Cardiometabolic risk, metabolic syndrome, and related diseases in severe mental illness: the role of pharmacy in the lived experience of patients

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Thesis Summary

Background: The thesis explores the role of pharmacy in the lived experience of patients with severe mental illness (SMI) who experience excess morbidity and mortality due to cardiometabolic risk (CMR), metabolic syndrome (MetS) and related diseases.

Aims and objectives: To understand and explain the role of pharmacy in providing care for CMR, MetS and related diseases in patients with SMI; achieved by 1. systematically reviewing the published evidence 2. exploring and document the views, perceptions, and experiences of patients with SMI, their informal carers, caring dyads (caring dyad defined here as a patient and their informal carer), care and pharmacy professionals 3. providing strategic recommendations for pharmacy for clinical practice, policy, and research to improve care.

Methods, results, and key findings: To address research objective 1. a systematic review of 33 articles found that face-to-face interactions of pharmacists with others consistently and significantly improved process outcomes such as the rate of blood tests 2. framework analysis of semi-structured interviews conducted with 16 patients, 8 informal carers, 21 care professionals and 11 pharmacists identified three themes: (i) CMR, MetS and related diseases, psychotropic medication, psychotropic medication side-effects and SMI (ii) barriers and (iii) facilitators to the role of pharmacy. Framework analysis contrasting and comparing data from each individual within 6 caring dyads identified three themes: (i) enhanced closeness (ii) dissonance, and (iii) balance within the caring dyad. In-depth meaningful impactful interactions between pharmacists and patients, informal carers, and caring dyads were infrequent. 3. Changes to pharmacy practice and policy could facilitate face-to-face interactions between pharmacists and other care professionals and more importantly patients, informal carers, and caring dyads.

Conclusion: Patients', informal carers', and caring dyads' desires and needs were not met. Changes to pharmacy practice could facilitate increased face-to-face interactions and encourage person-centred care with the goal of building long lasting trusting relationships which is key in this vulnerable population.

Key words: comorbidity**,** informal carers, caring dyad, physical health, mental health.

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Dedication

This thesis is dedicated to my daughters Shanti and Shivani, I love you.

Scholarly outputs from this thesis

Published peer reviewed papers:

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Sud D. Utilising dyads in medicines optimisation and illness management research. Res Social Adm Pharm. 2021; 14:S1551-7411(21)00080-2. doi: 10.1016/j.sapharm.2021.02.018.

Sud D, Maidment I, Bradley E, Tritter J. The experiences of the caring dyad: (Un)articulated realities of living with cardiometabolic risk, metabolic syndrome and related diseases in severe mental illness. Health Expect. 2021 Oct;24(5):1821-1832. doi: 10.1111/hex.13322. Epub 2021 Aug 2. PMID: 34339575; PMCID: PMC8483201.

Papers and associated work currently under peer review:

Sud D. Utilising dyads in medicines optimisation and illness management research. Book Chapter: Contemporary Research Methods in Pharmacy and Health Services, Elsevier.

Sud D, Pratt P. Managing predictable side-effects of prescribed psychotropic medication. Book Chapter: Essentials of Physical Health in Psychiatry, Royal College of Psychiatrists.

Conference presentations and posters:

Sud D. Utilising dyads in medicines optimisation and illness management research. Oral presentation. At: Institute of Mental Health Annual Research Day (Online). 2021. Nottingham, UK.

Sud D, Bradley E, Tritter J, Maidment I. The views, experiences, and perceptions of pharmacy of individuals with co-morbid severe mental illness and physical ill health. Oral presentation. At: Aston University Postgraduate Annual Research Day (Online). 2020. Birmingham, UK.

Sud D, Bradley E, Maidment I. CARDIOPHITNESS: Cardiometabolic Health and Pharmacy in Severe Mental Illness: a qualitative research study. Poster. At: European Network for Mental Health Service Evaluation. 2019. Lisbon, Portugal.

Sud D, Laughton E, McAskill R, Bradley E, Maidment I. The role of pharmacy in the management of cardiometabolic risk and metabolic syndrome in severe mental illness: a mixed methods review. Poster and oral presentation. At: Health Services Research UK Conference. 2019. Manchester, UK.

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Sud D, Bradley E, Maidment I. CARDIOPHITNESS: Cardiometabolic Health and Pharmacy in Severe Mental Illness: a qualitative research study. Poster. At: 3rd Multidisciplinary Research Celebration Conference. 2019. Queen Elizabeth Hospital, Birmingham, UK.

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Abbreviations

Abbreviation	Definition
ADA	American Diabetes Association
AMH	Adult Mental Health
APA	American Psychiatric Association
CCG	Clinical Commissioning Group
CHD	Coronary Heart Disease
CMHT	Community Mental Health Team
CMR	Cardiometabolic Risk
COREQ	Consolidated Criteria for Reporting Qualitative Research
CPA	Care Programme Approach
CPN	Community Psychiatric Nurse
CQUIN	Commissioning for Quality and Innovation
CRD	Centre for Reviews and Dissemination
CRN	Clinical Research Network
CVR	Cardiovascular Risk
CVD	Cardiovascular Disease
DSM	Diagnostic and Statistical Manual of Mental Disorders
EIP	Early Intervention in Psychosis
EPOC	Effective Practice and Organisation of Care
FIP	International Pharmaceutical Federation
FDA	Food and Drug Administration
GP	General Practitioner
GPhC	General Pharmaceutical Council
HbA_1c	Glycosylated Haemoglobin
LD	Learning Disability
LTC	Long Term Condition
MHSOP	Mental Health Services for Older People
MMAT	Mixed Methods Appraisal Tool
MDT	Multidisciplinary Team
MetS	Metabolic Syndrome
MUR	Medicines Use Review
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NIHR	National Institute for Health Research
NMS	New Medicine Service
OT	Occupational Therapist
PIL	Patient Information Leaflet
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
QoF	Quality and Outcome Framework
RCT	Randomised Control Trial
R&D	Research and Development
RMN	Registered Mental Nurse
RPS	Royal Pharmaceutical Society
SCR	Summary Care Record
SDM	Shared Decision Making
SMI	Severe Mental Illness
STR	Support Time Recovery
TA	Thematic Analysis
T2DM	Type 2 Diabetes Mellitus
WHO	World Health Organization
USA	United States of America
UK	United Kingdom

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Chapter One: Introduction

1.1 Introduction

The overall aim of this doctoral research was to explore the role of pharmacy in the lived experience of patients with cardiometabolic risk (CMR), metabolic syndrome (MetS), and related diseases in severe mental illness (SMI). This introductory chapter, therefore, provides an overview of the significance of the research, key definitions, risk factors for morbidity and mortality and of pharmacy practice. The chapter ends with a statement of the overall research aims and overview of the thesis structure.

1.2 Significance of the study

People with SMI, defined here as bipolar affective disorder, schizophrenia, schizoaffective disorder and other non-organic psychotic disorders, are at a substantially higher risk of premature death, in that they die 10–20 years earlier than the general population (1,2). SMI represents a leading cause of the global burden of disease with high morbidity rates and an estimated excess mortality of one and a half to three times higher than the general population (3). While unnatural causes, including suicide, homicide and accidents explain some of this reduced life expectancy (1,4), it is now firmly established that physical health diseases account for the overwhelming majority of premature deaths (3,5).

The mortality gap exists in countries considered to have high standards of healthcare (6–10) and there is also evidence that the mortality gap has increased over time (3,11,12). This appears to indicate that individuals with SMI have not experienced the same benefits from developments in healthcare as the general population (12). The premature and excess morbidity and mortality in people with SMI has ramifications not only for mental health and all health services but also for human rights and equity. A situation that has been labelled a scandal and in contravention of international conventions for the 'right to health' (13).

Among physical health diseases, cardiovascular disease (CVD) and diabetes are the main potentially avoidable contributors to early death in people with SMI (5). In a comprehensive meta-analysis of CVD risk in individuals with SMI, which included 3,211,768 patients and 113,383,368 controls, individuals with SMI had a statistically significant increased risk of coronary heart disease (CHD) compared to controls; a 54% higher risk in longitudinal studies and 51% higher risk in cross-sectional studies (14). Studies have reported that among patients diagnosed with diabetes, those with SMI have 50% higher mortality (15) and an increased risk of

complications requiring specialist treatment (16) compared to people without SMI. These findings are well substantiated by meta-analyses and systematic reviews (3,12,17–20).

Collectively, there is a paucity of published literature providing a comprehensive and contextualised understanding of the role of pharmacy in providing care and support for CVD, diabetes and contributory risk factors and diseases in patients with SMI (21), thus justifying further research within this area.

1.3 Severe mental illness

Psychosis is a syndrome associated with abnormal functioning of the temporal and frontal lobes and dopaminergic and serotoninergic neuronal projections to these areas of the brain (22,23). Individuals who have psychosis may experience delusions, hallucinations (e.g., auditory, visual, tactile) and disorganised thoughts and actions. Psychosis can be a result of a primary psychiatric disorder or can be secondary to substance use or specific medical aetiologies (23,24). Primary psychiatric psychotic disorders include schizophrenia, schizoaffective disorder, and other non-organic psychoses. Psychosis may also be present in other psychiatric conditions such as bipolar affective disorder and major depressive disorder (22,23). Individuals with psychosis associated with psychiatric disorders often present with hallucinations (mainly auditory), delusions, and disorganised thought process (22,23).

There is limited consensus regarding broader definitions of 'severe' or 'serious' mental illness in the literature (25). The National Institute for Mental Health in the United States of America (USA) adopts a definition of SMI (26) to include adults who currently or at any time in the past year have had a diagnosable mental, behavioural, or emotional disorder (excluding developmental and substance use disorders) of sufficient duration to meet diagnostic criteria specified within the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) (24), that has resulted in serious functional impairment which substantially interferes with or limits one or more major life activities.

The National Health Service (NHS) England definition, used as part of the Quality and Outcome Framework (QoF) (27) for primary care and Commissioning for Quality and Innovation (CQUIN) framework for secondary care (28,29), defines SMI as including schizophrenia, schizophrenia-like psychosis (e.g., schizoaffective disorder), bipolar affective disorder and other non-organic psychoses. This definition will be used here. Other large research studies and groups whose focus is physical health in SMI within the UK also adopt this definition (30,31).

1.4 Global burden of cardiometabolic risk, metabolic syndrome, and related diseases in people with severe mental illness

1.4.1 Cardiometabolic risk

CMR encompasses a cluster of risk factors and markers that identify individuals at increased risk for cardiovascular disease (CVD) and type 2 diabetes mellitus (T2DM) and includes those who smoke (32–36), are overweight/obese (36,37), hyperglycaemic (35,37,38), hypertensive (35,36,39,40), dyslipidaemic, hyperlipidaemic (36,39–41), and have MetS (42–48). People with SMI have a higher relative risk (one- to fivefold) (21) for modifiable CMR factors. The prevalence of hyperglycaemia, hypertension, dyslipidaemia and hyperlipidaemia in those with SMI has been reported to be 19% (38), 33.2% (40), approximately 48% (40) and 61% (41) respectively.

Public health data from the United Kingdom (UK) (49) and the USA (50) suggest that around two-thirds of people with SMI are current smokers, approximately double that of the general population (49,50). Literature reviews indicate that people with SMI are two to three fold times more likely than in the general population to be overweight or obese (51,52). This may be related to a poor diet as reported in a recent systematic review and meta-analysis of 58 studies (53).

1.4.2 Metabolic syndrome

MetS is a more specific term that describes the concurrence of the most dangerous CVD risk factors (54–57). MetS is defined by the International Diabetes Federation as central obesity accompanied by any two of the following four factors: raised triglycerides (or specific treatment for this), reduced high density lipoprotein cholesterol (or specific treatment for this lipid abnormality), raised blood pressure (or treatment of previously diagnosed hypertension) or raised fasting plasma glucose (56). MetS is one of the most prevalent risk factors for developing CVD in those with SMI (58,59). Thirty-seven per cent of those with chronic schizophrenia have MetS (42) compared with 24% in the general population (42).

1.4.3 Individual, health system, and social risk factors

The World Health Organization (WHO) considers the premature and excess morbidity and mortality in individuals with SMI a public health priority and it is included within the WHO's Comprehensive Mental Health Action Plan (60). The WHO also led an initiative on this issue publishing a multilevel model of risk factors contributing to excess morbidity and mortality in people with SMI, and a framework for interventions

in 2017 (1). Consistent with findings of a more recent study carried out within the UK (61) risk factors included in this model are categorised into three groups: individual, health system and social.

1.4.3.1 Individual risk factors

Within this multilevel model, risk factors at the individual level are those which are considered inherent to SMI or a patient's health-related behaviours. They include factors that are related to SMI severity, for example, symptoms and hospitalisations; those that affect how the patient engages or interacts with the healthcare system such as cognitive impairment or low motivation; or behavioural risk factors like tobacco use, diet, and physical activity (1,61). Cognitive impairment is commonly associated with SMI (62) and may impact upon a patient's ability to utilise health services and understand health information. Lack of motivation and self-neglect are also common in people with SMI and may affect concordance and adherence to advice about health (63).

1.4.3.2 Health system risk factors

Health system risk factors (1,61) include treatments, service delivery (care coordination and management), organisational characteristics such as the workforce or information systems infrastructure, and psychotropic medication. Evidence from worldwide studies demonstrate that it is now well established that people with SMI receive a poor quality of care for their physical health when compared to the general population, from health promotion and disease prevention and screening through to interventions (1,61,64–66). Despite having twice as many contacts with healthcare services, individuals with SMI receive less physical health screening, fewer prescriptions and fewer procedures (67,68) and lower rates of CVD diagnosis even though, as outlined earlier, the risk of these patients dying from CVD is higher (67,69,70). Specific examples include lower rates of surgical procedures such as coronary artery by-pass and revascularisation and fewer prescriptions for cardiovascular medication such as beta-blockers and statins (68,70).

Evidence from international studies report that during inpatient admission for medical (physical) care, people with SMI often have poor outcomes including higher rates of adverse events and more complications than patients without SMI (71,72). International studies have also highlighted a peak in excess mortality due to natural and unnatural causes within the first year following discharge from inpatient psychiatric care (73,74) indicating the possibility of flaws in healthcare systems to prevent, identify and treat physical diseases during hospitalisation.

It has been suggested that poorer health outcomes could be related to healthcare providers' negative beliefs and attitudes towards individuals with SMI and beliefs about the ability of individuals with SMI to initiate and maintain active and healthy lifestyle behaviours (75). A study conducted in the USA reported that attitudes of mental health and primary care healthcare providers towards people with SMI may impact on treatment intentions, including the likelihood of specialist referral for a physical health condition or providing repeat prescriptions (76). Evidence from a comprehensive literature review also suggests that the quality of care may be linked the provider and the type of healthcare system (77).

Fragmentation in the delivery of care for mental health and physical health poses a challenge in meeting complex needs and outcomes where the intersection of physical and mental illness occurs. A possible contributory factor are limitations in the knowledge, expertise and skills within mental health services to recognise and provide care for physical healthcare needs and similarly, and in parallel, physical health services may fail to recognise and provide mental healthcare (66). Furthermore, the intersection of both physical health needs and SMI is associated with greater disability, this is not purely additive, but synergistic. In other words, the severity of disability in those with both physical illness and SMI is significantly higher than the sum of each source of limitation (78). Studies have shown that the occurrence of multiple long-term conditions (LTCs) is associated with poorer quality care and health outcomes as well as increased costs (79).

The mainstay of treatment for most people with SMI is antipsychotic medication. Mortality in individuals with SMI appears to be highest where there is both a lack (73,80–82) or excess (high-dose or use of multiple) antipsychotic medication (83–85). When compared to the general population people with SMI using antipsychotics are more likely to die prematurely (85). Antipsychotics are associated with an increased prevalence of CMR, MetS and related diseases including, dyslipidaemia, impaired glucose tolerance and weight gain (86,87); the greatest weight gain has been reported to occur during the first few months of use (86,88,89). Marked differences exist in the incidence of CMR, MetS and related diseases associated with different antipsychotic medication, the (so-called) second generation olanzapine and clozapine being associated with the highest incidence and aripiprazole, lurasidone amongst others associated with the lowest (90,91).

No exposure to antipsychotic medication has been reported to be associated with a higher risk of CVD mortality than that observed with long-term treatment with low to moderate doses, although not with high-dose treatment (92,93). Large-scale observational studies indicate that all-cause mortality is reduced when continuous long-term antipsychotic use is maintained, this is attributed to reduced relapse rates, healthier lifestyles, less psychosis-related cortisol increases, and increased engagement with health services

(69,94,95). Judicious prescribing can reduce excess mortality in individuals with SMI. Recent studies and evidence summaries highlight the positive impact on mortality of continuous treatment (92,93), appropriate dose ranges (81), and current and long-term use compared with no medication (91).

Specific patient related factors may also be important. A recent systematic review and network meta-analysis of 18 antipsychotics, including both (so-called) first generation (such as haloperidol, flupenthixol and fluphenazine) and second generation antipsychotics, reported higher baseline weight, male sex, and non-white ethnicity as predictors of greater vulnerability to antipsychotic induced metabolic abnormalities (91). This supports the approach to avoid using antipsychotics with a high metabolic burden particularly in the presence of existing risk factors or physical illness such as obesity, diabetes or CVD (96). Some antipsychotics with recognised adverse effects on CMR, MetS and related diseases remain the treatment of choice, for example, clozapine for patients suffering from Treatment Resistant Schizophrenia.

