions between stakeholder groups which warrant further investigation.

The identification of a tension between the pharmaceutical industries desire for greater collaborative working with the NHS and the deep held suspicion by healthcare professionals of the pharmaceutical industries motives could serve as a basis for future research. This study focused on the attitudes of senior GPs and psychiatrists, however, future research could explore the views of more junior medical staff and non-medical prescribers on joint working with the pharmaceutical industry, the study could focus on the role of the pharmaceutical industry in education and training.

Further research could be undertaken to evaluate the impact on patient outcomes of existing joint working between the pharmaceutical industry and mental health services.

Considering the planned move by the pharmaceutical industry to publish details of sponsorship, gifts and hospitality offered to healthcare providers and commissioning bodies, a future study could explore the impact of publication, on the frequency and nature of the activity between mental health services and the pharmaceutical industry.

This study identified a tension between the rhetoric of service user choice and shared decision making. There are two areas that need to be addressed in future research exploring shared decision-making and patient choice:

- identifying different methods that can be used to explore shared decision-making and;
- exploring the effectiveness of different ways of making decisions.

Identifying patient preferences and priorities, alongside measures capturing clinical outcomes such as illness severity, may reveal more about the factors that patients identify as important.

Identifying individuals’ needs and understanding better their perception of a ‘good’ treatment outcome may enhance patient satisfaction and modify healthcare professional expectations regarding patient outcomes.

Patient-centred care versus the existing service delivery was identified as a tension in this study which is consistent with the findings of other studies (Seale et al., 2006, p. 2870; Smith-Merry et al., 2010, p. 130). An ethnographic approach could be adopted in a future study to
explore through observing actual consultations. This approach would allow for the exploration of decision-making and holistic care in a more natural context than the method used within this study. It may also have the potential to evaluate the indirect ways that patient preferences may or may not influence decision making during the consultation. While such an approach might yield useful insights, it would not be without limitations and the incorporation of more ‘intrusive’ measures may reduce the likelihood that professionals and service users will participate in such a study.

In addition to the identified tensions from this study, further research could incorporate the findings from this study, where applicable, and determine quantitatively if implementation has any impact on service user care. Furthermore, this study did not include non-medical prescribers as a stakeholder group because of the limited numbers in practice across the trust. A future study could incorporate their views and explore ways of improving prescribing practice across a health-economy.

6.7 Practice and organisation development
At the request of the author, the trust service user groups across the local health economy have been approached and an on-going programme has been developed. Pharmacists provide updates to these groups to promote the resources that are available to empower individuals to optimise the use of medicines. The pharmacy team is also actively engaged in communicating medicines related issues to colleagues in primary care. This is intended to support the individual with the transition from one healthcare setting to another and to mitigate the risks of future admissions to hospital due to medication.

A Medicines Management Competency Framework has been developed to support nursing and medical staff across the trust to understand in greater detail medicines management standards and the role of medication in the treatment of both psychiatric and physical health conditions. The framework promotes an understanding of the benefits and limitations of prescribed medicines and empowers nurses and doctors to better engage with individuals about their medication.

The pharmacy team is working in conjunction with colleagues from the psychology department to develop joint guidelines and to promote patient engagement and empowerment with medication taking. All service users on admission to hospital wards are offered the opportunity to discuss prescribed medicines with a member of the pharmacy team. In addition to engagement with healthcare professionals across the trust, the pharmacy team also supports
Social Care staff in medicines optimisation by delivering training and education. This initiative supports staff who may have engagement with service users regarding medication.

**Pharmacy**

All members of the pharmacy team are expected to be actively involved in continual professional development (CPD) as required by the General Pharmaceutical Council and are expected to be active in delivering training and education to service users/carers, Social Care staff and healthcare professionals.

All pharmacists are expected to undertake the Postgraduate Certificate in Psychiatric Therapeutics run by Aston University which is designed to support pharmacists who wish to specialise in mental health. The training supports the role of the clinical pharmacist in engaging with healthcare professionals and services users alike to promote the optimal use of medicines.

Pharmacy technicians have become increasingly engaged in providing clinical information to healthcare professionals and service users. As part of a development programme, pharmacy technicians are actively encouraged to undertake training to support their emerging role. All technicians are expected to undertake the Centre for Pharmacy Postgraduate Education (CPPE) training on consultation skills prior to completion of the module in mental health. Following successful completion of this, pharmacy technicians will be supported to undertake clinical modules from the Aston University Postgraduate Certificate in Psychiatric Therapeutics.
Chapter 7: Reflective account

Personal reflections

As a pharmacist with a special interest in mental health and a responsibility for developing localised prescribing guidance, I was often curious about the extent to which clinicians valued prescribing guidance, if at all, and the perceived needs of GPs, when compared with specialist prescribers in a mental health setting. Furthermore, I was intrigued at the possibility of considering the potential barriers and facilitators to guideline implementation across the local health economy. As a Chief Pharmacist, I was mindful that my own profession was often responsible for developing and monitoring compliance with prescribing guidance and therefore it was logical to include its views on how to best optimise evidence-based prescribing across the local health economy.

Following conversations with expert by experience service users, I was intrigued at the extent to which they felt that their experience was central to their therapeutic journey. Several discussions with service users had led to the expression of dissatisfaction with the pharmacological treatments they had received; in particular, a lack of information on medication. These conversations broadened my initial research idea to incorporate the views and perspectives of the service users as the recipients of care, and to explore the extent to which they perceived involvement in making treatment decisions, and the factors that influence this.

The inclusion of the pharmaceutical industry as part of the research, occurred after several conversations with representatives from various companies who expressed the need for more collaborative working between the industry and the NHS. The research project explored with representatives from the pharmaceutical industry the perceived factors that influence prescribing and implementation of guidelines in mental health. Also, the research explored the ways in which the pharmaceutical industry and the NHS can collaborate to deliver better patient-care.
Part 1 - Reflections on taught component of the Doctorate

7.1 Statistical methods (SPSS)

The statistical module was challenging and very relevant to my practice as a pharmacist involved in reviewing clinical trial data. There are numerous statistical approaches that are adopted to demonstrate the efficacy of medicines in clinical trials and the statistical module was a useful revision for information that I had learned from various post-graduate studies. I discovered the use of YouTube as a means of supplementing information gained from lectures. The use of a visual means of learning was linked to the feedback on my learning style, which was never assessed prior to my doctoral studies. As a visual learner I was able to supplement formal lectures with online visual resources.

7.2 Qualitative research

As a novice researcher, I was unfamiliar with qualitative research and its underpinning philosophical beliefs, about values, concepts, and the nature of knowledge itself. In order to understand these philosophical perspectives, I read several texts, but found that definitions, were at times confusing. Following a discussion with a colleague, I read Patton’s Qualitative Research and Evaluation Methods. This text was a useful, practical, comprehensive and reader-friendly guide for a novice researcher and supported my learning.

7.3 Publication and dissemination

The publication and dissemination unit enabled me to think about the importance and relevance of publication. This was particularly important as I was involved in a regional work-stream which was aimed at promoting and disseminating good practice amongst NHS employed pharmacy staff in the West Midlands.
7.4 Part 2 – The research project

In some ways, the progression to Part 2 of the professional doctorate felt like a new beginning. In essence, I was able to focus on the goal of undertaking the research project, which was the primary reason for enrolling on the course.

The aim of the research project was to gain an understanding of the views of a variety of stakeholders on prescribing practice in mental setting. It was anticipated that the findings from the study would lead to recommendations for improving prescribing practice.

One of the challenges that had to be overcome was the engagement with the pharmaceutical industry and GPs in particular. The pharmaceutical industry representatives were initially cautious about taking part in the study. However, I decided that I would adopt the principle of peer pressure to encourage participation in this group. Following the first interview with the pharmaceutical industry representative, subsequent representatives were informed that a competitor had already participated, although the identity of the competitor was never revealed. This seemed to catalyse involvement in the study and near completion of the data collection, the Chief Executive of a pharmaceutical company approached me in person to participate.

In one instance, an appointment with a GP was made 6 months in advance of the planned interview, due to his busy schedule. I was mindful that personal relationships which had been developed over a number of years were a contributory factor in agreeing to participate for healthcare professional and service users.

This study was the first occasion in which I had undertaken qualitative research and a key concern was the lack of experience in interviewing subjects; despite reading several textbooks and watching numerous videos. The pilot interviews were the best way to prepare for data collection and they informed my approach on questioning subjects which led me to adopt more of a ‘conversational’ rather than ‘question and answer’ style of interviewing.

7.5 Impact of the doctorate in the workplace

The professional doctorate was the first multidisciplinary post-graduate study that I had undertaken. This enabled me to consider the target audience more carefully as I am often responsible for conveying key messages both verbal and written to a variety of healthcare professionals. This was also reflected in my work environment in which I would be required to write a variety of papers for submission at board-level that would detail the role, achievements
and strategic intent of the pharmacy service. The recipients of these papers would often include non-clinical staff and therefore prior understanding of the role of pharmacy could not be assumed.

7.6 Professional development

Throughout my career, I have enjoyed and valued the role of education and training which have been a key aspect of my professional development. As a resident pharmacist, I was faced with the challenge of providing medicines information and framing answers in a context based on the knowledge and experience of the recipient. The provision of information outside of the core working hours for pharmacy would involve information retrieval and dissemination swiftly, depending on the nature of the enquiry. The importance of remaining up-to-date with clinical knowledge was further reinforced by studying for the Clinical Diploma at Keele University.