Weight gain has also been shown to occur with some antidepressants (used to treat negative symptoms in people with SMI), and mood stabilisers, including valproate/valproic acid and lithium salts (79). Improvements in the severity of psychiatric symptoms in people with SMI may lead to better health behaviours such as reduced smoking (97) and the risks must be balanced against the potential benefits. Any comparison of impact on long-term outcomes of health, however, is obscured by heterogeneity in the drug class used (98) and variation in underlying comorbidities (99).

1.4.3.3 Social risk factors

The third category of risk factors (1,61) are associated with the social determinants of health and include (100) social support, environmental vulnerabilities, socio-economic position, cultural and societal values and public policies. People with SMI frequently have limited access to (good quality) healthcare (63) and are more likely to be homeless and be financially disadvantaged (1,61). Studies have shown that in high-income countries low socio-economic status coupled with homelessness confers additional mortality risk for people with SMI (101,102).

Other contributors to poor lifestyle behaviours for individuals with SMI include limited access to healthy foods and fewer opportunities to take part in healthy activities (1,61). Social and family support can also be limited, almost 75% of those diagnosed with SMI have never been married (69). Informal carers are often family members or close friends. The term informal carer has been defined as *"someone who spends a significant proportion of their life providing unpaid support to family or potentially friends. This could be*

caring for a relative, partner or friend who is ill, frail, disabled or has mental health or substance misuse problems" (103). Informal carers may have other caring roles which contribute to personal emotional, material, social, and physical strain (caregiver burden), informal carers of people with SMI are themselves more vulnerable to both physical and mental health problems (104,105).

In one study around 40% of informal carers of people with psychotic disorders reported poor psychological functioning including depression and other stress-related disorders such as anxiety (106). Informal carer distress can persist over the course of the illness and escalate during the early phase of the illness and during inpatient admissions (106). In addition, burnout and exhaustion amongst carers have been reported to occur even during first episode psychosis (106). Feelings of loss and grief have also been found to be highly prevalent in informal carers of individuals with psychotic illnesses (106), these have been reported as being not dissimilar in presentation and content to those observed following a bereavement (106). Poor levels of physical health, including sleep difficulties have been reported (107). In one study two-thirds of carers (n=264) of individuals with SMI reported having at least one physical health condition in the preceding five years (e.g., arthritis, hypertension, and emphysema), and the remaining one-third reported having at least two physical health condition (108). Informal carers of people with SMI have been reported to have a reduced quality of life and experience greater social isolation when compared to non-caregiving peers. Published evidence indicates that they are up to 10 times more isolated when compared to non-carers but also significantly more socially isolated than informal carers of those with other health conditions (108–110).

For people with SMI, individual and health system risk factors and social determinants of health are all interrelated and intertwined at various levels and in various ways. High rates of lifestyle behaviours such as smoking exist but studies clearly and consistently demonstrate that contributory factors to morbidity and mortality extend beyond diagnosis and lifestyle behaviours (1,61). For example, despite the wealth of evidence that a large majority die of CVD, only one quarter receive a diagnosis for this (69). After controlling for whether a diagnosis has been made the risk of death due to ischemic heart disease equates almost equal to that of someone in the general population (69).

A comprehensive approach is needed to improve the health and longevity of people with SMI given that these factors are interrelated and intertwined at various levels and in various ways. A study that explored the potential gain in life expectancy from addressing modifiable risk factors for all-cause mortality (excluding suicide and deaths from accidents or violence) in individuals with SMI (61) concluded that the whole is greater than the sum of the parts. Greater benefits could be achieved using a multifaceted approach to simultaneously address individual behaviour, health system and social factors (1,61).

The availability of rigorous economic data on these issues is limited. In a recent retrospective database review of 57,506 patients with schizophrenia and bipolar disorder, each incremental CMR factor was associated with an 8.3% and 13.4% increase in total hospital spend respectively (111). An estimated net cost saving of at least £108 million per year could be made with sustained investment of £83 million per year over at least a four year period (112).

Guidelines have been developed and disseminated to address this excess morbidity and mortality in individuals with SMI. These primarily target mental health, lifestyle behavioural risk factors, and screening and management for physical health. As far back as 1995, elements of physical healthcare including CMR, MetS and related diseases were incorporated into government guidelines for SMI in parts of Australia (113). In the UK, guidelines for schizophrenia were first published by the National Institute for Health and Clinical Excellence (NICE) in 2002 (114) and included recommendations for regular physical health screening. Then, in 2004, as a result of a Food and Drug Administration (FDA) warning in the USA about the association of antipsychotics with an elevated risk of T2DM, the American Diabetes Association (ADA) and the American Psychiatry Association (APA) published joint guidelines explicitly outlining the need for routine screening for diabetes for people taking antipsychotics (115).

Up to date versions of these guidelines recommend coordination among mental health and primary care providers, and delivery of general physical health services in mental health settings (86,93,116–118). Manufacturers of antipsychotics have more recently included clear statements about screening and management for CMR, MetS and related diseases in their Summary of Product Characteristics (119,120); the prescription of such medication should be in line with this legal document.

1.5 Pharmacy

The research presented in this thesis took place within the UK, this section provides an overview of pharmacy. Within the UK the pharmacy workforce is comprised of pharmacists and pharmacy technicians who must be registered with the GPhC, and unregistered support staff such as dispensers and pharmacy assistants. There are three main areas of practice: community pharmacy, secondary care (mainly hospital) and primary care (mainly general practice surgeries). In 2019 a total of 79,770 pharmacists and pharmacy technicians were registered with the GPhC (169). According to a GPhC registrant survey (169) undertaken in 2019, 63% of pharmacists and 46% of pharmacy technicians worked in a community pharmacy setting as their main job. Twenty two percent of pharmacists and 41% of pharmacy technicians work in hospital

settings, 2% and 3% work in secondary care mental health and learning disability (LD) services, respectively. While general practice surgeries were the context for 12% and 9% of pharmacists and pharmacy technicians. The remainder of registrants worked in healthcare commissioning organisations, academia, or the pharmaceutical industry.

The pharmacy profession has undergone immense changes over the past few decades. These have led to significant evolution and developments in the breadth of professional practice. Roles are no longer limited to drug preparation and distribution; boundaries have been expanded to encompass more person-centred services with a focus on optimal therapeutic outcomes (121,122). These include provision of specialised information to other care professionals, education and counselling of patients and their informal carers, health promotion and disease prevention and management of a variety of disease states. Factors that have driven the need for broadening the scope of practice include increased occurrence of drug-related morbidity and mortality (123), increased complexity of medication regimens and rates of polypharmacy (124) and increase in patient needs (125). Ultimately, the role of pharmacy is to ensure the safe, effective and person-centred pharmaceutical care to enable the best possible outcomes; this is commonly known as medicines optimisation (126).

According to the UK General Pharmaceutical Council (GPhC) (127), pharmacists are responsible for the quality of medication supplied, ensuring that the supply of medication is within the law, ensuring that medication is suitable and appropriate, advising about medicines, including how they should be taken, what reactions may occur and answering patients' questions. Pharmacists also supervise the medication supply chain and ensure pharmacy systems and premises are fit for purpose. They advise others about safe and effective medication use, and safe and secure supply of medication, respond to patients' symptoms and advise on medicines for sale in pharmacies, provide services to patients such as smoking cessation, supervise the production and preparation of medication and assess of quality of medication before they are supplied by pharmaceutical manufacturers (127).

Under pharmacist supervision (128), pharmacy technicians: supply medication to patients, assemble medication for prescriptions, provide information to patients and healthcare professionals. Pharmacy technicians also manage areas of medicines supply, for example pharmacy dispensaries, supervise pharmacy staff, produce medication in hospitals and the pharmaceutical industry.

The International Pharmaceutical Federation (FIP) have conducted Global Pharmacy Workforce Surveys in 2006, 2009 and 2012 (129). In 2012, the survey collected workforce data for 90 countries and territories

representing 2.5 million pharmacists and nearly one and a half million pharmacy technicians. A key message from these surveys (129) was that there was considerable variation in pharmacy workforce density between countries and across WHO regions. In general, this correlated with economic development indicators and population numbers. Countries and territories with lower economic indicators tended to have relatively fewer pharmacists and pharmacy technicians (129).

Access to high quality health services is essential for positive health outcomes and this includes access to pharmacy teams who can provide medicines optimisation services which are essential for improvements to morbidity and mortality associated with LTCs (129). The availability of an appropriately skilled pharmacy workforce is an important aspect of improving equitable access to healthcare (129). Pharmacy productivity in many countries has increased due to improvements in technology such as electronic prescribing, automated dispensing robots and the optimisation of skill mix within the pharmacy workforce (mainly through the expansion of the pharmacy technician role). The creation of new roles for pharmacists to mitigate shortfalls in other healthcare professions such as doctors and nurses has resulted in an increase in demand for pharmacists (129).

There is increasing recognition for pharmacists' current and emerging roles in mental healthcare in both primary and secondary care settings, as evidenced by guidelines, reports and frameworks which highlight their integral contribution to screening, initiating and maintaining treatment, improving medicine adherence and providing medicines information (130–133). This is also supported by published literature; recent studies have documented the role of pharmacists in screening and identifying people at risk of depression with referral for diagnosis and treatment (134–136) and managing psychotropic medication-related problems (137–140). Other studies have shown a beneficial impact on antidepressant adherence of pharmacists working as part of a psychiatric multidisciplinary team (MDT) (141–143). Recent literature has recognised the role of pharmacy technicians in medicines reconciliation within mental healthcare settings (144,145). This evidence must be viewed critically though, as most of the studies cited were conducted by pharmacists. In addition, they fall quite low on the hierarchy of evidence.

1.5.1 Community pharmacy

Community pharmacies represent an accessible and convenient primary healthcare resource. A survey carried out in 2017 of 69 countries and territories reported around 1.5 million community pharmacies serving a population of 5,549 million (75% of the world's population) (146). Globally the median number of individuals served by a community pharmacy is 4,182. Community pharmacies in higher income countries

serve between 2,000 and 8,000 and those in lower income countries serve larger numbers of individuals (146). There are variations in the regulatory systems, health policies and remuneration systems which underpin community pharmacy practice but core services in 85% of the countries surveyed (n=63) were medication dispensing and counselling as well as pharmacovigilance 81% (n=60) and compounding 80% (n=59) (146).

Despite the accessibility and convenience of community pharmacy and the qualifications and training of pharmacy staff it has been suggested, mainly by pharmacists, that the services offered are significantly underutilised (147,148). A statement on Good Pharmacy Practice (149) co-authored in 2015 by the WHO and the FIP outlined a number of key areas where pharmacists need to expand their role to provide greater benefits to patients and health services. These include 'traditional' functions such as medication supply and (newer) roles such as administration of vaccines, medication therapy management, health promotion and disease prevention. The pharmacy profession has responded to this call for a professional evolution and a number of national pharmacy organisations have outlined their future vision for community pharmacy practice developments (147,150–154). The role of pharmacy technicians within the community sector is less well developed than that of technicians working in other sectors such as hospital, this will be explored further in the next section (155).

1.5.2 Hospital pharmacy

A recent survey of 72 countries and territories (146) reported over 1.1 million hospital pharmacies serving a population of 3.6 billion people (49% of the world's population). Globally the median density of hospital pharmacies per 100,000 population is 1.05 with the Southeast Asian region having the highest density at 2.74, more than almost seven times higher than that in Africa (0.40 per 100,000). These variations in part reflect the structure of healthcare systems and the intensity of hospital versus outpatient care as well as the roles and activities of hospital pharmacy teams and accessibility of hospitals by patients.

Of the countries surveyed (146) 96% (n=69) reported that hospital pharmacies are involved in providing medication and support to emergency departments, 94.4% (n=68) in pharmacovigilance and 94.4% (n=68) in pharmacy and therapeutics committees. In addition, 91.7% (n=66) reported activities relating to quality assurance to reduce errors in the administration of medication and 87.5% (n=62) in providing advice and guidance about medication to other healthcare professionals. The authors of a scoping review published in 2020 exploring hospital pharmacy practice called for researchers in hospital pharmacy practice publish their work relating to current practice to substantiate current evidence and knowledge on its practice (156).

Over the last 40 years, the roles of pharmacy technicians in hospital have developed significantly beyond that defined by the GPhC. Structured career frameworks for both hospital pharmacists and hospital pharmacy technicians exist (157). Pharmacy technicians working in hospitals can specialise and degrees of autonomy conferred on their roles has increased (155). Hospital pharmacists are well supported by roles undertaken by pharmacy technicians (155,157).

1.5.3 Mental health/psychiatric pharmacy

Psychiatric (mental health) pharmacists are qualified pharmacists who may have specialised training in the disciplines of psychiatry and neurology . Australia (158) and the USA (159) have published standards and guidelines for pharmacists working in this area of care. Psychiatric pharmacy speciality colleges exist in the UK (160) and the USA (161). Psychiatric pharmacists and, in the UK, pharmacy technicians can become members of these colleges; some membership categories require recognition through formal accreditation schemes. In the USA psychiatric pharmacy specialisation by pharmacists is achieved after graduating from a Doctor of Pharmacy program and then post-graduate residency training, clinical experience, or a combination of the two. In the UK, a specific postgraduate qualification in psychiatric pharmacy exists which is accessible to pharmacy technicians (up to postgraduate certificate level) and pharmacists (to postgraduate diploma and masters level).

A recent electronic survey (162) reported that practice settings for psychiatric pharmacists in the USA were split evenly between inpatient, outpatient and a combination of these. Of those who took part, 46.5% (n=155) reported having authority to prescribe as part of their practice and this was more likely in outpatient settings (162). In addition, 41.3% (n=137) reported treating non-psychiatric as well as psychiatric illnesses. CMR, MetS and related diseases were reported as the most common non-psychiatric conditions for which psychiatric pharmacists supported and prescribed for, specifically, diabetes and metabolic diseases (25.7%) and CVD (25.1%) (162).

1.5.4 General practice based pharmacy professionals

General practice based pharmacists are a relatively recent phenomenon in the UK (163). Two systematic reviews (164,165) reported the evidence of benefits of practice based pharmacists were mixed and may be affected by heterogeneity in patient population (i.e., those with specific health conditions or generally at risk of medication related problems), outcomes assessed (i.e., clinical, surrogate or patient-reported) and the

extent to which pharmacists were integrated into the general practice setting. There also appears to be large variations in current practices related to for example whether or not practice based pharmacists had prescribing rights for example (166).

In November 2019, the Pharmacists Defence Association issued a warning to general practice based pharmacist prescribers after serious incidents were reported involving patients under the care of practice based pharmacist (167). These cases were linked to pharmacists prescribing inappropriately or offering poor advice because they had an *'ill-founded'* assumption of competence (167). This highlighted the need for these pharmacists and their employers to consider and understand the levels of experience and skill in relation to the responsibilities of the role.

Pharmacy technician roles in general practices settings more recent than those of pharmacists (163). A survey conducted in the UK between 2018 and 2019 reported general practice pharmacy technicians' roles in clinical and non-clinical pharmacy services. These included medicines reconciliation, management of repeat prescribing requests, domiciliary visits and medication reviews (168). However, only 10 pharmacy technicians were included in this survey and some had multiple roles. Technicians formed 22.7% of the total cohort of survey respondents, the remainder being pharmacists (168).

1.5 Interventions for cardiometabolic risk, metabolic syndrome, and related diseases in people with severe mental illness and the potential contribution of pharmacy

1.6.1 Interventions focused on the individual patient

These include interventions delivered to individuals with SMI aimed at their mental health, physical health, and lifestyle behaviours. Implementation and impact of these interventions are affected by the function of larger healthcare systems. Currently the consensus and views are that recommended interventions and targets for outcomes of the management of CMR, MetS and related diseases for people with SMI should be no different than the general population. However, some interventions such as self-management may require tailoring or individualising to take into account cognitive, functional or motivational deficits which may be present in individuals with a diagnosis of an SMI (1,169).

1.6.1.1 Interventions addressing lifestyle behaviours

Smoking has been shown to be the best single modifiable behaviour for increasing life expectancy in people with schizophrenia (2.4 years) (61). Tobacco cessation interventions have proven beneficial in people with SMI and their use is recommended as early as possible (77,93). A combination of counselling with medication (e.g., bupropion, nicotine replacement therapy) has been shown to promote abstinence though relapse is common (170). Studies have found that healthcare professionals are frequently reluctant to engage individuals with SMI in smoking cessation behaviours (154,155), various reasons were reported for this including a fear of the damaging effects it might have on relationships with patients and beliefs that smoking cessation may damage mental health (154,155). Further, smoking cessation services may be less accessible to people with SMI (173). A recent trial of a bespoke smoking cessation intervention delivered as part of routine mental healthcare (31) resulted in a 56% greater reduction in smoking rates compared to usual care in people with SMI. However, further studies of this intervention show lower rates of smoking cessation (174).

A recent literature review (175) found strong evidence that pharmacists have a positive attitude to smoking cessation counselling and that pharmacists believe that smoking cessation counselling will be effective. This review did not mention mental health conditions or any other diseases specifically. Systematic reviews of pharmacy involvement in smoking cessation in the general population have consistently found limited and low quality evidence, so the clinical effectiveness and cost-effectiveness of pharmacist-led interventions for smoking cessation remain uncertain (175–177). Pharmacy, in particular community pharmacy and community pharmacists, are often considered more accessible to the general population than general practices (178). In addition, pharmacy technicians routinely deliver smoking cessation interventions to the general population in the community pharmacy environment (179).

Sedentary behaviour is the best single modifiable behaviour for increasing life expectancy (1.2 years) in people with bipolar affective disorder (61). Randomised controlled trials (RCTs) of behavioural weight loss programmes for people with SMI have yielded mixed results in achieving clinically significant weight loss, some have shown positive results (180–182) whilst others have reported no impact at all (183). A recent systematic review of RCTs concluded that overall, there was a statistically significant, but clinically insignificant, mean effect of individualised lifestyle interventions for weight reduction in people with SMI (184).

Studies have found that people with SMI are well motivated to improve lifestyle behaviours (185). Despite this evidence suggests that lifestyle behaviours within the SMI population continue to be marginalised and poorly integrated into care pathways (186). The literature also highlights that there are many unanswered questions regarding the implementation and dissemination of lifestyle programmes and more fundamental questions about how or whether specific adaptations are needed for individuals with SMI (1). First, the optimum duration and intensity for sustainable long-term outcomes; current evidence suggests that people with SMI who are obesity or overweight may require more frequent contact over a longer period (1). However, long-term data for behavioural interventions such as lifestyle interventions is difficult to generate, for example, due to high rates of participant attrition (187). Second, who is best placed to deliver these interventions in different contexts and environments. Finally, how lay providers can be given the knowledge, understanding and training to deliver effective healthy lifestyle behaviour change interventions to patients.

A systematic review published in 2019 (188) reported that structured education and dietary interventions delivered in the community pharmacy setting to patients newly diagnosed with diabetes were effective in improving blood glucose levels without pharmacological intervention. Interventions were delivered by to patients by doctors, diabetes nurses, dietitians and nutritionists, not by pharmacists (188). The authors commented that there was a lack of published data on pharmacist-led interventions in this context (188). Important elements of these interventions included face-to-face interaction with the patient, individualising care and multicomponent interventions lasting at least six months. This reflects the place of community pharmacy as a healthcare destination but not the role of pharmacists or pharmacy professionals specifically. Another systematic review of community pharmacists' interventions in reducing major risk factors for CVD (189) reported potential for substantial benefits in hypertension and diabetes, specifically, clinically important reductions in glycosylated haemoglobin (HbA1c) and systolic blood pressure. However, no clear benefits of the community pharmacists' involvement in the management of lipids were found (189).

1.6.2 Interventions focused on health systems

The next category encompasses health systems interventions and programmes that focus on healthcare providers and service delivery components. There is wide variation across settings relating to many different parameters such as the provision of universal healthcare. In 2007 the WHO published a document which argues for the need to strengthen the building blocks of health systems including service delivery, health workforce, information, technologies, financing, and leadership and governance to improve outcomes for people with SMI (190).

Integrated care models underpinned by the principle of improving the coordination of services provided to patients have the aim of achieving improved care with patient's perspective as the central focus (191). Target populations for integrated care models often have multiple LTCs and often take multiple medications (polypharmacy), despite this, integrated care models rarely include or focus on the importance of pharmacy. Integrated care models are often cited as being a way of potentially reducing the current 'siloed' nature of specialist care such as non-integrated primary and specialist psychiatric care services (192). RCTs have shown that patients receiving care from pharmacists within integrated care models experienced improved diabetes care in community pharmacy settings for instance reductions in HbA1c (193,194), hypertension in primary care settings (such as improvements in blood pressure control) and depression (such as increased adherence to treatment, satisfaction (195)). However, measures such as increased adherence or satisfaction in depression do not necessarily equate to significant improvement in clinical outcomes for patients.

Programmes of care coordination, integrated care, or collaborative care for CMR, MetS and related diseases in individuals SMI aim to provide liaison between mental health and physical healthcare systems or through linking the delivery of physical and mental health services. Few studies have been conducted which explore these programmes for CMR, MetS and related diseases and SMI. Guidelines that incorporate combinations of screening for CMR, MetS and related diseases and, care coordination among mental health and primary care providers have been implemented in several countries, including the US, UK and Australia (196–200).

Leaders of healthcare organisations are responsible for ensuring the implementation of national and international guidelines for CMR, MetS and related diseases in people with SMI within their organisations as well as facilitating appropriate levels of funding for systems, such as information technology, that will facilitate improvements in care. The question as to who will implement evidence-based preventive health or care coordination intervention to improve CMR, MetS and related diseases in people with SMI also needs to be addressed (1,61). For example, implementation by dieticians may be cost prohibitive or the number available may be lacking (1,61), sustainability may be more likely if members of the pharmacy team, like pharmacy technicians, could deliver a physical health intervention.

There has not been a systematic review of the impact of switching antipsychotics on the basis or presence of CMR, MetS and related diseases in individuals with SMI. However, individual studies including open label studies and RCTs have been conducted (201–205), these studies only included second generation antipsychotics. Switching to antipsychotics with lower propensity for CMR, MetS and related diseases has been shown to result in improvements in body adiposity and insulin sensitivity (201), a greater reduction in CVD risk when compared to a behavioural program that promoted healthy diet and exercise (202,204) and

MetS parameters (203,205). Most of these studies emphasised that switching antipsychotics to achieve these improvements must be balanced against risk of discontinuation or relapse in individuals with SMI (201–205).

As noted previously the risk of CMR, MetS and related diseases in people with SMI is increased with the use of high-dose antipsychotic therapy. Approximately between one-quarter and one-third of patients on inpatient psychiatric wards are prescribed high-dose antipsychotic regimes (196) and the population may be even higher in psychiatric intensive care units, rehabilitation wards and forensic units (196,206). Antipsychotic polypharmacy frequently results in high-dose prescribing (207). An audit of inpatient psychiatric services reported that almost 73% of combined polypharmacy regimens were high-dose (197). This may reflect the refractory nature of treating patients prescribed multiple antipsychotics and may partially account for increased side-effects including CMR, MetS and related diseases observed with polypharmacy (207).

Uncertainty still exists about which models of healthcare are the most sustainable, most effective, and most cost-efficient (1) for patients with physical health disease and SMI. Many are based on systems, which exist in high-income countries, as such, their applicability within low to middle income countries requires further exploration (1,61). As the role of pharmacy and care for SMI changes within low to middle income countries then these may provide opportunities to further assess and refine effective models of that can improve morbidity and reduce excess mortality.

1.6.3 Interventions focused on socio-environmental and social determinants of health

Interventions focused on socio-environmental factors and the social determinants of health operate at the broadest level. These include clinical guidelines, public health policies and social support such as peer support programmes, family support programmes and acknowledge the scope of potential interventions arising from the community to address contributors to morbidity and mortality (1,61). These interventions aim to address issues such as health behaviours or self-management of LTCs. Importantly, interventions that focus on socio-environmental and social determinants of health connect both health system and individual-focused interventions.

Guidelines incorporate coordination among mental health and primary care providers, and delivery of general physical health services in mental health settings (86,93,116–118). Authors of a paper (208) on the USA Schizophrenia Patient Outcomes Research Team (PORT) guidelines (93) identified the difficulty of

evidence based guidelines changing clinical practice. Other studies also support this position, all the studies that assessed the impact of the USA ADA/APA 2004 guidelines (115) that were simultaneously accompanied by extensive educational efforts indicate that the impact on screening and monitoring rates for people receiving antipsychotics was at best minimal (209–215). Studies conducted within the UK have yielded similar results (196,197).

Despite the convincing evidence for the association of antipsychotic use and CMR, MetS and related diseases in people with SMI and explicit recommendations provided by guidelines screening is often incomplete or inconsistent (216). A review carried out in 2012 of 39 internationally published studies reported that rates of routine baseline screening were low (50% solely for blood pressure and 59.9% for triglycerides), less than 50% for cholesterol (41.5 %), glucose (44.3 %), weight (47.9 %) and HbA1c (<25%) (216). However, a more recent review conducted in 2016 suggested that interventions to improve screening for obesity, hyperlipidaemia and hypertension can be effective at improving the detection of CMR, MetS and related diseases. What is not clear is whether such interventions are sustainable in everyday clinical practice in the long-term.

A recent systematic review of pharmacist interventions for MetS alone, its management and its prevention (217) concluded that there was a lack of evidence. There were a few models of care that could be implemented in practice but a lack of evidence for patient benefit (217). The authors reported that there was limited amount of evidence of the role of pharmacy associated with positive outcomes from screening and management and that further research is needed provide more robust evidence of clinical and cost-effectiveness (217). The review also called for further research with key stakeholders (patients and healthcare professionals) to determine the readiness and acceptance for pharmacists to implement interventions in MetS.

The Health and Social Care Act 2012 (UK) set out a clear and explicitly legal responsibility for the National Health System (NHS) to deliver parity between mental and physical health. Further, secondary care psychiatric/mental health NHS trusts were given financial incentives to work towards meeting indicators under the CQUIN. This included carrying out and recording screening and management for CMR, MetS and related diseases for people with SMI. Significantly, the scheme mandated communication with the patient's general practitioner (GP) on discharge from secondary care. In the USA, a proposition was put forward that individuals with SMI be considered a health disparity group by the federal government (182). This included a requirement to track health statistics of this population and to provide more opportunities supporting these patients with their health (182).

Since 2018 the Royal Pharmaceutical Society (RPS) in the UK has published three documents (130,131,218) which focused on the need for pharmacy to have a greater role in supporting parity between mental and physical health. Specific recommendations were made about providing care to support people with SMI manage CMR, MetS and related diseases. The earliest policy documents (130,131) made several key recommendations. First, that pharmacists are commissioned to deliver services for physical health screening and management of people with mental health conditions. Second, that there was a need to identify how community pharmacists could be enabled to better support people with mental health problems with their medication. Finally, that all mental health teams should have access to a specialist mental health/psychiatric pharmacist and that this should be as a member of the MDT in community teams, mental health inpatient hospital wards or acute hospitals.

The most recent document (219) published in 2020 makes further specific recommendations:

- Individuals prescribed a new medication for a mental health condition would benefit from support from community pharmacy as part of an integrated model with GPs.
- Further use should be made of the clinical skills of pharmacists working in all settings (community pharmacy, GP practices, mental health services, primary and secondary care) to improve care.
- Patient access to physical health monitoring and public health initiatives in community pharmacy should be improved.
- Mental health first aid and suicide prevention training should be undertaken by pharmacy teams to facilitate their response to crisis situations.
- More specialist mental health pharmacists are needed so that existing services are sustainable, and teams across all care settings have access to their expertise through psychiatric pharmacist liaison posts.
- Pharmacists should have read and write access to patient medical records to facilitate the delivery of safe, integrated, and effective patient care.

1.7 Research aims and objectives

Individuals with SMI represent a vulnerable group with multiple and substantial healthcare needs. The excess morbidity and mortality in individuals with SMI continue to be an important global public health problem. The excess morbidity and mortality in this population are mainly due to preventable physical health illnesses related to CMR, MetS and related diseases. Despite identified and established risk factors for morbidity and premature mortality, evidence for effective interventions for CMR, MetS and related diseases in people with

SMI is limited. Pharmacy is increasingly being highlighted as a profession that has the potential to contribute to comorbid physical and mental healthcare in both primary and secondary care settings. However, robust high quality research supporting the role of pharmacy providing care for CMR, MetS and related diseases in individuals with SMI is lacking.

The overarching aim of the work presented in this thesis is to understand and explain the role of pharmacy in the lived experience of patients with SMI and CMR, MetS and related diseases (individuals with SMI in phase 2 of this research referred to themselves as patients and this term is used throughout this thesis). At present, not enough is known about key stakeholders' views, perceptions, and experiences of this role. Ultimately, this research aims to develop new knowledge in the area and identify key actions for clinical practice, policy, and research to move towards health equity for those with SMI. The specific research objectives are:

1. To systematically review evidence relating to the role of pharmacy in CMR, MetS and related diseases in patients with SMI.
2. To explore, document and analyse the views, perceptions, and experiences of patients with SMI, their informal carers, caring dyads (defined here as a patient and their informal carer), care professionals and pharmacy professionals on the role of pharmacy in managing CMR and MetS. This will be informed by objective 1.
3. To provide strategic recommendations for pharmacy for clinical practice, policy, and research to improve care for CMR, MetS and related diseases in patients with SMI. This will be based on the findings from objectives 1. and 2.

1.8 Thesis structure

This chapter (**Chapter One**) has provided the background to the thesis including details of the burden of cardiometabolic risk, metabolic syndrome, and related diseases for patients with severe mental illness. It also provides an overview of the place of pharmacy in healthcare in engaging with people with these conditions.

Chapter Two presents a mixed methods systematic review of the existing literature of the role of pharmacy in cardiometabolic risk, metabolic syndrome, and related diseases for patients with severe mental illness. This will identify and clarify the knowledge gaps in the field. The chapter concludes with a robust rationale for this study.

Chapter Three outlines the methodology and methods used in this study. The philosophical and methodological underpinnings are outlined. The utilisation of an exploratory, qualitative, semi-structured interview approach is justified. Methods utilised for data collection, analytical techniques, and authenticity and reliability in qualitative research are outlined. Personal reflections pertaining on the doctoral student's own role and position as the researcher are expounded.

Chapters Four to Eight present the study findings in a sequential manner, placing the patient at the centre and front of this exploratory research study. Each chapter builds on the previous ones to provide novel insights into the phenomenon. The findings of interviews with patients, informal carers, caring dyads, care professionals and pharmacy professionals are presented, with one chapter dedicated to each of these categories. In this study a caring dyads is defined as a patient and their informal carer. Each chapter provides in-depth, unique, and contextualised insights into the lived experience of patients and the role of pharmacy.

The final chapter, **Chapter Nine,** discusses the key study findings with reference to existing research. Reflexive and methodological insights in relation to situating the study and the researcher are expounded and the implications for clinical practice, policy and future research are presented.

Chapter Two: The role of pharmacy in the management of cardiometabolic risk, metabolic syndrome, and related diseases in patients with severe mental illness: a mixed methods systematic literature review

2.1 Introduction

The first step in undertaking any research is to review the literature to establish what is already known setting the context for the research and informing the study design. This chapter presents the findings from a mixed methods systematic literature review of the role of pharmacy in the management of CMR, MetS and related diseases in patients with SMI.

2.2 Conducting a literature review

Literature reviews require comprehensive searching, quality assessment which may determine inclusion or exclusion and narrative synthesis with the use of tables of evidence (220). A protocol, which specifies exactly what is to be done, developed in advance specifies these requirements.

The protocol for a literature review should include the review question(s), inclusion criteria, search strategy, study selection, quality assessment, data extraction, and approach to data analysis (221). Publication of the protocol alerts other researchers that the review is being undertaken and minimises the potential for duplication. Publication also provides evidence of peer review and therefore of the quality of the protocol.

Systematic reviews involve a systematic search, appraisal, and synthesis of research evidence, commonly adheres to guidelines on the conduct of a review. Systematic reviews are used inform evidence-based practice and this is promoted by numerous organisations including the Cochrane Collaboration (222) and the Centre for Reviews and Dissemination (CRD) at the University of York (223).

2.3 Approach taken to systematic review in this research

The review was undertaken in accordance with guidance provided by the CRD and used a mixed methods approach. According to the CRD (224): *"The relevance of qualitative research to the assessment of health interventions, especially those that are complex, has been recognised. As a result, qualitative and quantitative methods are increasingly being used together in primary evaluative research. The main reason for the*

adoption of mixed-methods in primary research is to enhance relevance in the decision-making process." The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (225–227) were used to standardise the conduct and reporting of the research (Appendix 1: PRISMA checklist). The PRISMA checklist is relevant for mixed methods systematic reviews (226).

Mixed methods literature reviews are associated with limitations. There are no universally adopted methods for conducting mixed methods reviews and they require significant methodological skill to conduct (228). The literature search may produce a larger number of citations and may require more time to create multiple searches for varying outcomes (228). There is the potential for an erosion in the depth, richness and flexibility that occurs when qualitative data are quantized. Conversely, quantitative data are fixed and one-dimensional. They consist of a single set of responses representing a conceptual category determined prior to data collection and cannot be changed in response to new insights in analysis (229). Qualitative data can be subject to collinearity, in other words theme or categories are linked to each other as a consequence of data analysis techniques adopted (230) and this may be lost during integration of quantitative and qualitative data in a mixed methods literature review (229).

Further, mixed methods reviews are resource intensive (228,231). Purely qualitative or quantitative systematic reviews involve one type of synthesis whereas the mixed methods approach can involve up to three (qualitative, quantitative and mixed/integrated) (231). This may be more challenging where resources available to conduct the review are limited or where timescales are tight. Reviewers may have to make pragmatic decisions about how to make the review manageable within these constraints. Finally, mixed methods reviews are not always inherently reproducible or transparent because of the highly iterative nature of the interpretative process (228).

2.4 Database search for any pre-existing systematic reviews

An initial search for pre-existing systematic reviews on the role of pharmacy in the management of CMR, Mets and related diseases in SMI was carried out using the following databases: The CRD database and the Cochrane Database of Systematic Reviews library. No systematic review was found.