Following my decision to specialise in mental health, I recognised that my knowledge was limited in this specialism and this motivated me to study a Post-Graduate Certificate and Diploma in Psychiatric Therapeutics. My first role in psychiatry proved very challenging as I was working in a general hospital that provided a pharmacy service to the local mental health trust. There was both limited understanding of, and importance given for developing the role. In some ways, this galvanised my working relationships with colleagues from the mental health trust and I sought help and support for my learning from both medical and nursing colleagues with whom I would later meet in my role as a Chief Pharmacist.

Following a period in mental health I decided that I needed to gain a differing perspective on healthcare provision and worked as a prescribing advisor for a PCT. This was a period of great professional development as I started to conceptualise the delivery of pharmaceutical care in terms of the health economy perspective and not the individual recipient of care. Furthermore, I was responsible for managing prescribing across a locality which involved close working with key GPs. This proved to be advantageous in future discussions with commissioners as I could understand the pressures they faced in managing prescribing costs.

My interest in mental health was not diminished in any way and so I decided to undertake a Master’s degree which evaluated the impact of interventions to minimise the use of benzodiazepines and z-hypnotics in primary care. During this period, I also undertook training to become a non-medical prescriber specialising in the management of depression and anxiety related disorders in primary care.
After three years in primary care I decided to return to my area of interest and was employed as the Deputy Director of Pharmacy at Birmingham and Solihull Mental Health Trust. It was during this period that I reviewed my ideas about research in mental health. I shared my initial thoughts with a colleague who helped to refine my thinking which ultimately contributed to the current study.

My career progression has been aligned with the drive for continual learning and professional development. Each career move and postgraduate study has helped to shape my thinking and refine my ideas in terms of communication, leadership and gaps in knowledge and awareness.

My professional development has been characterised by the need to challenge my own boundaries. Perhaps one of the most significant insights that I have gained in recent years is my passion for delivering education and training, which I suspect, will play an important role in my future career progression as well as contributing to practice-based research.
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Appendix 1: Literature search strategy
Literature search strategy

A review of the literature was undertaken using the NHS Healthcare databases advanced search (HDAS) to identify studies or relevant publications that would address the aims and objectives of the study or that would help to set a context to the New NHS following the 2012 Health and Social Care reforms.

The principles of a systematic review (i.e. comprehensive searches, transparency and consideration of study quality) were adhered to using the approach as outlined by the Critical Appraisal Skills Programme (CASP).

The search was kept purposefully extensive to encompass the complexities of the literature relevant to the following aspects of the study. Any study investigating these issues was considered relevant:

- The impact of the Health and Social Care Act and subsequent NHS reforms
- The role of the Pharmaceutical industry and its relationship with the NHS
- The history and role of mental health service user engagement within the NHS
- Prescribing guidance in mental health

The following databases were systematically searched in February 2014 and auto-alert searches were set-up to ensure new literature was identified throughout the study’s duration. A hand search of retrieved articles was undertaken to obtain publications of interest for inclusion in the review.

A final search was conducted in February 2016 of the following databases:

- MEDLINE
- PsycINFO
- EMBASE
- The Cochrane Library
- Department of Health Database
- Health Management Information Consortium
- Health Business Elite

The search was conducted using a mix of subject headings (see examples below) and freetext terms. Relevant terms were combined for the differing subject headings.

Individual searches were conducted on each database because of the varied subject coverage, indexed content, date coverage and other features such as the facility to ‘map to a thesaurus.’

The literature searches were based on the main headings and subheadings as identified in the tables below, e.g. NHS Transformation, economic imperative for change, Clinical Commissioning Groups and payment by results.

Examples are given of specific searches within each subsection of the literature review. The examples highlight the use of a range of databases.
# NHS Transformation - Database and search terms used

<table>
<thead>
<tr>
<th>Main heading &amp; subheadings</th>
<th>Database/ sources</th>
<th>Key search terms</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NHS transformation</strong></td>
<td></td>
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<tr>
<td>• The economic imperative</td>
<td>• EMBASE</td>
<td>• 5 Year forward view</td>
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<tr>
<td>• Clinical Commissioning Groups</td>
<td>• Contacts at the DoH</td>
<td>• Care closer to home</td>
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<tr>
<td>• Payment by results</td>
<td>• Health Management Information Consortium</td>
<td>• Care clusters</td>
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<td></td>
<td>• Health Business Elite</td>
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<td></td>
<td>• Medline</td>
<td>• Commissioning Groups</td>
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<td>• General practice</td>
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<td>• Health and Social Care Act</td>
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<td>• Healthcare quality</td>
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<td>• Interface</td>
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<td>• Mental health</td>
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<td>• Models of Care</td>
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<td></td>
<td>• Commissioning</td>
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<td>• NHS reformation</td>
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<td>• NHS structure</td>
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<td>• Payment by Results (PbR)</td>
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<td>• Primary care</td>
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<td></td>
<td>• Quality outcomes framework</td>
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<td></td>
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<td>• Regulation</td>
</tr>
</tbody>
</table>
Below is an example of a search of the EMBASE database for literature relating to the implementation of Payment by Results in English NHS mental health providers. Similar searches were conducted using the Health Business Elite, Health Management Information Consortium and Medline.

Payment by results (PbR) search using EMBASE

<table>
<thead>
<tr>
<th>EMBASE Search Query</th>
<th>Number of Results</th>
<th>EMTREE Index Headers</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. exp REIMBURSEMENT/ OR exp PROSPECTIVE PAYMENT/ OR exp NATIONAL HEALTH SERVICE/ OR exp HEALTH CARE COST/ OR exp ECONOMICS/ OR exp HEALTH ECONOMICS/ OR exp HEALTH CARE QUALITY/ OR exp FINANCIAL MANAGEMENT/</td>
<td>3095687</td>
<td>reimbursement, prospective payment, national health service, health care cost, economics, health economics, health care quality, financial management</td>
</tr>
<tr>
<td>2. &quot;payment by results&quot;.ti,ab</td>
<td>268</td>
<td></td>
</tr>
<tr>
<td>3. exp COST EFFECTIVENESS ANALYSIS/ OR exp ECONOMICS/</td>
<td>351168</td>
<td>cost effectiveness analysis, economics</td>
</tr>
<tr>
<td>4. &quot;price tariff*&quot;.ti,ab</td>
<td>54</td>
<td></td>
</tr>
<tr>
<td>5. &quot;pbr&quot;.ti,ab</td>
<td>1799</td>
<td></td>
</tr>
<tr>
<td>6. exp MENTAL HEALTH/</td>
<td>103789</td>
<td>mental disease, schizophrenia, depression, mental health</td>
</tr>
<tr>
<td>7. &quot;mental health&quot;.ti,ab</td>
<td>118621</td>
<td></td>
</tr>
<tr>
<td>8. exp MENTAL DISORDERS/ OR exp MENTAL DISEASE/ OR exp ORGANIZATION AND MANAGEMENT/</td>
<td>3034984</td>
<td></td>
</tr>
<tr>
<td>9. &quot;mental disorder*&quot;.ti,ab</td>
<td>35743</td>
<td></td>
</tr>
<tr>
<td>10. exp MENTAL DISEASE/ OR exp MENTAL HEALTH/ OR exp DEPRESSION/ OR exp HEALTH/</td>
<td>2487814</td>
<td></td>
</tr>
<tr>
<td>11. &quot;mental ill*&quot;.ti,ab</td>
<td>28353</td>
<td></td>
</tr>
<tr>
<td>12. exp MENTAL DISEASE/ OR exp SCHIZOPHRENIA/ OR exp MEDICAL PRACTICE/</td>
<td>1812855</td>
<td></td>
</tr>
<tr>
<td>13. &quot;mental disease*&quot;.ti,ab</td>
<td>3290</td>
<td></td>
</tr>
<tr>
<td>14. exp FORENSIC PSYCHIATRY/ OR exp LIAISON PSYCHIATRY/ OR exp PSYCHIATRY/</td>
<td>123613</td>
<td>forensic psychiatry [Scope], liaison psychiatry [Scope]</td>
</tr>
<tr>
<td>15. &quot;psychiatry&quot;.ti,ab</td>
<td>64115</td>
<td></td>
</tr>
<tr>
<td>16. exp ORGANIZATION AND MANAGEMENT/ OR exp ORGANIZATION, HEALTH CARE/ OR exp ORGANIZATION,HOSPITAL/ OR exp HEALTH CARE QUALITY/ OR exp HEALTH CARE</td>
<td></td>
<td>health care organization, organization and management, health care quality</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td></td>
</tr>
</tbody>
</table>
| **POLICY/ OR exp EUROPEAN UNION/;** 4093691 results. | - health care policy  
- European Union |
| 17. EMBASE; "commission*".ti,ab; 38879 results. |   |
| 18. EMBASE; exp UNITED KINGDOM/; 374030 results. |   |
| 19. EMBASE; "england".ti,ab; 46954 results. |   |
| 20. EMBASE; exp FINANCIAL MANAGEMENT/ OR exp ORGANIZATION AND MANAGEMENT/ OR exp HEALTH CARE COST/ OR exp GOVERNMENT/ OR exp FINANCE/ OR exp HEALTH CARE POLICY/ OR exp HEALTH CARE DELIVERY/; 5134775 results. | The term “Financ” identified the following (EMTREE) index headers:  
- financial management  
- cost benefit analysis  
- cost of illness  
- health care cost  
- health care policy  
- finance  
- health care delivery |
<p>| 21. EMBASE; &quot;financ*&quot;.ti,ab; 99695 results. |   |
| 22. EMBASE; &quot;incentiv*&quot;.ti,ab; 26523 results. |   |
| 23. EMBASE; &quot;prospective payment&quot;.ti,ab; 2527 results. |   |
| 24. EMBASE &quot;payment system*&quot;.ti,ab; 3519 |   |
| 25. EMBASE; 1 OR 2 OR 3 OR 4 OR 5; 3097391 results. |   |
| 26. EMBASE; 6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12 OR 13 OR 14 OR 15; 3774132 results. |   |
| 27. EMBASE; 16 OR 17 OR 18 OR 19 OR 20 OR 21 OR 22 OR 23 OR 24; 6938662 results. |   |
| 28. EMBASE; 25 AND 26 AND 27; 1012266 results. |   |
| 29. EMBASE; 60 [Limit to: Priority Journals and Human and (Languages English) and (Publication Types Article or Journal) and (Human Age Groups Adult 18 to 64 years or Aged 65+ years) and (Year Published Last 4 Years or Last 5 Years)]; 3050 results. | All titles and abstracts were read to determine their suitability for inclusion to the literature review. Articles of interest that were referenced to in the identified literature were also obtained for use in the literature review. |</p>
<table>
<thead>
<tr>
<th>Main heading &amp; subheadings</th>
<th>Database/ Sources</th>
<th>Key Search terms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Service user engagement within the NHS</td>
<td>CINAHL • Cochrane Library • EMBASE • Health Management Information Consortium • MEDLINE • PsycINFO • The Cochrane Library</td>
<td>Adherence • Adverse effects • Choice • Collaboration • Compulsion • Compliance • Concordance • Contribution • Consent • Consult • Consumer • Customer • Engagement • Francis report • NHS Constitution • Illness beliefs • Inclusion • Information • Involvement • Knowledge • Mental Health Act • Mental health • Mental Illness • NHS &amp; Community Care Act • National Service Framework • Negotiation • Participation • Partnership • Patient • Provider • Psychiatrist • Psychiatry • Service user • Shared decision making • Wellbeing</td>
</tr>
</tbody>
</table>