2.5 Details of the systematic review in this research

2.5.1 Aims and objectives

The primary aim of this systematic literature review was to undertake a detailed analysis and review of the published studies that existed relating to the role of pharmacy, or pharmacy professionals in CMR, MetS or related diseases for individuals with SMI; exploring the range of roles for pharmacy or pharmacy teams as part of interventions relating to CMR, Mets and related diseases, for example, undertaking screening or managing a CMR factor or advising on medication that alters CMR risk. This could include, for example, a new or existing pharmacy service or part of an intentional research study intervention; the phrase study intervention will be used here when referring to any and all of these. Another aim was to also undertake a review of implementation strategies used in study interventions and their effectiveness in informing practice and identify evidence gaps to provide a focus for future research studies.

The objectives were as follows:

1. Identify published quantitative, qualitative, or mixed methods studies relating to the role of pharmacy or pharmacy professionals in CMR, MetS or related diseases in individuals with SMI.
2. Summarise the data and conclusions from those studies.
3. Undertake a collective appraisal of that data which consisted of a mapping review and a detailed analysis and review of the implementation strategies used in study interventions that involved pharmacy or pharmacy professionals in CMR, MetS and related diseases in patients with SMI.
4. Identify limitations and evidence gaps from the studies identified and make recommendations for areas that require further research.

2.5.2 Literature search procedure and databases searched

Protocol development was informed by CRD guidance for undertaking systematic reviews (224). Discussions with the supervisory team clarified the objectives and specialist librarians advised on the search strategy and searching techniques. The systematic review protocol was accepted for registration and published by PROSPERO (Appendix 3) the international prospective register of systematic reviews in health and social care maintained by the CRD (221); registration number CRD42018086411 (232). A search strategy (Appendix 4) was developed iteratively through discussion as outlined above.

Database-specific search strategies were developed with assistance from a medical librarian. Eleven electronic databases were searched from inception to January 2018: Medline, EMBASE, PsycINFO, British

Nursing Index, AMED, Health Business Elite, Health Management Information Consortium, The Cochrane Library, Health Technology Assessments, Scopus, and Web of Science. Appendix 4 provides detailed information on search strategy including hand and grey literature searches. The search was repeated in August 2020 and no new studies were identified for inclusion.

A systematic search was conducted for primary studies in which the study intervention involved pharmacy or pharmacy professionals in CMR, MetS or related diseases in patients with SMI. Any published literature that described an intervention involving pharmacy or pharmacy professionals in CMR, MetS or related diseases was included; this could include, for example, a new pharmacy service or an existing service or part of an intentional research study intervention. Elaborating on what is meant by the term 'role', this could include, for example, pharmacists or pharmacy technicians, undertaking screening like weight checks, managing a CMR factor such as smoking cessation or advising on medication such as switching medication with lower risk propensity for weight gain. The eligibility criteria for full text review are summarised in Table 2.1 below.

Table 2.1: Participant, Intervention, Comparator, Outcome, Study design: eligibility criteria for full-text assessment

Category	Inclusion Criteria	Exclusion Criteria
Participants	Individuals with SMI ≥ 18 years SMI: bipolar affective disorder, schizophrenia, schizoaffective disorder, psychosis, any non-organic psychosis	Individuals with SMI under the age of 18
Intervention	Pharmacy professionals carrying out any of the following activities to any degree: • Screening for cardiometabolic risk or metabolic syndrome, syndrome X or cardiometabolic disease or related diseases and any of the associated risk factors including lifestyle advice, diet, smoking, alcohol, exercise, cardiovascular disease, diabetes or prediabetes, weight, BMI, waist circumference, overweight, obesity, lipid abnormalities and blood pressure • Health promotion or risk reduction intervention for cardiometabolic risk or metabolic syndrome, syndrome X or cardiometabolic disease or related diseases or any of the associated risk factors Medicines management activities relating to the above	Any of the activities carried out wholly by staff who are not pharmacy professionals Activities that are carried out by pharmacy professionals that are not listed
Comparators (NB it is not compulsory to have a comparator for the study to be included)	Patients with SMI ≥ 18 years who did not receive any intervention Patients who do not have SMI who have any intervention	
Outcome	Primary outcome: • Change in rate of screening of cardiometabolic risk or metabolic syndrome, cardiometabolic diseases or syndrome X or any of the associated risk factors • Change in health behaviour (risk reduction or health promotion) • Diagnosis or identification of individual at high risk of metabolic syndrome • Diagnosis of diseases related to cardiometabolic risk metabolic syndrome including diabetes, cardiovascular disease, hypertension, obesity, overweight, diabetes/high risk of diabetes/prediabetes • Change in patient or physical health parameter (e.g., blood pressure) outcome for the above Views, perception, opinions, experiences of patients, carers, or any care professionals on the role of pharmacy to deliver ANY of the interventions	Studies that do not measure the primary outcomes .
Study Design	Any study designs Any country Papers written in English only	No study design will be excluded Papers not written in the English language

2.5.3 Study selection process

Studies were included if they met the following inclusion criteria: English-language, primary study, published in full, utilising qualitative, quantitative, or mixed methods. Only aspects of the studies involving pharmacy or pharmacy professionals were extracted for analysis.

First, the doctoral student (DS) conducted preliminary screening of titles to exclude any publications that were clearly not relevant (e.g., preclinical studies). Second, the doctoral student with two other members of the systematic review team Eileen Laughton (EL) (community hospital pharmacist) and Robyn McAskill (RM)(mental health pharmacist) independently screened article titles and abstracts against inclusion criteria, to identify potentially relevant studies. Third, DS, EL and RM independently reviewed full texts of studies. Consensus on inclusion was reached by discussion between DS, EL and RM, when necessary, with supervisors (Eleanor Bradley (EB) or Ian Maidment (IM)) available for arbitration.

2.5.4 Quality assessment

A modified Mixed Methods Appraisal Tool (MMAT) (Appendix 5) was used to assess the quality of included studies (233) by DS and EL independently. Consensus on scoring was reached by discussion between DS and EL with supervisory team (IM and EB) available for arbitration but this was not needed.

Studies were not excluded on the assessed level of quality but the quality assessment process enhanced study interrogation and informed interpretation of the results. In addition, one of the main aims of this review was to obtain an overview of all the research conducted in this area; DS, EL and RM agreed that exclusion of studies would have potentially resulted in loss of important data.

The quality assessment conducted addressed threats to external validity (e.g., risk of selection bias such as the use of convenience sampling, lack of randomisation, lack of control groups), threats to internal validity (e.g., contamination between the pre and post groups for quasi studies). None of the included studies reported undertaking power analysis calculations to determine the minimum number of participants they required.

2.5.5 Summary of the data, data extraction, and collective appraisal

This was carried out using the following steps: summary of study characteristics, outcomes and conclusions, mapping review and then an analysis and review of the implementation strategies used in the study intervention. The doctoral student (DS) utilised a reading support tool (Capti®) to listen to each of the chosen studies three times, EL and RM read and re-read the included studies. All three individuals DS, EL and RM independently extracted data regarding information contained within each included study. Discrepancies were resolved through discussion between DS, EL and RM. There was variability among studies for all characteristics including participant characteristics such as definition of SMI and age, study setting, outcomes measured and data collected.

A mapping review (234) (qualitative, quantitative and mixed methods studies) was conducted to obtain an overview of the landscape of this particular research area. It also facilitated the identification of trends or themes as well as identification of specific gaps prior to the more detailed analysis and review of implementation strategies used in study interventions (234).

Thirty of the studies included an intervention that could be classified into one of three categories (i) screening for CMR, MetS or related diseases (ii) screening, identification of risk and implementation of interventions for CMR, MetS and related diseases (iii) implementation of clinical interventions for CMR, MetS and related diseases.

For this review to be meaningful in informing clinical practice an understanding of **how** study interventions were implemented was sought, to do this a two-step, detailed analysis and review of the implementation strategies and their effectiveness with regards pharmacy or pharmacy professionals in CMR, MetS and related diseases was undertaken. First, the individual implementation strategies for the study intervention were classified into five categories: 'Professional' (e.g., distribution of educational materials, reminders), 'Organisational' (e.g., provider-oriented interventions, structural interventions), 'Financial' (e.g., provider incentives), 'Patient-centred' (e.g., patient education) and 'Regulatory' (e.g., peer review). This was done using the Cochrane Effective Practice and Organisation of Care (EPOC) taxonomy (235) (Appendix 6) independently by three of the co-authors of the systematic review (DS, EL and RM) with discrepancies being resolved through discussion between DS, EL and RM.

Second, an analysis of implementation strategies identified was undertaken using the Cochrane EPOC classification system checklist (235); within each category the individual implementation strategies were

identified. For example, within the category of 'Professional' the individual implementation strategies used to implement the study intervention could be the distribution of educational material or reminders. This was only carried out for those studies where impact of the study intervention could be assessed from quantitative outcome data provided (statistical tests of significance of data obtained for outcome parameters reported by study authors) such as the rate of screening for MetS before and after implementation of study intervention. Qualitative data was not analysed for this part of the review. Outcomes were further distinguished as being either a process outcome, for example, any screening such as blood tests, rate of identification of metabolic syndrome (236)) or a clinical outcome like smoking cessation or weight loss (237).

The results of statistical tests of significance of data obtained for outcome parameters reported by study authors were used to classify studies into three categories as follows (see Table 2.3):

↑ or ↓ (bold) statistically significant change in all outcome parameters

↑ or ↓statistically significant increase in at least one but not all outcome parameters

= no statistically significant change.

2.6 Results

2.6.1 Study selection and study characteristics

After duplicates were removed, 4234 unique records were found (Figure 1.1). Title screening resulted in the exclusion of 3845 records. Title and abstract screening led to further records being excluded (n = 275) and the remaining 114 full texts were assessed for eligibility. Eighty full texts were excluded at this stage (Figure 1.1). Appendix 7 provides detailed information on the reasons for excluding studies after full text review. The final review included 34 studies.

34 studies were identified (Figure 1.1) but the results of two of these were combined (238,239) and analysed as one study as the findings were from a single research study. The 33 studies showed variability for all characteristics and outcomes (Appendix 8: Table 1). The majority of the studies (n=25) (143,186,245–254,196,255–260,197,239–244) were quantitative, four were qualitative (261–264) and four used a mixed methods (265–268) study design. Twenty of these studies included a study intervention where quantitative outcome data allowed for the impact of the study intervention to be understood. These twenty studies included statistical tests of significance of the data obtained for outcome parameters (a pre-post study design (n=14)), five of the studies compared groups where the study intervention was implemented versus groups where the study intervention was not implemented (a case control study design (n=5) (242,250,253,266,267) and one adopted a randomised controlled study design (n=1) (252).

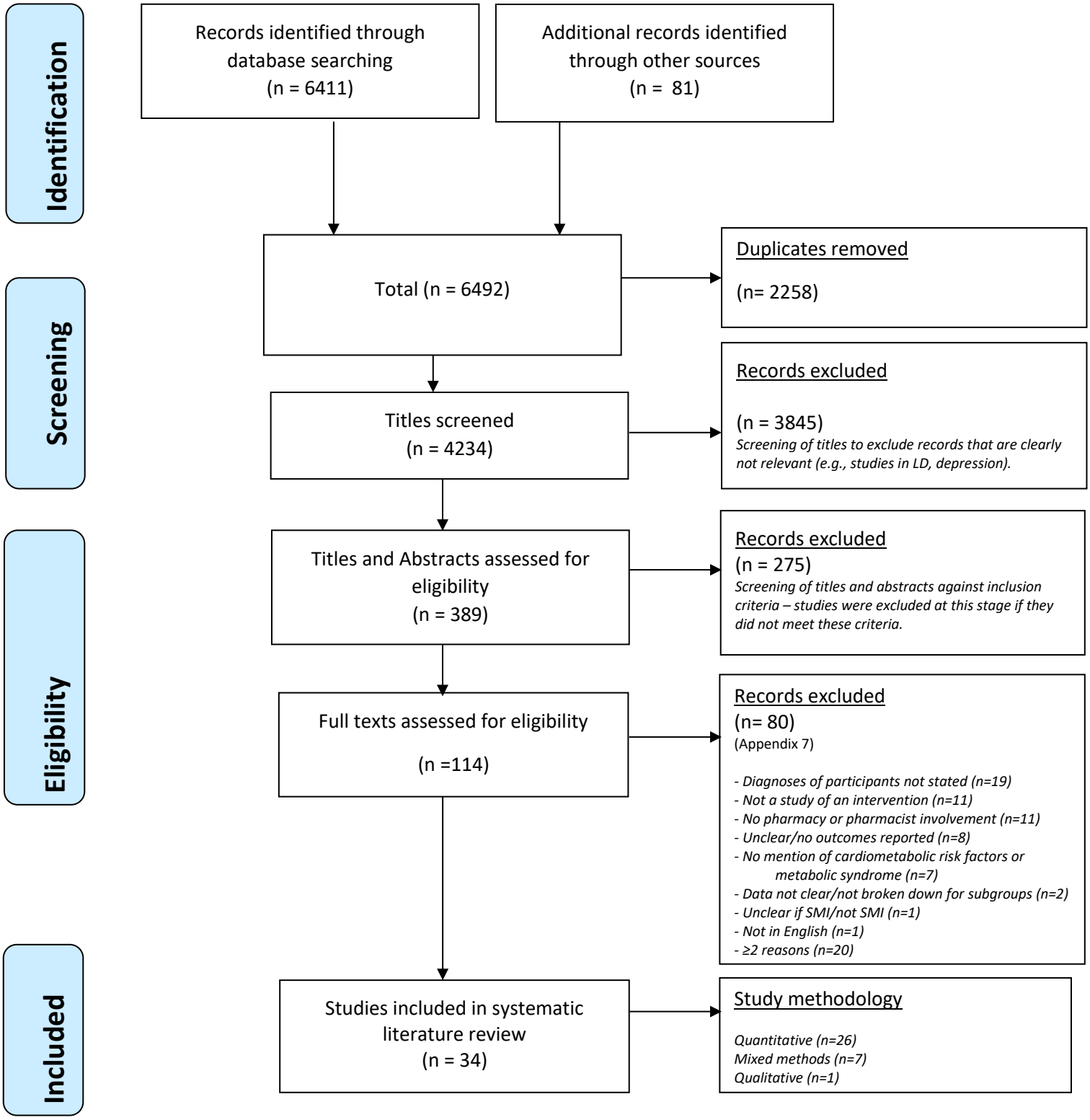


Figure 1.1: Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram of search strategy results

The most common study setting for pharmacy/pharmacist intervention was a community mental health/psychiatric outpatient clinic - 45% (n=15) of studies, followed by psychiatric inpatient wards- 36% (n=12) of studies (Appendix 8: Table 2). Four studies were based in primary care settings (community pharmacy (n=1) (268)), one in a General Practitioner (GP) surgery (260) and two in a primary care clinic (242,250). Early intervention/psychosis services were included as a study setting in one study (257). One study was based in a mix of urban, non-urban and metropolitan public and private health centres – this was classed as a separate category in the data extraction process (238,239).

Pharmacists were involved to some extent in delivering the interventions across all the studies, and those involved were mostly commonly specialist mental health/psychiatric pharmacists (n=9) (143,243,245,253,256,257,260,261,267) or clinical pharmacists (n=9) (242,249–251,255,258,259,264,266) (Appendix 8: Table 3) as specified by study authors. It is acknowledged that the terminology used becomes problematic here as mental health/psychiatric pharmacists consider themselves to be clinical by the nature of their role. Differences in terminology across studies due to differences in country of origin did not allow us to differentiate grades or qualification of pharmacists. Pharmacy technicians were involved in one study (260) and community pharmacists were involved in one study (268). Two studies made a broad reference to pharmacy team involvement but did not specify specific pharmacy roles (263,268). There was a lack of diversity in the country of origin of the studies: 53% (n= 18) were conducted in the USA and 35% (n=12) were conducted in the UK (Appendix 8: Table 1).

2.7 Summary of quality assessment

Overall the quality of the reported studies, assessed using the Mixed Methods Appraisal Tool (MMAT) (233,269) was generally good, with twelve studies scoring **** (100%), eight studies scoring *** (75%), and thirteen studies scoring ** (50%) or less (Table 2.2).

A limitation was identified amongst those studies that utilised qualitative data (261–264); the authors of these studies were not clear about how collecting qualitative data was relevant to answering the research question they were considering. Other limitations included either not reporting (n=4) (262,264–266) or providing a justification for the method of data analysis (267). A further limitation was a lack of reporting of researcher reflexivity within qualitative studies (n=3) (262–264) and qualitative aspects of mixed methods studies (n=4) (265–268).

All four mixed methods studies (265–268) exhibited limitations and scored poorly (50% or less) on the MMAT. These studies were not described by their authors as being 'mixed methods', but all included the collection and analysis of both qualitative and quantitative data with the purpose of meeting the overall research objective. Of these, one (267) made reference to the use of mixed data as being relevant to the research questions. Therefore, all four mixed methods studies scored zero for integration of qualitative and quantitative data as they provided no evidence of results obtained from different methods being integrated during data analysis, or any discussion of integration.

The randomized controlled study (252) identified for this review scored poorly *(25%) due to the lack of description of participant allocation, <80% reporting of outcome data and a high rate of participant attrition (>20%). Quasi experimental approaches were utilised in thirteen (196,197,257–259,241,244–249,254) of the quantitative outcome studies, 12 (196,197,258,259,241,245–249,254,257) of these scored more than 50%. Seventy one per cent (143,238,251,255,256,260) (n=5) of the quantitative descriptive studies scored 50% or more. A summary of the results of the quality assessment is shown in Table 2.2.

Table 2.2: Quality assessment using modified Mixed Methods Appraisal Tool
Quality Appraisal of Included Studies: first author, (reference)

Qualitative studies:

	Clear question	Data allows question to be addressed	Relevant sources of data	Data processing relevant	Consideration of context	Reflexivity	Overall assessment of quality
Taylor (261)	✓	✓	✓	✓	✓	✓	****
McMorris,(262)	✓	✓	✓	X	✓	X	***
Quirk, (263)	✓	✓	✓	✓	✓	X	***
Shanker (264)	✓	✓	X	X	✓	X	*

Quantitative: randomized controlled trial

	Clear question	Data allows question to be addressed	Clear description of randomisation	Clear description of allocation	Outcome data: complete > 80%	Low withdrawal (<20%)	Overall assessment of quality
Schneiderhan (252)	✓	✓	✓	X	X	X	*

Quantitative: non-randomised (assessed using modified assessment criteria)

	Clear question	Data allows question to be addressed	Recruitment minimises bias	Appropriate measurements	Pre and post groups comparable	Outcome data complete (>80%) or response rate (>60%)	Overall assessment of quality
Runcie (241)	✓	✓	✓	X	✓	✓	***
Barnes (196)	✓	✓	✓	✓	✓	✓	****
Schneiderhan (243)	✓	✓	✓	✓	✓	✓	****
Lizer (244)	✓	✓	X	✓	X	X	*
DelMonte (245)	✓	✓	✓	X	✓	✓	***
McCleeary-Monthei (247)	✓	✓	✓	✓	X	X	**

Kjeldsen (249)	✓	✓	✓	✓	✓	✓	****
Ramanuj (248)	✓	✓	✓	✓	✓	✓	****
Sud (257)	✓	✓	✓	✓	X	✓	***
Koffarnus (246)	✓	✓	✓	✓	✓	✓	****
Barnes (197)	✓	✓	✓	✓	✓	✓	****
Fischler (254)	✓	✓	✓	✓	✓	✓	****
Sasson (258)	✓	✓	✓	✓	✓	✓	****
Pena (259)	✓	✓	✓	✓	X	X	**

Quantitative non-randomised

	Clear question	Data allows question to be addressed	Recruitment minimises bias	Appropriate measurements & absence of contamination	Groups comparable	Outcome data complete (>80%) or response rate (>60%)	Overall assessment of quality
Taveira (242)	✓	✓	✓	✓	✓	✓	****
Cohen (250)	✓	✓	✓	✓	✓	✓	****
Bozymski (253)	✓	✓	✓	✓	X	X	**

Quantitative descriptive

	Clear question	Data allows question to be addressed	Sampling strategy relevant	Sample representative	Appropriate measurements	Response rate (>60%)	Overall assessment of quality
MacHaffie (240)	✓	✓	X	X	✓	X	*
Gable (143)	✓	✓	✓	X	✓	X	**
Lucca (251)	✓	✓	✓	✓	X	✓	***
Porras-Segovia (255)	✓	✓	✓	✓	✓	✓	****
Bozymski (256)	✓	✓	X	X	X	X	***
Sharma (238,239)	✓	✓	X	✓	✓	✓	***
Raynsford (260)	✓	✓	✓	X	✓	X	**

Mixed methods studies:

	Clear question	Data allows question to be addressed	Mixed methods design relevant	Integration relevant	Limitations associated with integration	Assessment of qualitative aspect	Assessment of quantitative aspect	Which aspect achieved lowest score	Overall assessment of quality
Ohlsen (265)	✓	✓	X	X	X	*	***	Qualitative	*
Watkins (266)	✓	✓	X	X	X	*	****	Qualitative	*
Lee (267)	✓	✓	✓	?	X	**	***	Qualitative	**
Health found(268)	✓	✓	✓	X	X	**	**	N/A both equal	**

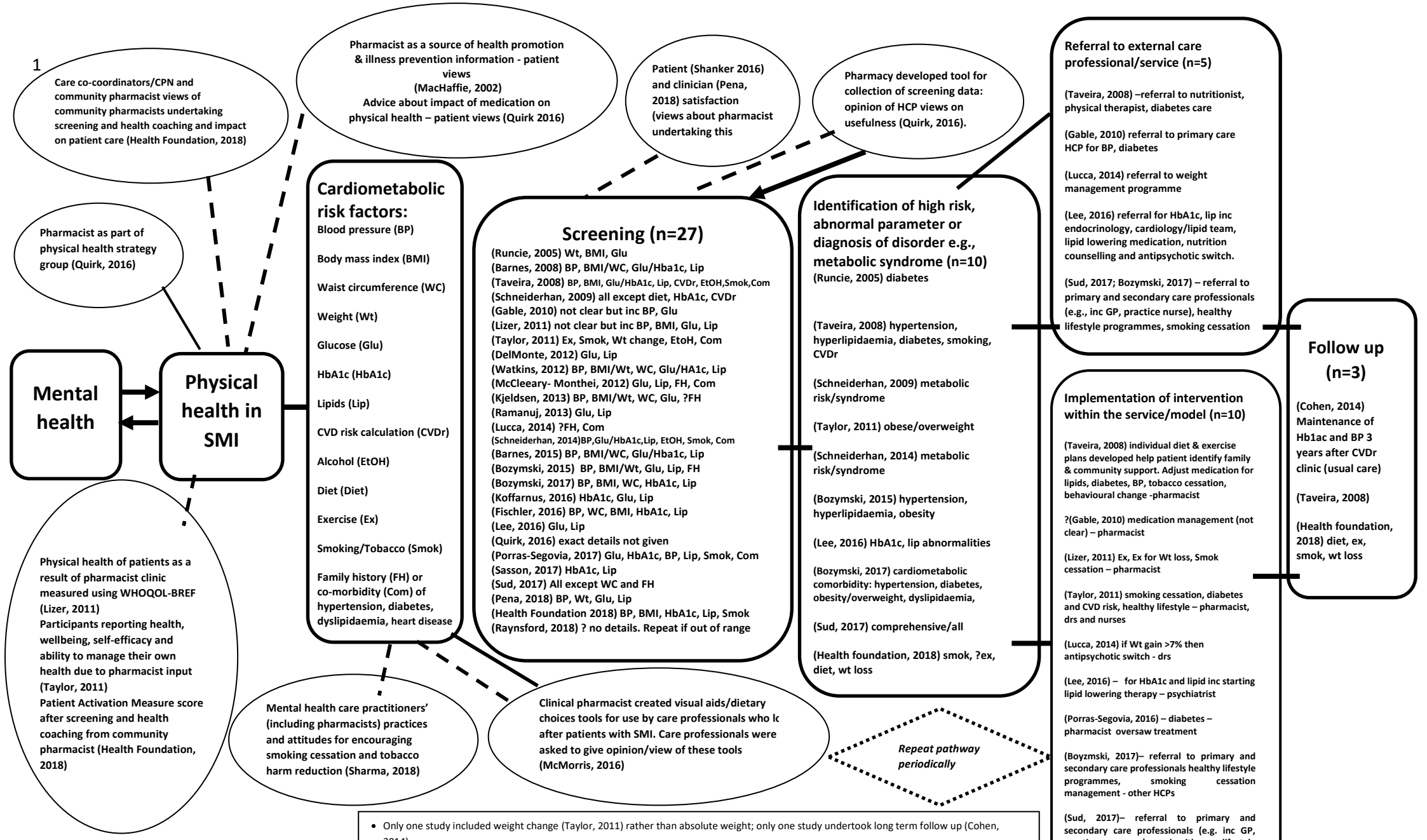
Key: ✓ Yes, or methodologically sound; X, no or not methodologically sound; ? cannot tell whether methodologically sound or not

2.8 Collective appraisal of data: mapping review and detailed analysis and review of the implementation strategies used in study interventions

2.8.1 Mapping review

2.8.1.1 Role of pharmacy in the healthcare pathway

The mapping review included all 33 studies (quantitative, qualitative, and mixed methods). Figure 2.1 shows the key components of the healthcare pathway for CMR, MetS and related diseases and the role of pharmacy in each key component.



Key

- Impact (and direction)
- Relationship/part of
- *Opinion/view/experience/subjective measure*

Figure 2.1: Mapping review

- Only one study included weight change (Taylor, 2011) rather than absolute weight; only one study undertook long term follow up (Cohen, 2014)
- Only one study included behavioural change intervention implemented by pharmacist (Taveira,2008) or pharmacist in helping identify community/family support (Taveira, 2008)
- Only two studies included CVDr (Taveira, 2008; Sud, 2017)
- We could not include Ohlsen, 2005 (no details on role of pharmacy; Just a statement that a joint working agreement existed with pharmacy). A few studies undertook renal monitoring (Taveira, 2008; Koffarnus, 2016) or substance misuse screening (Taylor 2011, Sud 2017); no consistency across studies as to whether bloods were fasting or not; a few studies collected FH and Com but only as part of demographic data but not as part of/towards intervention (Barnes, 2008; Lizer, 2011; DelMonte, 2012;Barnes 2015; Koffarnus, 2016).

Fourteen studies (143,241,257,261,267,268,242–244,251–253,255,256) included pharmacists in more than one key component of the healthcare pathway. Twenty-seven (143,196,252–259,263,267,197,268,241–244,246,248,251) of the 33 studies included direct (e.g., pharmacist undertaking screening such as weight measurements or blood tests) and indirect (e.g., pharmacist writing protocols for other healthcare professionals to use) roles in screening. Ten studies (30 %) included the identification of high risk, abnormal result or diagnosis of disorder e.g. MetS (241–243,252,253,256,257,261,267,268). Ten studies (30%) (143,242,244,251,255–257,261,267,268) included a clinical intervention for health promotion or risk reduction delivered directly by pharmacist to the patient. Five studies (15%) (143,242,251,257,267) also included pharmacists referring patients to external care professional/service as a result of identification of risk, abnormal results or diagnosis of a disorder.

2.8.1.2 Role of pharmacy in other activities

The mapping review also illustrated pharmacists roles in other activities. This included a pharmacist as part of a physical health strategy group (263) and clinical pharmacists creating visual aids/dietary choices tools for use by care professionals who look after patients with SMI (262).

2.8.1.3 Gaps in the evidence base

As well as identifying the key components of the healthcare pathway where pharmacy was involved, the mapping review also highlighted important gaps in the published evidence base where little or no literature was found; screening of waist circumference and weight/weight change, cardiovascular and diabetes risk assessment using formal risk assessment tools/calculators or high-dose antipsychotic or polypharmacy with antipsychotics. Currently, national guidance within the UK recommends the use of QRISK® (270) to assess the risk of CVD in people with schizophrenia (271). The most recent version of this risk calculator specifically includes SMI and antipsychotic use as part of the risk assessment where previous versions did not (272). Studies have also been published which detail risk prediction models/algorithms specifically for CVD in patients with SMI (30) and for CMR in young people with psychosis (273). Also lacking were studies involving pharmacy technicians in any patient facing roles. A lack of data was found about the role/involvement of community pharmacy or pharmacy professionals other than pharmacists (i.e., pharmacy technicians) within primary care, follow up of individuals after implementation of a study intervention, utilisation of behaviour change, or self-management techniques community or family support. Finally, the views, perceptions, or experiences of patients,

(their) informal carers or caring dyads, pharmacy and care professionals where formal qualitative data synthesis had been undertaken.

Sustainable lifestyle modification strategies as well as pharmacological treatments are needed to address both risk factors and diseases and typically rely on support and intervention from informal carers. It could be argued that to understand the complex interactions that underpin the management of multiple LTCs, such as SMI and cardiometabolic risk, metabolic syndrome, and related diseases, situating the experience of patients within the context of the caring dyad would provide insights that would otherwise not be realised through studies where patients and their informal carers are recruited separately. Comparing and contrasting views of each individual within the caring dyad could provide a better understanding of the co-construction of illness management within a caring dyad.

To date, it appears that 15 observational studies have been conducted that recruited individuals with SMI and their informal carers as dyads (13,274,283–287,275–282). All these studies employed validated instruments such as the Zarit Burden Interview to collect data and then contrasted and compared data collected from both the individual with SMI and their informal carer to explore possible determinants and factors relating to the informal carer burden. One such study explored the link between the rewards of caregiving and the coping strategies of caregivers of those with an SMI (schizophrenia) (277). Coping efficacy accounted for significant variance both in caregivers' psychological distress and in their expressions of praise, approval, or affection toward their ill relatives (277). This was beyond that beyond that accounted for by the individual with SMI's symptoms and caregiver burden (277).

Assessment of weight gain

Weight gain was part of the screening undertaken by a pharmacist in two studies (251,261); in one study 75.7% of patients who attended pharmacist-led clozapine clinic (261) gained weight after starting clozapine. In the other study (251) weight gain (n = 30) was the most commonly observed adverse drug reaction observed by the pharmacist. The latter study (251) also included ≥7% weight gain as a trigger for referral for dietary support and antipsychotic switch as recommended in current guidance (86).

Application of risk assessment tools/calculators

Three studies (242,250,257) included CVD risk assessment and none included diabetes risk assessment using formal tools/calculators. Fifteen per cent of the studies (249,254,256,266) included waist circumference as an outcome measure: this may reflect a lack of understanding of its importance as a predictor of CVD or lack of inclusion in guidelines on which study protocols were based. Taveira et al (242) concluded that patients with diabetes and with mental health conditions achieve the same CVD risk reduction (using a formal CVD risk assessment calculator as an outcome measure) as those without mental health conditions. The duration of enrolment of patients with mental health conditions with the risk reduction clinic required to achieve outcome this was around 25% longer than those without mental health conditions.

Follow up of patients after completion of the study intervention

One study (250) reported findings of follow up of patients after the study intervention had been completed (242); these patients received usual care between the study intervention and the point of collection of outcome data for follow up. This study concluded that there was no significant difference in the duration of maintenance of blood pressure and HbA1c up to three years after people with diabetes with mental health conditions were discharged from a pharmacist-led cardiovascular risk reduction clinic (250). The authors point out that their model of care was effective for treating specific aspects of CMR or MetS or related diseases in patients with and without mental health conditions but that more work is needed in relation to specific mental health conditions and whether further benefits could be gained by treating both mental health conditions and physical health conditions concurrently. This study did not provide detailed breakdown of outcomes for those with SMI and instead reported results for those with SMI under the general heading of mental health conditions that included diagnoses of schizophrenic disorder, episodic mood disorders including depression, bipolar disorder, depressive disorder, and anxiety.

2.8.2 Detailed analysis and review of implementation strategies of study intervention using the Cochrane Effective Practice and Organisation of Care taxonomy

2.8.2.1 Studies that included quantitative data that allowed for an assessment of the impact of the study intervention

Thirty of the studies included a study intervention that could be classified into one of three categories (i) screening for CMR, MetS or related diseases (ii) screening, identification of risk and implementation of interventions for CMR, MetS and related diseases (iii) Implementation of clinical interventions for CMR, MetS and related diseases (Appendix 8: Table 4). Detailed analysis of the 20 studies that included quantitative outcome data, classified as being process or clinical, allowing for assessment and understanding of the impact of the study intervention is shown in Table 2.3.