- The background and the history
- Consumerism and service user participation
- Involvement in mental health services
- The rationale for involvement
- Optimising the use of medicines
- Choice and medication
- Adherence
- Intentional non-adherence
- Specific side effects
- Illness beliefs and knowledge
- Non-adherence
- Shared decision making
- Service user perspective
- Service user in policy development
- Service user in medicines priority setting
Below is an example of a search for compliance with treatment in mental health. This search demonstrates the number of references identified following use of the CINAHL database.

Similar independent searches were conducted using the Cochrane Library, EMBASE, Health Management Information Consortium, MEDLINE and PsycINFO.

<table>
<thead>
<tr>
<th>Search Details</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. CINAHL; exp MEDICATION COMPLIANCE/ OR exp PATIENT COMPLIANCE/; 25650 results.</td>
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</tr>
<tr>
<td>Medication compliance identified the following headings:</td>
<td></td>
</tr>
<tr>
<td>• Patient compliance</td>
<td></td>
</tr>
<tr>
<td>• Medication compliance</td>
<td></td>
</tr>
<tr>
<td>2. CINAHL; &quot;adhere*&quot;.ti,ab; 19752 results.</td>
<td></td>
</tr>
<tr>
<td>3. CINAHL; exp &quot;COMPLIANCE WITH THERAPEUTIC REGIMEN (SABA CCC)/ OR exp &quot;COMPLIANCE WITH MEDICATION REGIMEN (SABA CCC)/; 2 results.</td>
<td></td>
</tr>
<tr>
<td>Compliance identified the following headings:</td>
<td></td>
</tr>
<tr>
<td>• Compliance with Therapeutic Regimen</td>
<td></td>
</tr>
<tr>
<td>• Compliance with Medication Regimen</td>
<td></td>
</tr>
<tr>
<td>4. CINAHL; &quot;complia*&quot;.ti,ab; 18059 results.</td>
<td></td>
</tr>
<tr>
<td>5. CINAHL; exp TREATMENT REFUSAL/; 3437 results.</td>
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</tr>
<tr>
<td>6. CINAHL; &quot;treatment refusal&quot;.ti,ab; 43 results.</td>
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</tr>
<tr>
<td>7. CINAHL; exp PROFESSIONAL-PATIENT RELATIONS/; 57134 results.</td>
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</tr>
<tr>
<td>8. CINAHL; (doctor ADJ patient*).ti,ab; 1298 results.</td>
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</tr>
<tr>
<td>9. CINAHL; (professional ADJ patient*).ti,ab; 439 results.</td>
<td></td>
</tr>
<tr>
<td>10. CINAHL; &quot;concordan*&quot;.ti,ab; 4074 results.</td>
<td></td>
</tr>
<tr>
<td>11. CINAHL; exp TREATMENT REFUSAL/; 3437 results.</td>
<td></td>
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<tr>
<td>12. CINAHL; exp CONSUMER PARTICIPATION/; 10925 results.</td>
<td></td>
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<tr>
<td>13. CINAHL; (patient ADJ partici*).ti,ab; 3956 results.</td>
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<tr>
<td>14. CINAHL; (patient ADJ engag*).ti,ab; 773 results.</td>
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<tr>
<td>15. CINAHL; &quot;patient participation&quot;.ti,ab; 696 results.</td>
<td></td>
</tr>
<tr>
<td>16. CINAHL; exp CONSUMER ATTITUDES/; 3722 results.</td>
<td></td>
</tr>
<tr>
<td>17. CINAHL; &quot;consumer*&quot;.ti,ab; 15124 results.</td>
<td></td>
</tr>
<tr>
<td>18. CINAHL; &quot;medication compliance&quot;.ti,ab; 384 results.</td>
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<tr>
<td>19. CINAHL; (medication ADJ adher*).ti,ab; 2242 results.</td>
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<tr>
<td>20. CINAHL; exp &quot;NONCOMPLIANCE (NANDA)/; 14 results.</td>
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<tr>
<td>21. CINAHL; &quot;noncompliance&quot;.ti,ab; 1163 results.</td>
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<tr>
<td>22. CINAHL; nonadherence.ti,ab; 1188 results.</td>
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<tr>
<td>23. CINAHL; exp SELF MEDICATION/; 868 results.</td>
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<tr>
<td>24. CINAHL; exp PSYCHIATRY/; 7962 results.</td>
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<tr>
<td>25. CINAHL; &quot;psychiatry&quot;.ti,ab; 6160 results.</td>
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<tr>
<td>26. CINAHL; exp MENTAL HEALTH/; 13776 results.</td>
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<tr>
<td>27. CINAHL; (mental ADJ health).ti,ab; 45496 results.</td>
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<tr>
<td>28. CINAHL; &quot;service user&quot;.ti,ab; 959 results.</td>
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<tr>
<td>29. CINAHL; &quot;patient*&quot;.ti,ab; 645663 results.</td>
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</tr>
<tr>
<td>30. CINAHL; 1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 10 OR 11 OR 12 OR 15 OR 18 OR 20 OR 21 OR 22 OR 23; 69609 results.</td>
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<tr>
<td>31. CINAHL; 7 OR 8 OR 9 OR 13 OR 14 OR 16 OR 17 OR 24 OR 25 OR 26 OR 27; 137602 results.</td>
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<tr>
<td>32. CINAHL; 28 OR 29; 646466 results.</td>
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<tr>
<td>33. CINAHL; 30 AND 31 AND 32; 5247 results.</td>
<td></td>
</tr>
<tr>
<td>34. CINAHL; 33 [Limit to: References Available and Publication Year 2006-2016 and Peer Reviewed and (Journal Subset Australia &amp; New Zealand or Blind</td>
<td></td>
</tr>
</tbody>
</table>

All titles and abstracts were read to determine their suitability for inclusion to the literature review.
Articles of interest that were referenced to in the identified literature were also obtained for use in the literature review.

<table>
<thead>
<tr>
<th>Main heading &amp; subheadings</th>
<th>Database/ Sources</th>
<th>Key search terms</th>
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</thead>
<tbody>
<tr>
<td>Pharmaceutical industry</td>
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<tr>
<td>• The industry and the NHS</td>
<td>Department of Health Database</td>
<td>Bias</td>
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<tr>
<td>• The economic imperative</td>
<td>EMBASE</td>
<td>Code of practice</td>
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<tr>
<td>• Research and development costs</td>
<td>MEDLINE</td>
<td>Company</td>
</tr>
<tr>
<td>• A crisis in innovation</td>
<td>PsycINFO</td>
<td>Conflict of interest</td>
</tr>
<tr>
<td>• The influence on research findings</td>
<td>The Cochrane Library</td>
<td>Development</td>
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<tr>
<td>• The influence on service users</td>
<td>ABPI website</td>
<td>Drug Industry</td>
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<td>• Joint working with the NHS</td>
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<td>Drugs</td>
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<td>• Risk sharing with the NHS</td>
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<td>Finance</td>
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<td>Funding</td>
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<td>Impact</td>
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<td>Industry</td>
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<td>Joint working</td>
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<td>Prescribing</td>
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<td>Publication bias</td>
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<td>Relationship</td>
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<td>Risk sharing</td>
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<td>Sponsor</td>
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<td>Support</td>
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</tbody>
</table>
Below is outlined a search strategy using the PsycINFO database. The search was undertaken to identify publications which explore the relationship between the pharmaceutical industry and prescribing practice. The literature search was run independently on several databases and websites as listed above.