Table 2.3: Detailed analysis of the 20 studies that included outcome data that allowed for assessment of the impact of the study intervention* (1= used, 0= not used)

Domain	First author (reference)		Runcie (241)	Barnes (196)	Taveira (242)	Lizer (244)	DelMonte (245)	McCleeary-Monthei (247)	Ramanuj (248)	Watkins (266)	Kjledsen (249)	Cohen (250)	Schneiderhan (252)	Bozymski (253)		Barnes (197)	Fischler (254)	Lee (267)	Koffarnus (246)	Sud (257)		Sasson (258)	Pena (259)	Health found. (268)	% using strategy
Professional	1	**Educational materials**	1	1	0	0	0	0	1	0	1	0	0	0		1	0	0	1	1		0	1	1	45
	2	**Educational meetings**	0	1	0	0	0	0	1	0	0	0	0	0		1	0	0	1	1		0	0	0	25
	3	**Local consensus process**	1	0	0	0	0	0	0	0	0	0	0	0		0	1	0	0	0		0	0	0	10
	4	**Educational outreach visits**	0	0	0	0	0	0	0	0	1	0	0	0		0	0	0	0	0		0	0	0	5
	5	**Local opinion Leaders**	0	0	0	0	1	0	0	0	0	0	0	0		0	0	0	0	1		0	0	0	10
	6	**Patient mediated interventions**	0	0	1	1	0	0	0	0	1	0	0	0		0	0	0	0	1		0	0	1	25
	7	**Audit and feedback**	0	1	0	0	0	0	1	0	0	0	0	0		1	1	0	0	1		0	0	0	25
	8	**Reminders**	0	0	0	0	1	1	0	1	0	0	0	0		0	0	1	0	1		0	1	0	30
	9	**Questionnaire****	0	1	0	0	0	0	0	0	0	0	0	0		1	0	0	0	0		0	0	0	10
Financial	10	**Provider incentive**	0	0	0	0	0	0	0	0	0	0	0	0		0	0	0	0	1		0	0	0	5
	11	**Patient**	0	0	0	0	0	0	0	0	0	0	0	0		0	0	0	0	0		0	1	0	5
Patient	12	**Educational materials**	0	1	0	1	0	0	0	0	0	0	0	0		1	0	0	0	0		0	1	0	20
	13	**Reminder card****	0	1	0	0	0	0	0	0	0	0	0	0		1	0	0	0	0		0	0	0	10
	14	**Questionnaire****	0	1	0	0	0	0	0	0	0	0	0	0		1	0	0	0	0		0	0	0	10
	15	**Behaviour change**	0	0	1	0	0	0	0	0	0	0	0	0		0	0	0	0	0		0	0	1	10
	16	**Education – face-to-face**	0	0	1	1	0	0	0	1	0	0	1	0		0	0	0	0	0		0	0	1	25
	17	**Medication change ****	0	0	1	0	0	0	0	0	0	0	?1	0		0	0	0	0	0		0	0	0	5(?10)
	18	**Facilitate adherence to medicines****	0	0	0	1	0	0	0	0	0	0	0	0		0	0	0	0	0		0	0	0	5
	19	**Identification of family support****	0	0	1	0	0	0	0	0	0	0	0	0		0	0	0	0	0		0	0	0	5
Organisational	20	**Revision of professional role**	0	0	1	0	0	0	0	0	0	0	1	0		0	0	0	0	1		0	0	0	15
	21	**Clinical MDT team**	0	0	0	0	0	0	0	0	0	0	0	1		0	0	0	0	0		1	0	1	15
	22	**Continuity of care**	0	0	1	1	0	0	0	1	0	0	0	0		0	0	0	0	1		0	0	0	20
	23	**Medical systems records change**	0	0	0	0	0	0	0	0	0	0	0	0		0	0	0	1	1		0	0	1	15
	24	**Changes in equipment**	0	0	0	0	0	0	0	0	0	0	0	0		0	0	0	0	0		0	1	0	5
Total number of implementation strategies used			2	7	7	5	2	1	3	3	3	0	2(?3)	1		7	2	1	3	10		1	5	6	
Process outcomes	**Screening**		↑	↑			↑	=	↑	?			=	↑		↑	↑***	=	↑	↑		↑	↑/↓	↑***	
	Rate of diagnosis of MetS										↑		=												
	Mean number of abnormal metabolic parameters as part of MetS												=												
	Advice about smoking, diet/healthy eating, exercise,																							↑***	
Clinical outcomes	**Physical health domain of WHOQOL-BREF**					↑																			
	Improvement in blood results e.g., reduced lipids					↑																			
	Time to achieve same outcome in CVDr as general population				↑																				
	Maintenance of HbA1c and blood pressure after discharge from CVDr clinic											=													
	Improved PAM score																							↑***	

* if data were provided to assess impact of the intervention before and after or to a comparator group or described impact over a period of time.

not explicitly listed in EPOC classification but agreed between authors (DS, EL, RM) * no statistical significance analyses undertaken ? unclear

WHOQOL-BREF (a quality-of-life assessment), the physical health domain includes activities of daily living, energy and fatigue, mobility, work capacity.

PAM Patient Activation Measure: a 22-item measure that assesses patient knowledge, skill, and confidence for self-management.

The results of statistical tests of significance of data obtained for outcome parameters reported by study authors were used to classify studies into three categories as follows (see the following rows of the table process outcomes and clinical outcomes):

↑ *or* ↓ (bold) statistically significant change in all outcome parameters ↑ *or* ↓statistically significant increase in at least one but not all outcome parameters = no statistically significant change

These studies were published between 2007 and 2018. The most frequently used implementation strategies identified using the EPOC taxonomy (235) were those orientated towards healthcare professionals and patients. Of the healthcare professional-oriented implementation strategies, distribution of educational materials (published or printed recommendations for clinical care, including clinical practice guidelines for CMR or MetS or related diseases) was the most commonly used (45%) (n=9) (196,197,241,246,248,249,257,259,268). Reminders, for example, computer pop-up alert, was the next most commonly used strategy being applied in 30% of studies (n=6) (245,247,257,259,266,267). With regards patient-orientated interventions, the use of face-to-face education, educational materials, reminder cards and questionnaires was applied in 25% (n=5) (242,244,252,266,268), 20% (n=4) (196,197,244,259), 10 % (n=2)(196,197) and 10% (n=2) (196,197) of studies, respectively. Two studies used finance-orientated interventions (provider incentives (257) (UK) and patient incentives (259) (USA) .

The total number of implementation strategies used varied from none to ten per study. The overall median number of implementation strategies used per study was three and the mathematical mean was 3.55. Sixteen studies (196,197,257–259,266,267,241,245,246,248,249,252–254) reported only process outcomes, three (242,244,250) clinical outcomes only and one (268) both process and clinical outcomes. The relationship between the total number of implementation strategies used and impact on the measured outcomes is unclear. The quality assessment data for these studies is reported below.

2.8.2.2 Process outcomes

Process outcomes included screening for CMR or MetS or related diseases and the rate of identification of MetS. In the studies with a statistically significant improvement in process outcomes (n=7), 50% used seven or more implementation strategies (196,197,257), 60% used educational materials (196,197,249,257), 50% used educational meetings (196,197,257) and 50% used audit and feedback (196,197,257) all targeted at healthcare professionals. Studies using a smaller number of implementation strategies (three or fewer) (245,249,258) also reported achieving significant improvement in process outcomes; all of these included some form of face-to-face contact between healthcare professionals (pharmacist-led MDT (258)), educational outreach (249) and local opinion leaders (245)). Including pharmacists alone as part of the clinical MDT team as the sole implementation strategy resulted in significant improvement in process outcomes in two studies (253,258).

Reminders such as pop-up alerts on computer systems were a frequently used implementation strategy across the studies. Despite this, their use alone did not appear to be associated with significant improvement in process outcomes. In one study, a pharmacist produced a template reminding clinicians to undertake screening and attached this to the medication charts of patients with SMI who needed screening (247); this had **no** impact on the rate of screening. In a study by DelMonte et al (245); a pharmacist-designed computer pop-up alert and 'champion psychiatrist' concurrently formed part of an intervention to improve the uptake of blood tests for CMR or MetS or related diseases. They found that most blood tests were ordered at the same time as the pop-up alert. However, a follow-up study conducted a few years later using the pop-up alert alone (267) revealed a statistically significant decline in the number of blood tests ordered within 24 hours of the reminder suggesting that the champion psychiatrist was the more effective aspect of the intervention.

All of the studies in which there was a statistically significant improvement in all process outcomes scored ***(75%) or more in the quality assessment except one (253) that scored **(50%). For the mixed methods studies the quality assessment score for the quantitative aspect of the study has been quoted here as this part of the review was specifically concerned with quantitative data.

2.8.2.3 Clinical outcomes

Three studies investigated the impact of study interventions only on clinical outcomes (242,244,250) two of which (242,250) scored **** (100%) and the other (244)* (25%) in the quality assessment. Two of these studies were linked to each other in that one (250) was a follow-up study of the other (242). The follow-up study (250) was included in the review despite the fact that it did not directly include the implementation of a study intervention as this three year observational study provided some valuable data and insight on follow up and long-term impact of the pharmacist intervention (cardiovascular risk reduction clinic) included in the first study (242). The follow-up study (250) found no significant difference between people living with diabetes with and without mental health conditions (including those with SMI) in maintenance of diabetic control (as measured by HbA1c) and systolic blood pressure in the three years after discharge from the cardiovascular risk reduction clinic.

In the other two studies (242,244), patient-mediated strategies and face-to-face patient education were both utilised. One of these studies reported a significant improvement in a measure of physical wellbeing (using the physical health domain of the WHOQOL-BREF a quality-of-life assessment tool,

this includes activities of daily living, energy and fatigue, mobility, work capacity) (244) and the other reported that a 25% longer (statistically significant) enrolment time in the research study was needed to achieve the same outcome in CVD risk reduction in diabetic individuals with mental health conditions compared with those without (242).

2.8.2.4 Study intervention with a negative impact on process outcomes

One study reported a **reduction** in the rate of screening (HbA1c and lipid blood tests) for CMR or MetS or related diseases (259). The intervention was a computerised consult added into the antipsychotic ordering menu of patient electronic health record for referral to a pharmacist-led metabolic syndrome monitoring clinic and was carried out over a four month period. This study scored ** (50%) as part of the quality assessment.

2.8.2.5 Process and clinical outcomes

One study (268) was identified which looked at both process and subsequent clinical outcomes. This study did not include any statistical analyses or statistical tests of significance of outcome data collected and reported the raw data, for example, the number of patients who had screening done. This study scored ** (50%) as part of the quality assessment. This study reported data on rate of screening, provision of advice on lifestyle factors such as smoking and patient activation measure scores.

2.9 Discussion

2.9.1 Discussion of findings

The primary aim of this literature review was to undertake a detailed analysis and review of the published studies that exist exploring the role of pharmacy, or pharmacy professionals in CMR or MetS or related diseases in individuals with SMI.

The majority of published evidence exists for specialist mental health or clinical pharmacists' involvement in screening either directly and indirectly based in community mental health/psychiatric outpatient clinics. Some evidence exists for pharmacists' involvement in identification of individuals at high risk for diagnosis of CMR, MetS or related disease and in the provision of a clinical intervention for health promotion or risk reduction. A small number (n=6) of studies included a pharmacist in the

study intervention at all key components of this healthcare pathway from screening, through to identification of high risk, abnormal parameter, or diagnosis of disorder such as MetS and then implementation of clinical intervention. However, only three studies included any follow up after implementation of an intervention.

Sixty percent (n=20) of studies included quantitative outcome data (process or clinical) that allowed for assessment of the impact of the study intervention. Fifty five per cent of these studies (n=11) included a pharmacist undertaking screening and 30% (n=6)((242,244,256,257,267,268) included a pharmacist in key components of the healthcare pathway. Of those, 20 studies 35% (n=7) (196,197,245,249,256–258) reported statistically significant improvement in all process outcomes (e.g. rate of diagnosis of MetS) and 10% (n=2)(242,244) in all clinical outcomes measured (e.g. physical health domain of WHOQOL-BREF).

Factors, some of which overlap, that facilitate specialist mental health or clinical pharmacist involvement in screening of CMR, MetS and related diseases in those with SMI may include: being part of and having a clearly defined role within a MDT; access to appropriate resources; effective engagement with those with SMI; effective collaboration with MDT/management within healthcare settings to facilitate set up and roll out of services; clinical knowledge, skills and training (e.g. taking blood samples and ordering lab measurements); systematic approach (e.g. application of standardised care) and trusted member of healthcare team and enhanced roles that include prescribing.

The risk of CMR, MetS and related diseases in patients with SMI is increased with the use of high-dose antipsychotic therapy (288–290). Antipsychotic polypharmacy frequently results in high-dose prescribing (197). No specific information was found in the published studies about the role of pharmacy in monitoring or managing either high-dose antipsychotic or antipsychotic polypharmacy in patients with SMI. This should be the focus of further studies particularly on inpatient units.

Very little evidence currently exists on the role of impact of pharmacy in direct patient facing activities other than screening or the role or impact of community pharmacists or other pharmacy professionals in primary care. No evidence exists for GP practice based pharmacists. This data primarily comes from the USA and the UK. Even in countries with well-developed secondary psychiatric care systems (including the UK) the role of primary care is key (291). Up to a third of people with SMI are treated solely in primary care in the UK (264). Accessibility is a known social determinant of health (179). Recent work has shown that 90% of the population can access a community pharmacy

within a 20 minute walk from where they live (292). Individuals who experience the highest rates of deprivation, which includes those with SMI, could benefit the greatest from this level of access (179). Thus, the role of community pharmacy in this area represents a significant gap in the evidence base.

Clinical outcomes were reported for two studies (242,244) where the study intervention was a pharmacist-led clinic, in each of these studies the pharmacists saw patients with at regular intervals and implemented a wide range of interventions including pharmacological and behavioural interventions for hypertension, hyperlipaemia, diabetes mellitus, and smoking. So, pharmacy could have a role to play beyond screening and towards identification of risk, abnormal result, diagnosis, and implementation of clinical interventions for CMR, MetS and related diseases. There is a lack of data and studies on clinical outcomes and studies that examine the link between specific process outcomes such as screening for diabetes using HbA1c and subsequent improvements in clinical outcomes like improved diabetes risk or control, diabetes risk calculators or cardiovascular risk calculators of those with SMI.

Very little evidence, however, was found for pharmacist's involvement in screening for weight, weight gain or change or waist circumference. This limited evidence is despite the fact that systematic reviews show that the prevalence of overweight and obesity is two- to three -fold higher in those with SMI than in the general population (51). A recent study conducted in North America found nearly 80% of a sample of over 10,000 people with diagnoses of SMI to be overweight or obese (293). Another systematic review found that waist circumference enables prediction of MetS with a sensitivity of 79.4% and a specificity of 78.8% (38). The International Diabetes Federation emphasises the importance of waist circumference as feature of MetS (56). Weight, weight gain and waist circumference should be included in any screening intervention involving pharmacists given their increased prevalence and usefulness in predicting MetS.

Improving the physical healthcare for those with SMI is a key component of current mental health guidelines, policies and commission documents globally (116,199,294–296). A recent cross sectional study of 5091 patients with schizophrenia in secondary care psychiatric services (297) found low rates of clinical interventions for elevated blood pressure (25.2%), cholesterol levels (19.9%), glucose levels (53.5%) and smoking (57.2%) where screening indicated a need. Such patients are also less likely to receive treatment for cardiovascular conditions (298) or diabetes (299). This represents a potential opportunity for pharmacy to become involved particularly as this review has shown the significant and positive impact of specialist mental health pharmacist/clinical pharmacists on improving rate process

outcomes (i.e., screening). However, much more needs to be done and published relating to those components of the healthcare pathway that follow screening. Namely, identification of high risk, abnormal parameter, calculation of risk using an appropriate tool or diagnosis of disorder e.g., metabolic syndrome, implementation of intervention or referral for intervention and follow up. The value, or lack of value, of screening can only be assessed if measures or action is taken to treat or prevent problems highlighted by the screening (300).

Where qualitative data was collected in studies this was not subject to any qualitative data synthesis by study authors and where it was the method of synthesis was not justified. In addition, researcher reflexivity was not reported; there was no examination or critique of how the researcher impacted on the study or the participants. As a result of this and the variability that existed within the studies that collected qualitative data utilisation of qualitative data in this systematic review was limited to the mapping review.

Qualitative data was included as part of the mapping review. Qualitative research has the potential to make significant contributions to health services and policy research. It provides valuable insights into the ways that health is conceptualised, experiences of health and illness, dynamics of MDTs and numerous aspects of care delivery (301). In addition, the potential value of the mixed methods approach of this review has not been fully realised due to the lack of qualitative data.

Three quarters of the studies that utilised a mixed methods approach did not explain how this approach was relevant to answering research question and all mixed methods studies failed to integrate the quantitative and qualitative data collected. In the absence of integration, the knowledge harvested is only equivalent to the sum of that derived from a qualitative study and a quantitative study undertaken separately, rather than achieving a *"whole greater than the sum of the parts"* (302). Overall, there is a lack of robust mixed methods studies on this topic.

High quality RCT data is lacking. Numerous good quality quantitative studies exist that utilise non-randomised (mainly quasi) and descriptive approaches. These quasi studies were performed at population level and may therefore have included individuals who may otherwise have been excluded from RCTs such as the severely unwell. Quasi studies are also viewed as being more pragmatic in evaluating the real-world effectiveness of a study intervention as it is usually implemented by clinical staff, rather than by research staff under research conditions (303). Therefore, quasi-experimental studies may also be more generalisable and have better external validity than RCTs (303). However,

bias can occur in these types of study leading to a threat to internal validity as differences between active and control groups are not accounted for (303).

Other aims of the systematic review were to undertake a detailed analysis and review of implementation strategies used in study interventions and their effectiveness to inform practice and to identify evidence gaps to provide a focus for future research studies. It was not clear how the total number or type of implementation strategies used for the study intervention were selected. None of the studies had any measures of implementation fidelity (304). Three studies discussed identification of particular barriers to care in clinical practice (196,197,259) with, in one study subsequent implementation strategies being developed/chosen to target these barriers in one study (259). In one study the authors acknowledge that information on the actual implementation of the intervention was not collected (197).

The duration of time over which the study was conducted is also important. The study that showed a **reduction** in the rate of screening for CMR or MetS or related diseases (259) was conducted over a four month period. There are several possible reasons for this reduction the intervention was not fully understood by the health professionals to whom it was targeted, fatigue to electronic alerts or that the timeframe selected was not appropriate (current guidelines recommend annual screening). This may represent a flaw in study design rather than a positive or negative outcome of the study; the study may not have been conducted over a clinically appropriate duration of time.

The relationship between the total number of implementation strategies chosen and the subsequent impact on outcomes measured is unclear for either process outcomes such as rate of blood testing or clinical outcomes such as improvement in lipid results. What may be more important is the specific type of implementation strategies chosen; the specificity of the implementation strategy chosen is important. In relations to process outcomes, the following strategies appear to be particularly effective: educational materials, educational meetings, clinical audit and feedback and any strategy that uses face-to-face interaction between healthcare professionals. The use of multiple strategies (> one strategy) carries with it an inherent problem in determination of causality and the effectiveness of individual implementation strategies when more than one is used. Any overlap, repetition, synergy or hindrance that may occur as a result is also difficult to determine. In common with other reviews, there is a lack of studies where head-to-head comparison of different implementation strategies (237,305).

The most important finding of this literature review is that the sole use of face-to-face interaction (as an implementation strategy) between pharmacists and other healthcare professionals, for example, as part of an MDT on a ward) consistently and significantly improves process outcomes (e.g., rate of screening for a comprehensive set of cardiometabolic risk factors or metabolic syndrome) for those with CMR, MetS and related diseases and SMI.

2.9.2 Strengths

This literature review used a robust systematic search strategy and data was appraised using validated methodology and appropriate tools. In addition, assessment of the methodological quality, mapping review and assessment of the implementation strategies was carried out and checked independently by three authors using an internationally recognised taxonomy (235). The inclusion of all types of study is also a major strength and reflects that studies and data and outcomes of all types contributes to the understanding of this area of clinical practice.

The authors of this review have direct experience relevant to the research area of this review. DS, EL, RM and IM have experience working as practising clinical pharmacists within MDTs. DS, RM, and IM also have experience of working within mental health settings and both IM and EB have extensive experience of conducting applied research within mental health settings.

The mapping review was conducted as a mixed methods review that facilitated the identification of trends or themes as well as identification of specific gaps which would otherwise not have been possible if we had only used either qualitative or quantitative studies.

Mixed methods combine the strengths of, and to compensate for, the limitations of quantitative and qualitative approaches and therefore allows insights that might be omitted when only a single method is adopted (306). Qualitative data can be used to interpret quantitative results and quantitative data to generalize the findings from qualitative research. A mixed methods approach allows for a better understand a new phenomenon (qualitative methods) and to measure magnitude, trends, causes, and effects (quantitative methods) (306).

Decision makers often face complex issues in healthcare that cannot be addressed using quantitative or qualitative research alone (307). As part of evidence-based practice, systematic reviews have become an essential resource used by decision makers to inform practices, policies, guidelines, and

the development of interventions (307). For example, systematic reviews that focus on the effectiveness of interventions and that meta-analysis may not be completely adequate in informing decision in that there may be a lack of information relating to intervention context, acceptability, and feasibility(2). In other words, mixed methods can generate evidence not only of the effectiveness of the intervention, but also on how it is delivered in clinical practice.

Conclusions based on mixed methods systematic reviews could therefore be seen to be much stronger as they are based on convergence and collaboration of findings from studies that use mixed methods, qualitative and quantitative methods.

2.9.3 Limitations

There are limitations at two levels within this review; limitations at an individual study level included in the results and discussion and more general limitations with this approach. Outcomes reported by studies may have been impacted by factors external to the study protocol such as concurrent healthcare or quality improvement programmes, initiatives or healthcare staff that distracted or raised awareness of the study intervention. This was acknowledged in some of the studies (197,245,267). Improvements in outcomes reported may have been an artefact arising from improved documentation or systems rather than the intervention itself. Conversely, where the impact of the intervention was found to be less effective on outcomes, this may be due to data collection issues such as inability to access records.

Interpretation of the association between the implementation strategy, improved process and/or clinical outcome is not possible without being able to assess the intervention fidelity as it was not reported. Study authors did not provide detailed description of how or to what extent the strategies were implemented.

A limitation of the use of any taxonomy is that the results presented are in part subjective, an interpretation by EL, RM and the doctoral student of the main method of delivery as described by the authors of the study under review. For instance, some interventions cannot be delivered in a mutually exclusive fashion, classification of a study as patient-orientated intervention using ‘educational materials’ could not have been completely free from ‘face-to-face education’ by the healthcare professional who gave these materials to the patient. Another limitation of using this taxonomy is that it states that screening for healthcare parameters is not considered or included as a patient-

centred intervention. It might be argued that undertaking a blood test, for example, is an intervention as it increases the awareness of the patient that there is a requirement for the screening to be done. Indeed, the rationale for screening might well be discussed with them at the point the screening is being undertaken. If patients are aware of the requirement to be screened, then then this is a form of education for the patient.

Finally, more recently there has been increasing consideration of using the concept of person-centred rather than patient-centred care. Although person-centred and patient-centred care differ, the terms are often used interchangeably in the literature (308–310). Patient-centred care has a greater focus on the need of care patients have in common related to their disease and treatment. Person-centred care on the includes needs but places emphasis on the capabilities and strengths that each person possesses as resources in a collaborative partnership between the patient and healthcare professionals (310,311). A concept review highlighted the key difference between person-centred when compared to patient-centred care in that the former focuses on a deeper level of a meaningful (person) versus a functional (patient) life (312). Published literature and guidance is increasingly using the term person-centred rather than patient-centred to reflect this focus on person-centred care - where used in this thesis the exact term used reflects that used in the that literature being cited.

Other limitations of note include:

(1) Variability among studies in healthcare setting, outcome measures chosen and timing of intervention - this makes it difficult to interpret what works for whom in what circumstances.
(2) Detailed exploration of and consideration was given to possible ways in which the studies could be compared however, variability of aims, study design/models delivered, population demographics, data collected and outcomes measured prevented integrated quantitative synthesis/data pooling (e.g., meta-analysis). This review relied wholly on statistical analyses carried out by study authors.
(3) Studies where outcomes were recorded under group headings rather than specific groups, for example, pharmacy professionals within healthcare professionals group (238,239), and those with SMI within all individuals with mental health conditions (242,250).
(4) Lack of reporting of patient diagnosis; nineteen studies were excluded purely on the basis that diagnoses were not stated as part of the data collection – potentially important data or information about the role of pharmacy may have been lost.

(5) The search was restricted to articles published in English; it is therefore possible that this literature review failed to retrieve all studies that may have been eligible for addressing the research question.
(6) Some of the studies identified for this review reported the results of audits conducted within healthcare settings. Within some of these audits the audit criteria allow for refusal or decline by the patient, like a refusal to have a blood test, to be recorded in outcome data as being compliant (i.e., the same as someone having a blood test). However, where research studies are conducted a refusal would be regarded as attrition. As such this may have resulted in an overestimation of the effect of the study intervention for those where audit data was being reported.

2.10 Chapter summary

The most important finding of this literature review is that the sole use of face-to-face interaction consistently and significantly improves the process outcomes for those with CMR, MetS and related diseases and SMI. Implementation strategies that did not include any form of face-to-face contact were less effective for process outcomes. Despite being frequently employed within studies, the sole use of reminders like pop-up alerts on computer systems appears to have no statistically significant impact on process outcomes. Two important recommendations can be made from this review, first, incorporation of face-to-face interaction as part of any implementation strategy chosen and, second, discourage the sole dependence on pop-up alerts.

There is a paucity of good quality qualitative and mixed methods studies which collect data on clinical outcomes, the link between process outcomes and clinical outcomes for example the provision of advice about lifestyle and improvements in CVD risk score, and studies conducted in primary care with community pharmacy teams. Qualitative data will provide important information about the views, experiences, and perceptions of key stakeholders: patients, informal carers, caring dyads, pharmacy professionals and care professionals about pharmacy. This type of data will inform current and future practice as well other qualitative and quantitative research studies.

A King's Fund document published in 2009 (313) states that the starting point for measuring patient's experiences is an agreed set of standards together with a set of measurable indicators. At the heart of these should be patient-centred care and patients' priorities. Implicit in this is the need to ensure that those things being measured are those that matter most to patients and this forms an essential

component of strategies to improve those experiences. This is underpinned by robust evidence on key stakeholders' experiences of individuals who receive care and those who deliver that care. The lack of standards and robust evidence on experiences outlined above point to the need for a qualitative exploratory study. This approach is also supported by the need to develop an in-depth understanding of unknown and potentially complex phenomenon (314,315).

Mixed method studies would be instrumental in the development and testing of interventions delivered by pharmacy - in the development of the intervention, during the evaluation of the intervention, and after the follow up and assessment of outcomes is completed. Mixed methods study designs also mitigate some of the intrinsic weakness or intrinsic biases and the problems that come from single method studies. Studies conducted in primary care and community are vital as there is great potential for impact; a significant proportion people with mental health problems are cared for entirely within primary care and a significant proportion of the population can access a community pharmacy a short walk from where they live.

Chapter Three: Research methodologies and methods

3.1 Introduction

This chapter presents the methodological and procedural approaches employed in this study exploring the lived experience of patients with CMR, MetS and related diseases and SMI and the role of pharmacy in this lived experience. The chapter begins by outlining the objectives for this empirical inquiry designed to address some of the deficits in the existing literature (outlined in Chapter Two). The ethical, methodological, and practical challenges of conducting research with key stakeholders including patients, informal carers, caring dyads, pharmacy professionals and care professionals are considered. A discussion of how these considerations informed the strategy, including the philosophical orientation, approaches used and study design is presented. The research setting and sampling framework is then described and the procedures for recruitment and consent outlined. Methods to collect, organise, analyse, and ensure the quality of the data collected are detailed.

This multi-methods study was conducted in three phases: phase 1, a systematic literature review (Chapter Two); phase 2, qualitative exploratory research using framework analysis (Chapters Four to Eight) and phase 3: recommendations and conclusions (Chapter Nine). Chapters One and Two provided the background to this study, outlining existing knowledge in the area. This highlighted the recommendations made for the role of pharmacy in relation to SMI with CMR, MetS and related diseases. However, currently no standards or guidelines detailing specific information about this role exist. Chapter Two provided the methods, results, and findings of the systematic literature review and demonstrated the need for robust qualitative exploratory research into the role of pharmacy in the lived experience of patients with SMI.

The lack of standards and robust evidence on experiences outlined in the systematic review in Chapter Two also point to the need for a qualitative exploratory study. This approach is also supported by the need to develop an in-depth understanding of unknown and potentially complex phenomenon (314,315).

The overall objective of phase 2 (Chapter Four to Eight) of this research is to explore and document the views, perceptions, and experiences of five key categories of individuals involved in the care of patients with CMR, MetS and related diseases and SMI: patients, informal carers, patients, caring dyads, care professionals (other than pharmacy) and pharmacy professionals.

3.2 Methodology

3.2.1 Philosophies underpinning research

A variety of philosophical approaches to research exist. At the outset of a research study it is important to select an appropriate philosophical approach as this will facilitate alignment of methodological choice, research strategy and data collection methods, this is imperative in the production of a coherent research design (316). This study aligned broadly to an Interpretivist-constructionist philosophical orientation philosophical orientation.

3.2.2 Research philosophies

The main research philosophies (316) are: positivism, post-positivism; interpretivism, constructivism, and critical realism. Positivism is used predominantly within the natural sciences. The philosophies most commonly used in social sciences and health research are post-positivism, interpretivism and constructivism (317).

Positivism assumes that reality is fixed, directly measurable and that there is just one truth, a deductive approach is taken. A hypothesis is developed and tested usually by quantitative methods, possibly resulting in the positing of a new theory (317). Post-positivism is also known as methodological pluralism (318) and evolved from the positivist paradigm. It is concerned with the subjectivity of reality and moves away from the purely objective stance adopted by the logical positivists (319). Interpretivism, on the other hand, takes an inductive approach and uses observation to develop fresh understandings and possibly theories (317).

Constructivists believe that there are multiple realities constructed by the individual's experiences and perceptions, rather than there being a single true reality (320). A constructivist paradigm therefore argues that our reality (the way we see the world) is guided by our individual subjective and socio-cultural experiences, suggesting that it is impossible to separate the values and assumptions, which make up an individual's identity and guide their activities. Constructivists therefore conclude that 'objective knowledge' cannot be achieved (321).

Critical realism distinguishes between the 'real' world and the 'observable' world (322). The 'real' world cannot be observed and exists independent from human perceptions, theories, and constructions (323). The world as we know and understand it is constructed from our perspectives and experiences, through what is 'observable' (324). According to critical realists, observable events are

caused by unobservable structures and the social world can be understood only if the structures that generate events are understood. The realist standpoint has greater congruence with the contextual variations within this inquiry but not the lived experience of patients.

3.2.3 Justification for adopting an Interpretivist-constructionist orientation

Research that seeks to understand human experience and behaviour is broadly situated within an interpretivist worldview (325,326). The term 'interpretivist' is used synonymously within the literature with other terms such as constructivist and naturalistic (327) because of their common 'intellectual heritage' (328). Research conducted from this orientation aims to gain insights into 'the complex world of experiences and social world. By studying the 'meanings' that the patients construct and negotiate through their language and interactions, insights into their individual and social worlds can be gained (326,329).

Within the Interpretivist philosophy there is no objective, value-neutral knowledge as all knowledge is interpreted and constructed (330). Constructionists focus on discourse or the social activities that occur (331). Meanings are negotiated and co-constructed through interactions with other agents in the social world of the individual and are created and re-created as a result of their perspectives within context (332). By ascribing to an interpretivist-constructionist standpoint within this study it upholds the view that patients' accounts may differ from that of others but remain valid. Furthermore, it comprehends the reciprocity between the individuals and their social world in the generation and interpretation of knowledge.

The use of an interpretivist approach is suitable where the problems and the research questions being explored aim to allow the researcher an understanding of specific issues or topics such as the conditions that serve to disadvantage and exclude individuals or cultures, such as hierarchy, hegemony, racism, sexism, unequal power relations, identity, or inequities in our society (326). This area of research is under-explored, involves some participants who could be considered to be marginalised and the doctoral researcher was driven to conduct research with a person-centred approach.

Ontologically, this study viewed the social world as 'in the making' (333) with multiple realities (325). Reality is a product of one's own creation and each individual sees and interprets the world and their experiences through personal belief systems (334,335). From this philosophical orientation the role of

the researcher is situated within the inquiry to explore experiences and co-construct reality (326). The doctoral student is an insider researcher and brings a wealth of experience, knowledge and understanding to the study.

The use of an interpretivist- constructionist approach can be justified because the philosophical beliefs associated with interpretivism are closely aligned with the beliefs of the doctoral student and the study.

Table 3.1: Aspects of an interpretivist-constructionist approach applied in this research

	Interpretivist-constructionist approach	In Phase 2 of this research.
Ontological (the nature of reality)	Multiple realities are constructed through an individuals' lived experience and interaction with other individuals	Participants were patients, informal carers, caring dyads, pharmacy professionals and care professionals Multiple realities constructed through lived experience Inquiry was made into views and experiences of care and illness
Epistemological (how reality is known, what you can know about it)	Co-construction of reality occurs between the researcher and the participant and moulded by individual experiences	Data was generated using semi-structured interviews undertaken by the doctoral student
Axiological (the role of values)	Individuals' values are honoured	Reflexivity: reflexive diary and field notes were kept throughout the course of data collection from participants
Methodological (the approach to inquiry)	Inductive analysis methods to identify patterns, deductive methods to structure and format patterns Methods used are qualitative in nature and include interviews, observation, focus groups and analysis of texts and dialogue	An inductive* method was chosen for use for the data collection process i.e., semi-structured interviews

**It is not possible, or indeed desirable, for research exploring the lived experience of disease and illness to be truly and entirely inductive, the values of the researcher are always present* (336).

3.2.4 Justification for the use of thematic analysis as an interpretive process

Thematic analysis (TA) can be applied across a range of theoretical and epistemological analytical approaches including interpretivism, the approach underpinning the present research, and is therefore a suitable method to identify key themes and address the research question or questions.

Smith & Firth (11) describe TA as an interpretive process, whereby the researcher systematically searches through data to identify patterns, with the aim of describing the phenomenon under investigation. In an interpretivist-constructionist approach, TA can emphasise the social, cultural, and structural contexts that influence individuals' experiences, enabling the development of knowledge that is constructed through interactions between the researcher and the research participants, revealing the meanings that are socially constructed (12). TA can generate unanticipated insights not overtly observed by the researcher (337,338). TA can be used to explore participants' lived experiences, perspectives, behaviour and practice; the factors and social processes that influence and shape particular phenomena (339) which is central to this study.

TA uses both inductive and deductive reasoning to analyse data. In inductive 'bottom up' reasoning categories of meaning, and relationships between categories are derived from the data collected from participants. In deductive 'top down' reasoning analysis is driven by the research question, broader theoretical assumptions, experience of the researcher, knowledge generated from background reading on this topic and findings generated from literature reviews.

Braun & Clarke offer a tripartite typology of TA, consisting of 'coding reliability', 'codebook' and 'reflexive' approaches (340) (see Figure 3.1 below). (i) 'Coding reliability' captures neopositivist approaches; at its core is concerned with 'objective' coding. The use of a codebook for the analytic process, and often multiple coders, is key to ensuring 'accurate' and 'reliable' coding. Themes are developed early on in, or even prior to, analysis. Inductive analysis is grounded in the data, deductive analysis is guided and informed by knowledge, skills and understanding of the research team and other information, for example a systematic literature review. (ii) 'Codebook' TA captures a group of methods that broadly sit within a qualitative paradigm. They use a structured coding framework for developing and documenting the analysis. Themes are initially developed early in the process but can be refined or new themes elaborated. Examples of this type of TA includes framework analysis and template analysis. (iii) 'Reflexive' TA includes approaches that fully embrace qualitative research values and the subjective skills the researcher brings. This does however, mean that there is a high degree of subjectivity as it is dependent on one person. Analysis, which can be more inductive or more deductive and theoretically led, is a situated interpretative reflexive process. Coding frameworks are not used in this approach. As for any type of qualitative research, themes are the final 'outcome' of data analysis and analytical iteration.