The pharmaceutical industry influence on prescribing - Search results using the PsychInfo database.

<table>
<thead>
<tr>
<th>Query</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 PsycInfo exp PHARMACEUTICAL INDUSTRY/ 1555 results</td>
<td></td>
</tr>
<tr>
<td>2 PsycInfo &quot;drug industry&quot;.ti,ab 88 results</td>
<td></td>
</tr>
<tr>
<td>3 PsycInfo &quot;pharmaceutical industry&quot;.ti,ab 1267 results</td>
<td></td>
</tr>
</tbody>
</table>
| 4 PsycInfo exp ANTIDEPRESSANT DRUGS/ OR exp CNS AFFECTING DRUGS/ OR exp CNS DEPRESSANT DRUGS/ OR exp CNS STIMULATING DRUGS/ OR exp DRUG THERAPY/ OR exp DRUGS/ OR exp HYPNOTIC DRUGS/ 317757 results | A search for drugs identified the following headings:  
  - Antidepressant drugs  
  - CNS affecting drugs  
  - CNS depressant drugs  
  - CNS stimulating drugs  
  - Drug therapy  
  - Drugs  
  - Hypnotic drugs |
| 5 PsycInfo "drug marketing".ti,ab 32 results                         |         |
| 6 PsycInfo exp INTERPERSONAL INFLUENCES/ 6196 results                |         |
| 7 PsycInfo "influen*".ti,ab 412835 results                           |         |
| 8 PsycInfo "bias*".ti,ab 71476 results                               |         |
| 9 PsycInfo exp "PRESCRIBING (DRUGS)"/ OR exp PRESCRIPTION DRUGS/ OR exp PRESCRIPTION PRIVILEGES/ 6115 results | A truncated search prescri* identified the following relevant headings:  
  - Prescribing drugs  
  - Prescription drugs  
  - Prescription privileges |
| 10 PsycInfo "prescri*".ti,ab 36275 results                           |         |
| 11 PsycInfo "impact*".ti,ab 268030 results                           |         |
| 12 PsycInfo exp COMMUNITY MENTAL HEALTH/ OR exp COMMUNITY MENTAL HEALTH SERVICES/ OR exp MENTAL HEALTH SERVICES/ 38171 results | A search for mental health identified the following relevant headings:  
  - Community mental health  
  - Community Mental Health Services  
  - Mental Health Services |
| 13 PsycInfo "mental health".ti,ab 136423 results                     |         |
| 14 PsycInfo exp COMMUNITY PSYCHIATRY/ OR exp NEUROPSYCHIATRY/ OR exp PSYCHIATRIC EVALUATION/ OR exp PSYCHIATRIC HOSPITALS/ OR exp PSYCHIATRISTS/ OR exp PSYCHIATRY/ 61562 results | A search for mental health identified the following relevant headings:  
  - Community Psychiatry  
  - Neuropsychiatry  
  - Psychiatric evaluation  
  - Psychiatric hospitals  
  - Psychiatrists  
  - Psychiatry |
| 15 PsycInfo "psychia*".ti,ab 206604 results                          |         |
| 16 PsycInfo 1 OR 2 OR 3 2216 results                                |         |
| 17 PsycInfo 4 OR 5 OR 6 OR 7 OR 8 OR 11 963366 results              |         |
All titles and abstracts were read to determine their suitability for inclusion to the literature review. Articles of interest that were referenced to in the identified literature were also obtained for use in the literature review.

<table>
<thead>
<tr>
<th>Main heading &amp; subheadings</th>
<th>Database/ Sources</th>
<th>Key search terms</th>
</tr>
</thead>
</table>
| Prescribing guidance in mental health | • Department of Health Database  
 • EMBASE  
 • MEDLINE  
 • PsycINFO  
 • The Cochrane Library  
 • ABPI | • Adherence  
 • Anxiety  
 • Bipolar  
 • Clinical  
 • Compliance  
 • Depression  
 • Dissemination  
 • Formulary  
 • General Practice  
 • Guide  
 • Implementation  
 • Influence  
 • Mental Health  
 • Organisation  
 • Practice  
 • Prescribing  
 • Protocol  
 • Primary care  
 • Psychiatry  
 • Schizophrenia |
Below is an example of a search of a Medline search for publications relating to the implementation of prescribing guidelines in mental health settings. Searches were also undertaken using the following databases/sources: EMBASE, Department of Health website, PsyclINFO, the Cochrane library and the ABPI website.

<table>
<thead>
<tr>
<th>Search</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Medline; exp PRACTICE GUIDELINE/ OR exp PRACTICE GUIDELINES AS TOPIC/</td>
<td>92486 results.</td>
</tr>
<tr>
<td>2. Medline; (practice ADJ guid*).ti,ab</td>
<td>4492 results.</td>
</tr>
<tr>
<td>3. Medline; (prescribing ADJ guid*).ti,ab</td>
<td>131 results.</td>
</tr>
<tr>
<td>4. Medline; exp GUIDELINE/ OR exp GUIDELINE ADHERENCE/</td>
<td>24714 results.</td>
</tr>
<tr>
<td>5. Medline; (guid* ADJ adher*).ti,ab</td>
<td>1026 results.</td>
</tr>
<tr>
<td>6. Medline; exp CLINICAL PROTOCOLS/</td>
<td>139240 results.</td>
</tr>
<tr>
<td>7. Medline; protocol*.ti,ab</td>
<td>306638 results.</td>
</tr>
<tr>
<td>8. Medline; implement*.ti,ab</td>
<td>307344 results.</td>
</tr>
<tr>
<td>9. Medline; (guid* ADJ implement*).ti,ab</td>
<td>1216 results.</td>
</tr>
<tr>
<td>10. Medline; (protocol ADJ implement*).ti,ab</td>
<td>504 results.</td>
</tr>
<tr>
<td>11. Medline; exp INFORMATION DISSEMINATION/ OR exp COMMUNICATION/ OR exp DIFFUSION OF INNOVATION/</td>
<td>426036 results.</td>
</tr>
<tr>
<td>12. Medline; disseminat*.ti,ab</td>
<td>93956 results.</td>
</tr>
<tr>
<td>13. Medline; (dissem* ADJ of ADJ information).ti,ab</td>
<td>1 results.</td>
</tr>
<tr>
<td>14. Medline; (clinical AND guid*).ti,ab</td>
<td>78126 results.</td>
</tr>
<tr>
<td>15. Medline; (imple* ADJ strat*).ti,ab</td>
<td>550 results.</td>
</tr>
<tr>
<td>17. Medline; (educ* ADJ out*).ti,ab</td>
<td>721 results.</td>
</tr>
<tr>
<td>18. Medline; exp FORMULARIES/ OR exp FORMULARIES AS TOPIC/</td>
<td>2812 results.</td>
</tr>
<tr>
<td>19. Medline; formu*.ti,ab</td>
<td>119151 results.</td>
</tr>
<tr>
<td>20. Medline; exp MENTAL HEALTH/</td>
<td>26266 results.</td>
</tr>
<tr>
<td>22. Medline; exp PSYCHIATRY/</td>
<td>120148 results.</td>
</tr>
<tr>
<td>23. Medline; psychia*.ti,ab</td>
<td>191754 results.</td>
</tr>
<tr>
<td>24. Medline; exp CLINICAL DECISION-MAKING, exp DECISION SUPPORT SYSTEMS, CLINICAL/ OR exp DECISION SUPPORT SYSTEMS, MANAGEMENT/</td>
<td>6605 results.</td>
</tr>
<tr>
<td>25. Medline; (decision ADJ support ADJ system).ti,ab</td>
<td>2218 results.</td>
</tr>
<tr>
<td>26. Medline; 1 OR 2 OR 3 OR 4 OR 6 OR 7 OR 14 OR 18 OR 19;</td>
<td>711596 results.</td>
</tr>
<tr>
<td>27. Medline; 5 OR 8 OR 9 OR 10 OR 11 OR 12 OR 13 OR 15 OR 16 OR 17 OR 24 OR 25;</td>
<td>809155 results.</td>
</tr>
<tr>
<td>28. Medline; 20 OR 21 OR 22 OR 23;</td>
<td>359247 results.</td>
</tr>
<tr>
<td>29. Medline; 26 AND 27 AND 28;</td>
<td>3127 results.</td>
</tr>
</tbody>
</table>

A truncated search disss* identified the following relevant headings:
- Communication
- Diffusion of innovation

A truncated search decisio* identified the following relevant headings:
- Decision support systems, clinical
- Decision support systems, management
- Clinical decision making
30. Medline; 29 [Limit to: Publication Year 2006-2016 and Peer reviewed and (Document type Comparative Study or Editorial or Evaluation Studies or Guideline or Journal Article or Meta-analysis or Multicenter Study or Observational Study or Review) and (Language English)]; 1686 results.

All titles and abstracts were read to determine their suitability for inclusion to the literature review. Articles of interest that were referenced to in the identified literature were also obtained for use in the literature review.
Appendix 2: Interview schedules
### Interview Guide: Pharmaceutical representative

<table>
<thead>
<tr>
<th>Category</th>
<th>Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1. What do you see as the role of prescribing guidelines in clinical practice?</td>
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<tr>
<td></td>
<td><strong>Prompts</strong></td>
</tr>
<tr>
<td></td>
<td>• Reduction in variation of patient care</td>
</tr>
<tr>
<td></td>
<td>• Addressing the issue of rising prescribing costs</td>
</tr>
<tr>
<td></td>
<td>• Keeping clinicians abreast of new evidence</td>
</tr>
<tr>
<td></td>
<td><strong>What are the main influences driving the prescribing of a new drug?</strong></td>
</tr>
<tr>
<td></td>
<td>explore Pharmaceutical industry Pharmaceutical representatives Adverts/ mailing Professional colleagues Hospital colleague endorsement Hospital colleague prescribing Patient request</td>
</tr>
<tr>
<td></td>
<td><strong>2. How might prescribing guidelines impact on new drug prescribing and innovation in mental health?</strong></td>
</tr>
<tr>
<td></td>
<td>Explore the issues in the context of the changing NHS landscape.</td>
</tr>
<tr>
<td></td>
<td><strong>3. How difficult is it to implement evidence based prescribing guidance in a mental health setting?</strong></td>
</tr>
<tr>
<td></td>
<td>Explore personal beliefs Evidence in the context of patients in a clinical setting</td>
</tr>
<tr>
<td></td>
<td><strong>4. What do you consider the practical barriers to guideline implementation?</strong></td>
</tr>
<tr>
<td></td>
<td>Explore issues such as Time Number of guidelines</td>
</tr>
<tr>
<td>Resources, presentation</td>
<td></td>
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<td>-------------------------</td>
<td></td>
</tr>
<tr>
<td>5. What factors are most important in enabling the implementation of prescribing guidelines in:</td>
<td></td>
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<tr>
<td><strong>Primary care:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Secondary care:</strong></td>
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</tr>
<tr>
<td>6. I want you to take some time to think about prescribing guidelines. In addition to recommended list of drugs what else should be incorporated into prescribing guidelines?</td>
<td></td>
</tr>
<tr>
<td>Explore Cost Physical health monitoring requirements Agreed endpoints for prescribing Incorporation in GP systems</td>
<td></td>
</tr>
<tr>
<td>7. How do you view the impact of prescribing guidelines on clinician freedom?</td>
<td></td>
</tr>
<tr>
<td>8. What are your views on shared decision-making? Prompts How might shared decision-making impact on: • The therapeutic relationship between clinician and patient? • Concordance with medication</td>
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<tr>
<td>In your opinion what are the barriers to shared decision-making during the recovery phase of mental illness?</td>
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By 2014 a new system of value-based pricing (VBP) will replace the existing pharmaceutical price regulation scheme (PPRS). Unlike NICE where rulings where mandatory for PCTs the new national body will make recommendations which will not be compulsory for a GP consortium, leading to variable prescribing of new drugs across differing GP consortia.

9. How might value-based pricing impact the prescribing of new medicines for mental health conditions?

What impact do you think this will have on your relationship with the NHS?

10. How might payment by results impact on choice medicines in psychiatry?

11. How can the demands for increased sales of newer medicines by pharmaceutical companies be balanced with the need for cost containment of prescribing budgets?

12. How important is the future working relationship with the NHS?

13. Thinking about the changing NHS landscape. How might the pharmaceutical industry work with the NHS to promote cost effective prescribing?

14. Thinking about the interface between mental health and primary care services, what are the key prescribing issues from the perspective of:
<table>
<thead>
<tr>
<th></th>
<th>GPs/ commissioners</th>
<th>Physicians</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychiatry</td>
<td></td>
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</tbody>
</table>

**Effectiveness**

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>15. When you think about treatment with medicines in a mental health setting, what does efficacy mean to you?</td>
<td></td>
</tr>
<tr>
<td>16. What do you think efficacy means to a service user?</td>
<td></td>
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<tr>
<td>Healthcare professional?</td>
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</tbody>
</table>

**General**

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Based on our discussion are there any other issues or comments that you wish to raise?</td>
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</tbody>
</table>
## Interview Guide: Service users

<table>
<thead>
<tr>
<th>Questions</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Summarising statement about the research project and the purpose of the interview.</td>
<td>Focus on overall feelings of medication, and relationship with psychiatrist.</td>
</tr>
<tr>
<td>• Clarify that the interview will be recorded.</td>
<td>Note cues for later questions / overall attitude and experience of medication and prescribing.</td>
</tr>
<tr>
<td>• Questions to be used as a guide only</td>
<td>Prompts: Side effects, effectiveness, long term impact, staying well or other.</td>
</tr>
<tr>
<td>1. Tell me how you feel about your condition and the treatment you receive?</td>
<td>Explore whether the service user is able to disclose complete and accurate information e.g. lack of compliance with treatment. If not why not?</td>
</tr>
<tr>
<td>2. How do you get on with your doctor?</td>
<td>Explore concordance vs compliance</td>
</tr>
<tr>
<td>3. Are you able to talk openly to your doctor about your medication?</td>
<td>Focus on side effects and how far these are taken seriously and imparted by psychiatrist.</td>
</tr>
<tr>
<td>Please give an example?</td>
<td>Explore relationship between side effects and concordance.</td>
</tr>
<tr>
<td>4. How useful is the information you are given about the side effects of treatment?</td>
<td>Probe about personal experience and how this might impact on their concordance.</td>
</tr>
</tbody>
</table>
5. When you visit your doctor how involved are you in the decision about the treatment you receive? Can you give an example?

6. How important is it to you that you have a choice in the medication you are treated with?

7. What are your thoughts about alternative treatments for your condition?

<table>
<thead>
<tr>
<th>Focus on how far treatment by the psychiatrist covers a range of available options, and how far this leads to choice. How far does the interviewee feel an active agent in their treatment? Possible issues arising – relationship with mental health services, negative and positive. Remain sensitive to bad experiences – allow critical accounts to be expressed by the interviewee within this section if necessary, before moving on to other sections. Probe Hypnotherapy? Acupuncture Talking therapies etc</th>
</tr>
</thead>
</table>

8. How much do medicines contribute to you feeling better? Probe for the rationale

   *How might they identify improvement in symptoms or is the perception related to side effects or something completely different?*

9. What would you do if you felt that your medication was not working? 

   *Does the service user have a clear understanding of the options available? Was the possibility of treatment failure discussed?* 

<p>| Focus on how service user registers the impact and effectiveness of medication, and any improvements in health. Possible issues arising – a picture of how far the service user feels medication is part of managing their condition, and staying well. |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
</table>
| **10.** | What are the most important factors in influencing your decision to take medication? | Prompts  
Personal experience  
Impact on others  
Professional input  
Other |
| **11.** | Where do you get information about your medication? | Probe  
Internet  
Professionals  
Other service users  
Other  
Focus on how service users become informed about medication, the sources they use and trust  
Possible issues arising – (for later analysis?) - links between service users' sources of information, and their overall attitude to relationship with MH services, medication and side effects. |
| **12.** | If a new drug became available to treat your condition, what would affect your decision to try it? | A focus on new treatments, and how open the service user would be to these. Explore why they have answered this way.  
Probe for their rationale. |
13. **What impact has psychiatric medicines had on your everyday life?**

Focus on how medication has impacted on everyday life, and the consequences to the service user of being treated with medication.

14. **Can you think of any additional support that might benefit your understanding of the medicines you are prescribed?**

15. **Based on your experience, what is the most important thing that mental health professionals should know in order to be helpful to people using medications?**

Probe for a rationale

16. **Based on our discussion is there anything that you wish to add?**

Focus on anything else which the service user feels is important, that hasn't been covered.

Chance to ask any further questions about overall issues arising, clarify any matters, and pick up on links between answers

Finally: Describe what will happen to the research and the availability of the findings.
### Interview Guide: Pharmacists

<table>
<thead>
<tr>
<th>Questions</th>
<th>Probe</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. What do you see as the role of prescribing guidelines in clinical practice?</td>
<td>Probe Reduction in variation of patient care Addressing the issue of rising prescribing costs Keeping clinicians abreast of new evidence</td>
</tr>
<tr>
<td>2. To what extent do we (pharmacists) take into account patient related factors when producing prescribing guidelines in mental health?</td>
<td>Probe Are guidelines contextual, taking into account difficult to treat</td>
</tr>
<tr>
<td>3. What are the main influences driving the prescribing of a new drug?</td>
<td>Probe Industry influence Professional colleagues Hospital colleague endorsement Hospital colleague prescribing Patient request</td>
</tr>
<tr>
<td>4. How might prescribing guidelines impact on new drug prescribing and innovation in mental health?</td>
<td>Explore the issues in the context of the changing NHS landscape.</td>
</tr>
<tr>
<td>5. What do you consider the practical barriers to guideline implementation?</td>
<td>Explore issues such as Time Number of guidelines Resources, presentation</td>
</tr>
<tr>
<td>6. What factors are most important in enabling the implementation of prescribing guidelines. in:</td>
<td>It is important to explore if there is an understanding of the issues across NHS organisations</td>
</tr>
<tr>
<td><strong>Primary care: PCT pharmacists</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Secondary care: hospital based pharmacists</strong></td>
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</tr>
</tbody>
</table>
| 7. | I want you to take some time to think about prescribing guidelines. In addition to recommended list of drugs what else should be incorporated into prescribing guidelines? | Explore
Cost
Physical health monitoring requirements
Agreed endpoints for prescribing
Incorporation in GP systems |
| 8. | How do you view the impact of prescribing guidelines on freedom of choice for patients? |   |
| 9. | How might shared decision-making impact on:
• The therapeutic relationship between clinician and patient?
• Concordance with medication | Seek a clear rationale for their thought process. |
| 10. | In your opinion what are the barriers to shared decision-making during the recovery phase of mental illness? |   |
|   | By 2014 a new system of value-based pricing (VBP) will replace the existing pharmaceutical price regulation scheme (PPRS). Unlike NICE where rulings were mandatory for PCTs the new national body will make recommendations which will not be compulsory for a GP consortium, leading to variable prescribing of new drugs across differing GP consortia. |   |
| 11. | How might value-based pricing impact the prescribing of new medicines for mental health conditions? |   |
| 12. | How might payment by results impact on choice medicines in psychiatry? |   |
13. What are your views on working with the pharmaceutical industry? | If a context is needed, focus on the promotion of cost effective prescribing.

14. Thinking about the changing NHS landscape. How might the pharmaceutical industry work with the NHS to promote cost effective prescribing?

15. Thinking about the interface between mental health and primary care services, what do you see as the key prescribing issues?

16. When you think about treatment with medicines in a mental health setting, what does efficacy mean to you?

17. What do you think efficacy means to a service user?

18. Based on our discussion are there any other issues or comments that you wish to raise?
<table>
<thead>
<tr>
<th>Questions</th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>1.</strong> What is the role of prescribing guidelines in your clinical practice?</td>
<td></td>
</tr>
<tr>
<td>Explore the relevance to the clinician</td>
<td></td>
</tr>
<tr>
<td><strong>2.</strong> What would influence your decision to prescribe a new drug to a patient with a mental health condition?</td>
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<tr>
<td>GPs</td>
<td></td>
</tr>
<tr>
<td>explore</td>
<td></td>
</tr>
<tr>
<td>Pharmaceutical industry</td>
<td></td>
</tr>
<tr>
<td>Pharmaceutical representatives</td>
<td></td>
</tr>
<tr>
<td>Adverts/ mailing</td>
<td></td>
</tr>
<tr>
<td>Patient request</td>
<td></td>
</tr>
<tr>
<td><strong>3.</strong> How might prescribing guidelines impact on new drug prescribing and innovation in mental health?</td>
<td></td>
</tr>
<tr>
<td>Explore the issues in the context of the changing NHS landscape.</td>
<td></td>
</tr>
<tr>
<td><strong>4.</strong> What do you consider the practical barriers to guideline implementation?</td>
<td></td>
</tr>
<tr>
<td>Explore issues such as Time, Number of guidelines, Resources, presentation</td>
<td></td>
</tr>
<tr>
<td><strong>5.</strong> What factors are most important in enabling the implementation of prescribing guidelines in:</td>
<td></td>
</tr>
<tr>
<td><strong>6.</strong> I want you to take some time to think about prescribing guidelines. In addition to recommended list of drugs what else would inform your clinical practice?</td>
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<tr>
<td>Explore</td>
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<tr>
<td>Cost</td>
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<tr>
<td>Physical health monitoring requirements</td>
<td></td>
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<tr>
<td>Agreed endpoints for prescribing</td>
<td></td>
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<tr>
<td>Incorporation in GP systems</td>
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<tr>
<td><strong>7.</strong> Is there anything that would make you more likely to refer to prescribing guidelines?</td>
<td></td>
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<tr>
<td>Explore</td>
<td></td>
</tr>
<tr>
<td>Accessibility</td>
<td></td>
</tr>
<tr>
<td>Simplicity</td>
<td></td>
</tr>
<tr>
<td>Presentation</td>
<td></td>
</tr>
<tr>
<td>Question</td>
<td>Answer</td>
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<td>-------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>8. How do you view the impact of prescribing guidelines on clinician freedom?</td>
<td></td>
</tr>
<tr>
<td>9. What are your views on shared decision-making?</td>
<td></td>
</tr>
<tr>
<td><strong>Prompts</strong></td>
<td></td>
</tr>
<tr>
<td>How might shared decision-making impact on:</td>
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<tr>
<td>• The therapeutic relationship between clinician and patient?</td>
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<tr>
<td>• Concordance with medication</td>
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<tr>
<td>10. In your opinion what are the barriers to shared decision-making during the recovery phase of mental illness?</td>
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<td>13. Do you think that the Pharmaceutical representatives could have a role in facilitating guideline implementation?</td>
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<tr>
<td>Please explain your response</td>
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</tr>
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## Interview Guide: Consultant psychiatrists

<table>
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<tr>
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<th>Probe</th>
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<tbody>
<tr>
<td>1. What is the role of prescribing guidelines in your clinical practice?</td>
<td>Explore the relevance to the clinician</td>
</tr>
<tr>
<td></td>
<td>Probe Reduction in variation of patient care</td>
</tr>
<tr>
<td></td>
<td>Addressing the issue of rising prescribing costs</td>
</tr>
<tr>
<td></td>
<td>Keeping clinicians abreast of new evidence</td>
</tr>
<tr>
<td>2. What would influence your decision to prescribe a new drug to a patient with a mental health condition?</td>
<td>Probe Industry influence</td>
</tr>
<tr>
<td></td>
<td>Professional colleagues</td>
</tr>
<tr>
<td></td>
<td>Hospital colleague endorsement</td>
</tr>
<tr>
<td></td>
<td>Hospital colleague prescribing</td>
</tr>
<tr>
<td></td>
<td>Patient request</td>
</tr>
<tr>
<td>3. How might prescribing guidelines impact on new drug prescribing and innovation in mental health?</td>
<td>Explore the issues in the context of the changing NHS landscape.</td>
</tr>
<tr>
<td>4. How difficult is it to implement evidence based prescribing guidance in a mental health setting?</td>
<td>Explore personal beliefs</td>
</tr>
<tr>
<td></td>
<td>Evidence in the context of patients in a clinical setting</td>
</tr>
<tr>
<td>5. What do you consider the practical barriers to guideline implementation?</td>
<td>Explore issues such as</td>
</tr>
<tr>
<td></td>
<td>Time</td>
</tr>
<tr>
<td></td>
<td>Number of guidelines</td>
</tr>
<tr>
<td></td>
<td>Resources, presentation</td>
</tr>
<tr>
<td>6. What factors are most important in enabling the implementation of prescribing guidelines in your practice?</td>
<td>Explore</td>
</tr>
<tr>
<td></td>
<td>Cost</td>
</tr>
<tr>
<td></td>
<td>Physical health monitoring requirements</td>
</tr>
<tr>
<td></td>
<td>Agreed endpoints for prescribing</td>
</tr>
<tr>
<td></td>
<td>Incorporation in GP systems</td>
</tr>
<tr>
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<td>Physical health monitoring requirements</td>
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<tr>
<td></td>
<td>Agreed endpoints for prescribing</td>
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<td></td>
<td>Incorporation in GP systems</td>
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<td>9.</td>
<td>How do you view the impact of prescribing guidelines on clinician freedom?</td>
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</tbody>
</table>
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Prompts  
How might shared decision-making impact on:  
- The therapeutic relationship between clinician and patient?  
- Concordance with medication |
| 11. | In your opinion what are the barriers to shared decision-making during the recovery phase of mental illness? |
| 12. | By 2014 a new system of value-based pricing (VBP) will replace the existing pharmaceutical price regulation scheme (PPRS).  
Unlike NICE where rulings where mandatory for PCTs the new national body will make recommendations which will not be compulsory for a GP consortium, leading to variable prescribing of new drugs across differing GP consortia. |
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| 14. | How might payment by results impact on choice medicines in psychiatry? |
| 15. | What are your views on working with the pharmaceutical industry? |</p>
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</table>
Appendix 3: Information for participants
Information for research participants

Prescribing guidance and practice: Exploring the factors that have an impact on prescribing in a mental health environment.

Professional Doctorate Research Project
University of Portsmouth

My name is Andrew Campbell and I am a doctoral student at the University of Portsmouth; I would like to invite you to participate in my research study. Before you decide whether or not to take part, it is important that you understand why this research is being done and what it will involve. Please take the time to read the following information carefully which should take about 10 minutes and ask me if there is anything that is not clear or if you would like more information.

What is the purpose of the study?
The purpose of the research is to understand from the perspective of a service user the extent to which you feel involved in making decisions about the medicines you take to treat your illness and the factors that influence your involvement.

Why have you been asked to join in?
This study will focus on a range of people linked directly or indirectly linked to the prescribing of medicines for the treatment of mental health conditions. The study will include a total of 5 service users.

Do I have to take part?
It is up to you to decide whether you wish to join the study. I will describe the study and go through this information sheet. If you agree to take part, you will then be asked to complete a pre-screening questionnaire to determine if you are suitable to participate in the study. If you are eligible to participate in the study you will be asked to sign a consent form. If you are not eligible to participate you will be given a full explanation why you have not been considered for inclusion into the study. Please note that potential participants are free to withdraw at any time, without giving a reason.

What will happen to me if I take part?
The research involves participation in a single interview, which will be audio taped. Your participation is voluntary, and you may withdraw from the process at any time.

If you decide to participate in the research and become uncomfortable during the interview at any time, please let the interviewer know. You may stop the interview at any time.
Reimbursement of expenses
Participants will be reimbursed travel expenses up to a maximum of £5 for taking part in the research. This will be to cover public transport fares or mileage at the rate of 25 pence per mile.

Will my taking part in the study be kept confidential?
If the results of the research are published, quotes from the audio-tapes may be published to illustrate the views of participants. Under no circumstances will the identity of individuals be made public and individuals will not be able to be identified from quotes or descriptions of participants.

Records identifying you will be kept confidential and, to the extent permitted by the laws and/or regulations, will not be made publicly available.

You have the right to see a summary of the final study results.

Audiotapes and transcripts will be archived and kept up to three years after consent has been obtained for participation in the study.

What are the possible benefits of taking part?
There are unlikely to be any benefits for you personally. It is hoped that as a result of the study future prescribing guidelines will take into account the views of service users which might lead to improved prescribing practice.

Contact details
For more information regarding the research and your rights please contact:

<table>
<thead>
<tr>
<th>Andrew Campbell</th>
<th>Prof David Brown</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chief Pharmacist</td>
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<td>Division of Pharmacy Practice</td>
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<tr>
<td>Clee Ward</td>
<td>School of Pharmacy and Biomedical Sciences</td>
</tr>
<tr>
<td>01384 365713</td>
<td>University of Portsmouth</td>
</tr>
<tr>
<td><a href="mailto:andrew.campbell@dwmh.nhs.uk">andrew.campbell@dwmh.nhs.uk</a></td>
<td>St Michael's Building</td>
</tr>
<tr>
<td></td>
<td>White Swan Road</td>
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<td></td>
<td>Portsmouth</td>
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<tr>
<td></td>
<td><a href="mailto:david.brown@port.ac.uk">david.brown@port.ac.uk</a></td>
</tr>
</tbody>
</table>

Thank you for reading so far – if you are still interested, please go to Part 2:
Part 2

What if there is a problem or something goes wrong?
If you are unhappy with any aspect of the research you should establish contact with Andrew Campbell, Professor David Brown or the Patient Advice and Liaison Service on 0800 0730510.

Will anyone else know I’m doing this?
All information collected will be kept confidential. This means we will only tell those who have a need or right to know.

Who is organising and funding the research?
This study is being conducted as part of a professional doctorate and is funded by the mental health trust and the researcher.

Who has reviewed the study?
Before any research goes ahead it has to be checked by a Research Ethics Committee. They make sure that the research is fair. Your project has been checked by the Research Ethics Committee.

Thank you for reading this – please ask any questions if you need to.
Information for research participants

Prescribing guidance and practice: Exploring the factors that have an impact on prescribing in a mental health environment

Professional Doctorate Research Project
University of Portsmouth

My name is Andrew Campbell and I am a doctoral student at the University of Portsmouth; I would like to invite you to participate in my research study. Before you decide whether or not to take part, it is important that you understand why this research is being done and what it will involve. Please take the time to read the following information carefully which should take about 10 minutes and ask me if there is anything that is not clear or if you would like more information.

Aim of the research
The purpose of the research is to understand from the perspective of a consultant psychiatrist what are the important issues in prescribing and the development of guidance for prescribing in a mental health setting?

How are decisions made now?
Decisions about which drugs are recommended for use across Dudley and Walsall Mental Health Trust are made by the Medicines Management Committee.

Why is this research important?
There is little work determining the views on how best to implement prescribing guidelines in a mental health setting.

There will be a need for clearer guidance on prescribing responsibility between mental health services and General Practitioners in light of the transition of patients from specialist to primary care.

This research aims to

- Develop an understanding of the perceived factors that influence the implementation of prescribing guidelines in a mental health setting.
- To explore the perceived factors that influences prescribing from healthcare professionals and representatives from the pharmaceutical industry.
- Explore the patient perception of their involvement in decisions regarding drug therapy.
Why have you been asked to join in?
This study will focus on a range of people linked directly or indirectly linked to the prescribing of medicines for the treatment of mental health conditions.

What will the research involve?
The research involves participation in a single interview, which will be audio taped?

Your participation is voluntary, and you may withdraw from the process at any time.

I would like you to consent to participate in this study as we believe that you can make an important contribution to the research.

If you do not wish to participate you do not have to do anything in response to this request.

If you become uncomfortable with the discussion at any time, please let the interviewer know. You may stop the interview at any time.

Will my taking part in the study be kept confidential?
If the results of the research are published, quotes from the audio-tapes may be published to illustrate the views of participants. Under no circumstances will the identity of individuals be made public and individuals will not be able to be identified from quotes or descriptions of participants.

Records identifying you will be kept confidential and, to the extent permitted by the laws and/or regulations, will not be made publicly available.

You have the right to see a summary of the final study results.

Audiotapes and transcripts will be archived and kept up to three years after consent has been obtained for participation in the study.

Reimbursement of expenses
Participants will be reimbursed travel expenses up to a maximum of £5 for taking part in the research. This will be to cover public transport fares or mileage at the rate of 25 pence per mile.

For more information regarding the research and your rights please contact:

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Better together
Information for research participants

Prescribing guidance and practice: Exploring the factors that have an impact on prescribing in a mental health environment.

Professional Doctorate Research Project
University of Portsmouth

My name is Andrew Campbell and I am a doctoral student at the University of Portsmouth; I would like to invite you to participate in my research study. Before you decide whether or not to take part, it is important that you understand why this research is being done and what it will involve. Please take the time to read the following information carefully which should take about 10 minutes and ask me if there is anything that is not clear or if you would like more information.

Aim of the research
The purpose of the research is to understand from the perspective of pharmacists what are the important issues in prescribing and the development of guidance for prescribing in a mental health setting?

How are decisions made now?
Decisions about which drugs are recommended for use across Dudley and Walsall Mental Health Trust are made by the Medicines Management Committee.

Why is this research important?
There is little work determining the views on how best to implement prescribing guidelines in a mental health setting.

NHS organisations are being encouraged to involve patients in the local decision making.

This research aims to

- Develop an understanding of the perceived factors that influence the implementation of prescribing guidelines in a mental health setting.
- Explore the patient perception of their involvement in decisions regarding drug therapy.
- To explore the perceived factors that influences prescribing from healthcare professionals and representatives from the pharmaceutical industry.

Why have you been asked to join in?
This study will focus on a range of people linked directly or indirectly linked to the prescribing of medicines for the treatment of mental health conditions.
What will the research involve?
The research involves participation in a single interview, which will be audio taped?

Your participation is voluntary, and you may withdraw from the process at anytime.

I would like you to consent to participate in this study as we believe that you can make an important contribution to the research.

If you do not wish to participate you do not have to do anything in response to this request.

If you become uncomfortable with the discussion at any time, please let the interviewer know. You may stop the interview at any time.

Will my taking part in the study be kept confidential?
If the results of the research are published, quotes from the audio-tapes may be published to illustrate the views of participants. Under no circumstances will the identity of individuals be made public and individuals will not be able to be identified from quotes or descriptions of participants.

Records identifying you will be kept confidential and, to the extent permitted by the laws and/or regulations, will not be made publicly available.

You have the right to see a summary of the final study results.

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Reimbursement of expenses
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Information for research participants

Prescribing guidance and practice: Exploring the factors that have an impact on prescribing in a mental health environment.

Professional Doctorate Research Project
University of Portsmouth

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Aim of the research
The purpose of the research is to understand from the pharmaceutical industry what are the important issues in prescribing and the development of guidance for prescribing in a mental health setting?

How are decisions made now?
Decisions about which drugs are recommended for use across Dudley and Walsall Mental Health Trust are made by the Medicines Management Committee.

Why is this research important?
There is little work determining the views on how best to implement prescribing guidelines in a mental health setting.

NHS organisations are being encouraged to work collaboratively with the pharmaceutical industry to improve patient outcomes.

This research aims to

- To explore the perceived factors that influences prescribing from healthcare professionals and representatives from the pharmaceutical industry.
- Explore the patient perception of their involvement in decisions regarding drug therapy.
- Develop an understanding of the perceived factors that influence the implementation of prescribing guidelines in a mental health setting.

Why have you been asked to join in?
This study will focus on a range of people linked directly or indirectly linked to the prescribing of medicines for the treatment of mental health conditions.
What will the research involve?
The research involves participation in a single interview, which will be audio taped?

Your participation is voluntary, and you may withdraw from the process at any time.

I would like you to consent to participate in this study as we believe that you can make an important contribution to the research.

If you do not wish to participate you do not have to do anything in response to this request.

If you become uncomfortable with the discussion at any time, please let the interviewer know. You may stop the interview at any time.

Will my taking part in the study be kept confidential?
If the results of the research are published, quotes from the audio-tapes may be published to illustrate the views of participants. Under no circumstances will the identity of individuals be made public and individuals will not be able to be identified from quotes or descriptions of participants.

Records identifying you will be kept confidential and, to the extent permitted by the laws and/or regulations, will not be made publicly available.

You have the right to see a summary of the final study results.

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Prescribing guidance and practice: Exploring the factors that have an impact on prescribing in a mental health environment.

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Aim of the research
The purpose of the research is to understand from the perspective of General Practitioners the important issues in prescribing and the development of guidance for prescribing in a mental health setting?

How are decisions made now?
Decisions about which drugs are recommended for use across Dudley and Walsall Mental Health Trust are made by the Medicines Management Committee in conjunction with the locality area prescribing committees.

Why is this research important?
There is little work determining the views on how best to implement prescribing guidelines in a mental health setting.

There will be a need for clearer guidance on prescribing responsibility between mental health services and General Practitioners in light of the transition of patients from specialist to primary care.

NHS organisations are being encouraged to involve patients in the local decision making.

This research aims to

- Explore the patient perception of their involvement in decisions regarding drug therapy.
- Develop an understanding of the perceived factors that influence the implementation of prescribing guidelines in a mental health setting.
- To explore the perceived factors that influences prescribing from healthcare professionals and representatives from the pharmaceutical industry.
Why have you been asked to join in?
This study will focus on a range of people linked directly or indirectly linked to the prescribing of medicines for the treatment of mental health conditions.

What will the research involve?
The research involves participation in a single interview, which will be audio taped?

Your participation is voluntary, and you may withdraw from the process at any time.

I would like you to consent to participate in this study as we believe that you can make an important contribution to the research.

If you do not wish to participate you do not have to do anything in response to this request.

If you become uncomfortable with the discussion at any time, please let the interviewer know. You may stop the interview at any time.

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St Michael's Building
White Swan Road
Portsmouth
Appendix 4: Screening questions for service users
Prescribing guidance and practice: Exploring the factors that have an impact on prescribing in a mental health environment.

Screening Questions for Service User involvement in research

1. Are you diagnosed with psychotic illness?
   E.g. Hearing voices or experiencing delusions
   Yes ☐  No ☐

2. Are you diagnosed with an anxiety related disorder?
   E.g. Generalised anxiety disorder
   Panic attacks
   Phobias (irrational fear)
   Obsessive Compulsive Disorder
   Yes ☐  No ☐

3. Are you diagnosed with a mood related disorder?
   E.g. Depression
   Seasonal affective disorder
   Bipolar disorder (manic depression)
   Yes ☐  No ☐

4. Is your mental illness caused by a head injury?
   Yes ☐  No ☐

5. Do you suffer with a dementia type illness?
   Yes ☐  No ☐

6. Are you currently attending outpatients or being cared for by a community mental health team?
   Yes ☐  No ☐

7. Have you been admitted to hospital in the previous 12 months?
   Yes ☐  No ☐

8. Have you taken any recreational drugs in the previous 12 months?
   Yes ☐  No ☐
Prescribing guidance and practice: Exploring the factors that have an impact on prescribing in a mental health environment.

Participant Personal Information

To enable effective analysis of your contribution to the research project, please answer the following questions by ticking the appropriate box.

Name:

Please tick the correct box

Gender

I am  

[ ] Male  [ ] Female

Age

I am aged between

[ ] 18 – 24 years  [ ] 25 – 60 years

[ ] 61 – 74 years  [ ] 75 – 84 years  [ ] 85 years and over

Education

I have been formally Educated up to the Following level

[ ] O level/GCSE or equivalent  [ ] Vocational qualification

[ ] A level or equivalent  [ ] Degree
Appendix 5: Flowchart for service user participation
Flowchart for service user recruitment v1
Appendix 6: Interview consent form
Consent form

Title of project: Prescribing guidance and practice: Exploring the factors that have an impact on prescribing in a mental health environment.

Name of Researcher: **Andrew Campbell**

1. I confirm that I have read and understood the information sheet for the above study. I have had the opportunity to consider the information, ask questions and had these answered to my satisfaction.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason without my medical or legal rights being affected.

3. I understand that the interview will be audio-taped and that verbatim quotes of what I say may be published. I understand that I will not be identifiable from any quotes published.

4. I voluntarily agree to take part in the above study.

____________________   _______   _______________________
Name of Participant       Date       Signature

____________________   _______   _______________________
Name of person taking consent       Date       Signature

When completed, 1 copy must be given to the participant and one copy retained by the researchers site file.
Appendix 7: Ethics approval letter
22 October 2013

Mr Andrew Campbell
Chief Pharmacist
Dudley and Walsall Mental Health Partnership NHS Trust
Clee
Bushey Fields Hospital
Dudley
DY1 2LZ

Dear Mr Campbell

Study title: Prescribing guidance and practice: Exploring the factors that have an impact on prescribing in a mental health environment.

REC reference: 13/LO/1162
IRAS project ID: 102686

Thank you for your letter responding to the Proportionate Review Sub-Committee’s request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator Mr Rajat Khullar, nrescommittee.london-cityandeast@nhs.net.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see...
“Conditions of the favourable opinion” below).

**Conditions of the favourable opinion**

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

*Management permission (“R&D approval”) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.*

*Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at [http://www.rdforum.nhs.uk](http://www.rdforum.nhs.uk).*

Where a NHS organisation’s role in the study is limited to identifying and referring potential participants to research sites (“participant identification centre”), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

*For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.*

*Sponsors are not required to notify the Committee of approvals from host organisations.*

**Registration of Clinical Trials**

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publicly accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett ([catherineblewett@nhs.net](mailto:catherineblewett@nhs.net)), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

*You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.*
It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The documents reviewed and approved by the Committee are:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
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<tr>
<td>Covering Letter</td>
<td></td>
<td>28 June 2013</td>
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<tr>
<td>Evidence of insurance or indemnity</td>
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<td>28 June 2013</td>
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<tr>
<td>Investigator CV</td>
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<td>28 June 2013</td>
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<tr>
<td>Other: Interview Guide for Patients</td>
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<td>28 June 2013</td>
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<td>Other: Letters of invitation to Patients</td>
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<td>Participant Information Sheet: Patients</td>
<td>3.1</td>
<td>28 June 2013</td>
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<td>Participant Information Sheet: Consultants</td>
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<td>Participant Information Sheet - GPs</td>
<td>4.1</td>
<td>01 August 2013</td>
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<tr>
<td>Participant Information Sheet - Pharmaceutical Industry</td>
<td>4.1</td>
<td>01 August 2013</td>
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<tr>
<td>Participant Information Sheet-Pharmacists</td>
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<td>01 August 2013</td>
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<td>Participant Information Sheet-Service Users</td>
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</tr>
<tr>
<td>Protocol</td>
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<td>01 September 2013</td>
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<tr>
<td>Questionnaire: Screening Questions for Service User involvement in research</td>
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<td>01 September 2013</td>
</tr>
<tr>
<td>REC application</td>
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<tr>
<td>Response to Request for Further Information</td>
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</table>
Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document “After ethical review – guidance for researchers” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

13/LO/1162 Please quote this number on all correspondence

We are pleased to welcome researchers and R & D staff at our NRES committee members’ training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee’s best wishes for the success of this project.

Yours sincerely

pp Professor David Wingate
Vice Chair

Email: nrescommittee.london-cityandeast@nhs.net
Appendix 8: Demographics of service users
Table 7.1 Service user demographics

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Gender</th>
<th>Age</th>
<th>Education</th>
<th>Diagnosis</th>
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<tbody>
<tr>
<td>Service User 1</td>
<td>Female</td>
<td>25-60</td>
<td>Vocational</td>
<td>Bipolar</td>
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<tr>
<td>Service User 2</td>
<td>Male</td>
<td>25-60</td>
<td>Degree</td>
<td>Schizophrenia</td>
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<td>Service User 3</td>
<td>Female</td>
<td>25-60</td>
<td>O levels</td>
<td>Bipolar</td>
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<td>Service User 4</td>
<td>Female</td>
<td>61-74</td>
<td>Degree</td>
<td>Bipolar</td>
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<td>Service User 5</td>
<td>Female</td>
<td>25-60</td>
<td>O levels</td>
<td>Bipolar</td>
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</tbody>
</table>
Appendix 9: Thematic map of the research themes
Thematic map of the research themes
Appendix 10: Form UPR16 - Research ethics review checklist
FORM UPR16
Research Ethics Review Checklist

Please include this completed form as an appendix to your thesis (see the Postgraduate Research Student Handbook for more information)

Postgraduate Research Student (PGRS) Information

Student ID: 47105801

Department: School of Pharmacy
First Supervisor: David Brown

Start Date: March 2012

Study Mode and Route: Part-time

Title of Thesis: Prescribing guidance and practice: exploring the factors that have an impact on precribing in a mental health environment.

Thesis Word Count: 71,249
(excluding ancillary data)

If you are unsure about any of the following, please contact the local representative on your Faculty Ethics Committee for advice. Please note that it is your responsibility to follow the University’s Ethics Policy and any relevant University, academic or professional guidelines in the conduct of your study.

Although the Ethics Committee may have given your study a favourable opinion, the final responsibility for the ethical conduct of this work lies with the researcher(s).

UKRI0 Finished Research Checklist:
(If you would like to know more about the checklist, please see your Faculty or Departmental Ethics Committee rep or see the online version of the full checklist at: http://www.ukri.org/what-we-do/model-of-practice-for-research/)

a) Have all of your research and findings been reported accurately, honestly and within a reasonable time frame? YES NO
b) Have all contributions to knowledge been acknowledged? YES NO
c) Have you complied with all agreements relating to intellectual property, publication and authorship? YES NO
d) Has your research data been retained in a secure and accessible form and will it remain so for the required duration? YES NO
e) Does your research comply with all legal, ethical, and contractual requirements? YES NO

Candidate Statement:
I have considered the ethical dimensions of the above named research project, and have successfully obtained the necessary ethical approval(s)

Ethical review number(s) from Faculty Ethics Committee (or from NRES/SCREC): 13/LO/1162

If you have not submitted your work for ethical review, and/or you have answered ‘No’ to one or more of questions a) to e), please explain below why this is so:

UPR16 – August 2015