Figure 3.1 Tripartite typology of thematic analysis (based on (340)**)**

3.2.5 Justification for the use of framework analysis

Data analysis, although supported by the supervisory team, was conducted by the doctoral student alone, as such a coding reliability approach was not considered suitable as it requires multiple coders. Framework analysis, a type of codebook approach, was considered a better choice than reflexive TA approach, because it emphasises how both a priori issues and themes identified from the data guide the development of the analytic framework. This was something that fitted the aims of this study in that there were predefined areas for exploration but also a need to be open to discover the unexpected. Framework analysis is designed to help manage relatively large qualitative data sets. Ritchie & Spencer (341) outline four types of research questions that framework analysis can helpfully address:

- Contextual: identifying the nature and form of what exists (e.g., research that explores the experiences of pregnant women who suffer from psychological distress (342));
- Diagnostic: examining the causes of, or reasons for, what exists (e.g., research that explores the barriers to young women with eating disorders seeking support and care (343));
- Evaluative: appraising the effectiveness of what exists (e.g., research that evaluates the helpful factors of group intervention for depression and anxiety (344));
- Strategic: identifying new theories, policies, plans or actions (e.g., research that identifies the requirements for implementing paediatric care closer to home (345)).

The research question guiding this study fits with all these categories in that patients' experiences of CMR, MetS and related diseases and SMI is being explored, (contextual), but also how these patients made sense of their illnesses (diagnostic) as well as their evaluation of the care they had received (evaluative). Further, in identifying recommendations and actions for pharmacy services to provide care and support for patients (strategic).

Part of this study involved recruiting caring dyads (patients and their informal carers). Themes were identified using framework analysis but because of the nature of the data additional techniques were

applied to fully realise the value of this data. Transcripts of patient and their informal carer were contrasted and compared with each other. It was anticipated that by using this qualitative dyadic approach, the dyadic version achieved would reveal more than the sum of two individual versions and enrich the perception of the phenomenon and shared experience of the phenomenon under study. The perspective of the dyad from the researcher's interpretation and synthesis would facilitate this.

3.3 Complete and transparent reporting

Complete and transparent reporting of research provides information about the significance and rigor of the work. The consolidated criteria for reporting qualitative studies (COREQ) (346) was completed as part of this research to demonstrate this (Appendix 2).

3.4 Authenticity and reliability in qualitative research

The idea of having a single pre-determined criterion for evaluating the authenticity and reliability of diverse approaches used within qualitative research has been challenged by interpretivist methodologists. Qualitative research encompasses numerous research methods underpinned by different research paradigms and theories thus rendering a single evaluative criteria inappropriate (25). Of central importance is the need to be transparent: declaring philosophical stance, justifying selection of specific methods in relation to the research question and avoid method slurring. Also, providing detailed accounts of data analysis to enhance the transparency of the research findings and strengthen the conclusions drawn (347).

There has been much debate about the most appropriate terms (trustworthiness, rigor, validity, reliability, authenticity) for assessing qualitative research (348). The most widely used criteria for evaluating qualitative research are those developed by Lincoln & Guba (349) and they use the term trustworthiness. Lincoln & Guba state that trustworthiness is used as the central concept to appraise the rigour of a qualitative study (350) and propose seven constructs which ensure trustworthiness: credibility, transferability, dependability, confirmability, deviant case analysis, social desirability, and member checking (350). The constructs which are applied in this research study are discussed below together with suggested approaches (349,351–353).

3.4.1 Aspects of phase 2 of this of this research contributing to trustworthiness

Table 3.2: Aspects of this research contributing to trustworthiness (349,351–353)

Constructs contributing to trustworthiness in qualitative research	Aspect of this research.
Credibility	• Adopted a recognised research method used previously by researchers working in same field • Familiarity with the culture of participating organisations, in this case mental health NHS Trust and GP surgeries • Potential participants were given the opportunity to refuse to participate and to withdraw at any time • Honest participation was encouraged • Emphasis was placed on the independence of the interviewer (in this case the doctoral researcher) • Frequent meetings between the researcher and supervisory team • Peer scrutiny of the research project • Thick description of the phenomenon was provided • Previous research in the field was examined carefully (systematic literature review)
Transferability	Context and details of the research is provided: • The employing organisation • Exclusion criteria • The number of participants • The data collection methods • The number and length of interviews • The data collection time period
Dependability	Information provided on: • Research design and its implementation • Operational detail of data collection • Reflective appraisal of the research
Confirmability	Providing: • Detailed methodological descriptions • Justification of methods used. • Reflexive approach • Critical review
Deviant case analysis	During the data analysis process any presentation of cases that were inconsistent with the emerging analysis were discussed with supervisory team Helped refine the analysis until all or most of the cases under scrutiny could be explained
Social desirability	The following strategies were taken to minimise the impact of this: • When the interviews were set up measures were taken to ensure that the location was private and not within earshot of others • Used approaches to establish rapport with participants, including the use of humour, and demonstrating respect • Questioning techniques were used such as indirect questioning, providing assurances, probing for more information, requesting examples, prefacing the question

3.5 Researcher reflections

3.5.1 Researcher positionality

In the absence of a unifying philosophical orientation, it is the responsibility of the researcher to define the position for viewing the strategy and products of the inquiry (354). It was evident that the philosophical position of this research was influenced by the doctoral researcher's own lens and the motivation and purpose of this study. The doctoral student came to this research as a healthcare professional, with a professional identity as a hospital pharmacist with 24 years of practice split almost equally between general medicine and psychiatry. The doctoral student is a female who identifies as South Asian born in the UK of first generation immigrants.

This history, background and identity influenced how the researcher viewed the world around them. Currently practicing as a mental health pharmacist in psychiatry, the doctoral student ascribed to a person-centred holistic model of clinical practice, that comprehends the whole patient and their informal carers in the assessment, planning, delivery and evaluation of care (355–357). This approach is individualised, underpinned by viewing the person (patient) as not reduced to organ systems or activities, but perceives body and mind as intertwined as a multifaceted human being (358). It must be acknowledged that whilst an interpretivist-constructionist approach is being taken the doctoral student's interpretations are shaped by their experiences as a healthcare professional and their life experiences.

3.5.2 Reflexivity

In qualitative research the researcher has a crucial and central role in data generation and analysis (as well as all the other components common to all types of research), there is potential for the researcher to unconsciously exert influence on these processes. The professional role and/or identity of the researcher may impact on participants' contributions in interviews (359).

Measures were taken throughout the research to try to minimise the impact of the doctoral student's role and professional background. For example, where participants did not otherwise know or enquire about the professional role of the doctoral researcher this was not discussed. The doctoral researcher kept a reflexive diary and field notes throughout the study and was acutely aware of the potential for their own background to 'cloud' the research process and has been scrupulous, as have the supervisory team to try to avoid this. Having a shared frame of reference with care professionals and

pharmacy professional participants has potential benefits through ensuring a common understanding of ideas and allusions. Knowledge and understanding of the practice of psychiatry and direct patient contact within current practice also has potential benefits by providing an understanding of some of the key issues that may be of importance. The interpretivist philosophy acknowledges that a shared understanding is essential to the development of knowledge (360).

3.5.3 The importance of being pragmatic

As a healthcare professional the doctoral researcher understands the importance of being pragmatic in the planning and conduct of this study. The use of the term pragmatic in everyday practice implies a focus on what is practical and achievable, rather than theoretical or ideal. The doctoral student judges the value of knowledge (and ways of knowing) by its context-dependent, extrinsic usefulness in addressing practical questions encountered daily (361). There is no such thing as perfect knowledge and neither is it required. Knowledge is only meaningful when it is coupled with action. Undertaking research within the real world brings with it merits and limitations it is therefore important to deal with things sensibly and realistically in a way that is based on practical rather than purely theoretical considerations. The methods used in this study have been judged by the researcher as the most appropriate for the type of data that is being gathered to address the research questions that guide this research.

3.6 Methods

3.6.1 Qualitative data collection methods

An interpretivist-constructionist paradigm and phenomenology are aligned to qualitative methods of data generation. Semi-structured interviews were selected as the method of data collection for this research study.

A range of methods are available for studies that adopt a qualitative research design, including interviews, focus groups, and participant observation (362). There are three main types of research interviews: structured, semi-structured, and unstructured interviews. Focus groups are group-based interviews that are facilitated by a moderator. The ideal number of participants per group is six to eight participants and suggested maximum number of participants is ten. Beyond this, the group becomes difficult to manage and some participants may not get the chance to contribute (363). A semi-structured topic guide is developed to guide the group discussion but conversation is not

restricted to set questions (362). Focus groups encourage group interaction and help to explore decision-making processes and uncover how participants think and feel (364).

In participant observation the researcher becomes immersed in a social setting relevant to the research in which they observe behaviours, listen to conversations and ask questions (362). This research method is more appropriate for research on group-based behaviours such as inpatient ward teams or community pharmacy teams and so will not be discussed or considered.

3.6.2 Justification for the use of interviews in phase 2 of this research

The focus of phase 2 of this research was participants' views, experiences, and perceptions. Notwithstanding the opportunities for generating rich data through focus group discussions (317) it was anticipated that participants' comments about their experience of CMR, MetS and related diseases and SMI might be highly personal and sensitive and they might feel more comfortable sharing these in anonymised one to one interviews rather than with strangers in a focus group (317).

3.6.3 Types of interviews

In a structured interview, there is little flexibility. Questions are asked in the same order and phrased in the same way for all participants. With semi-structured interviews, the researcher follows a pre-prepared topic guide, a list of questions or ideas, to ensure consistency. But semi-structured interviews have flexibility as additional questions can be posed based on the participant's responses. In unstructured interviews, the researcher has an idea of the main themes for the interview but the participant is encouraged to talk freely about the topic under study (365).

3.6.4 Justification for the use of semi-structured interviews in phase 2 of this research.

Semi-structured interviews were considered the most appropriate approach allowing in-depth description and understanding of the participants' perspectives leading to the generation of rich data (366). This method is guided by a flexible interview topic guide and supplemented by follow-up questions, probes, and comments. It also allows for the collection of open-ended data, to explore participant thoughts, feelings and beliefs about a particular topic and to delve deeply into personal and sometimes sensitive issues (367). All the interviews with participants were carried out by the doctoral student. Other than the doctoral student and the participant no-one else was present at the interview.

3.7 Sampling approach and sampling frame

3.7.1 Approaches to sampling

It is logistically impossible and neither is it relevant to include the whole of a population of interest in qualitative research; instead, various approaches to sampling may be used. To recruit patients to this study, convenience/opportunistic sampling, purposive sampling, and snowball sampling were all used.

This combination of approaches was used to capture diversity around the phenomenon under study and therefore maximise the potential contribution of inductive data analysis alongside a priori knowledge and understanding to the study findings.

3.7.2 Justification for use of convenience/opportunistic, purposive, and snowballing methods of sampling in phase 2 of this research

Purposive sampling was used to recruit those individuals who could contribute most to the specific research aim and objectives. Snowball sampling was used as interviewees were asked to suggest others who they thought it might be appropriate to interview. Convenience sampling was also used, the doctoral student was employed by a mental health trust and as a result has personal knowledge of potential participants.

3.7.3 Sampling frame

Detailed information on inclusion and exclusion criteria is provided in the study protocol provided in Appendix 9. A summary of the study protocol is provided in Table 3.3 below. Copies of letters of invitation and participants information sheets are provided in Appendix 10.

Table 3.3: Sampling frame for phase 2 of the research

Participant	Inclusion criteria	Exclusion criteria	Details of methods for recruitment
Patients	• Aged 18 years old or over • No upper age limit • A diagnosis of schizophrenia, bipolar disorder, schizoaffective disorder, or other non-organic psychosis • Have a CMR or MetS or related disease • Have had support from pharmacy • With capacity to provide informed consent to participate in the study	• Individuals with SMI under the age of 18 years old • Non-English speaking • Lack of capacity to consent	Indirect methods Poster: • displayed at site reception areas of mental health clinics • sent to patient support groups • sent to research manager at local NHS mental health trust who will contact patients via patient research participation groups • displayed on People in Research platform https://www.peopleinresearch.org/ • circulated to other patient and public involvement platforms including social media and newsletters Direct methods: • Local NHS mental health trust identified patients who met the eligibility criteria through reporting systems and team leader/care coordinators/consultants and provided those patients with a letter of invitation • Local National Institute for Health Research (NIHR) Clinical Research Network (CRN) and the Research & Development (R&D) Lead for local Clinical Commissioning Groups (CCGs) contacted GP surgeries and sent them an introductory letter Interested practices identified patients who met the eligibility criteria through reporting systems and posted out study documentation, in addition, opportunistic recruitment was be undertaken by the GP surgeries (poster was given to eligible patients)
Informal carers and caring dyads	• Adults aged 18 years and over • No upper age limit • Informal carers: carer who provides care for a patient (defined above) • Informal carer dyad for a patient recruited to the study: this person was identified by the patient as the person (who is not a care professional)	• Individuals under the age of 18 years old • Non-English speaking • Lack of capacity to consent	Poster: •displayed in site reception areas of mental health clinics •sent to informal carer support groups •sent to research manager at local NHS mental health trust who contacted informal carers via carer research participation groups •displayed on People in Research platform https://www.peopleinresearch.org/ •displayed/included in other carer and public involvement platforms including social media and newsletters Specific approach to recruit informal carer dyads • When interviews took place with patients, the patient was given an information pack about the study to hand to their nominated informal carer • The nominated informal carer should be someone who the individual with patient identifies as the person they get most support from

	they get most support from, not necessarily a family member) • With capacity to provide informed consent to participate in the study		
Pharmacy and care professionals	Pharmacy and care professionals are professionals who were directly involved in the care of patient group defined above who have a CMR, MetS or related disease This group could include doctors, nurses, healthcare assistants, physiotherapists, occupational therapists, pharmacists, pharmacy technicians, social workers	Pharmacy and care professionals who were not directly involved in the care of patient group as defined above	Poster: • sent to local NIHR CRN and R&D Lead local CCGs and for distribution to GP practices. • sent to the R&D department of local NHS mental health trust for distribution to mental health professionals via mechanisms including global email, NHS Trust e-newsletter and as an attachment to their postgraduate education session timetable. Doctoral student asked LPT NHS Trust Senior Pharmacist/Pharmacy Manager to send out email and poster to: • team leaders/consultants within LPT NHS trust. • local pharmaceutical committee and ask them to forward to their community pharmacist members. • medicines optimisation pharmacist lead for each CCG for distribution to their pharmacists. • the lead for the College of Mental Health Pharmacists so they can contact their members via appropriate channels. • pharmacy team at the local NHS Mental Health trust Pharmacy and care professionals were also recruited via other professional contacts as appropriate through snowballing and use of social media

3.8 Setting

Phase 2 (Chapters Four to Eight) of the research recruited individuals from both primary and secondary care across the UK.

3.9 Sample size

As above, qualitative research is used to explore in-depth participants' views and experiences. Whereas in quantitative research a power calculation is used to determine the optimum sample size (317) in qualitative research the appropriate sample size is influenced by several study-specific and more general factors. There has been much debate about what constitutes an appropriate number of participants to include in qualitative research (368–370) in relation to the concept of data saturation.

A provisional anticipated upper sample size that might potentially generate adequate data that would provide rich, complex and multifaceted data about patternings related to the phenomena of interest was estimated (369). Consideration was also given to other similar types of studies conducted (371,372,381–384,373–380). The provisional upper sample size was around 15 of each key stakeholder (patient, informal carers, care professionals, pharmacy professionals). The figure provided is an estimate only. During the process of data collection an iterative approach was taken as far as was practically possible, there was a constant back and forth between data collection and analysis (385). In other words, the researcher started with the initial data collection, analysed the data for themes, and then used this to provide focus for subsequent data collection. In line with similar studies the topic guide was modified during the process of data collection and this iterative process (386). The doctoral researcher then made an in-situ decision about the final sample size, shaped by the adequacy, richness and complexity of the data collected for addressing the research question. The decision was made within the process of data collection, reviewing data quality during the process (370).

3.10 Development of topic guide

Topic guides (Appendix 11) were developed iteratively during extensive discussions with the supervisory team. Supervisory team discussions took the form of monthly face-to-face meetings during which possible amendments to the topic guides were identified and agreed and then incorporated by the doctoral student and discussed again the following month. Discussion was informed by:

- the research objectives
- a systematic review of the role of pharmacy in CMR, MetS and related diseases in patients with SMI (387).
- the results of an earlier scoping review of the literature
- experience and knowledge of the doctoral researcher

The final draft of the topic guide for care professionals and pharmacy professionals was trialled over the phone with a care professional and a pharmacist respectively who met the inclusion criteria for the study. The final draft of the topic guide for patients and informal carers was piloted face-to-face with a patient and an informal carer respectively who met the inclusion criteria for the study. Suggested amendments were incorporated to produce the final topic guide. Questions were added to the topic guide during the process of gathering data (388) as part of the iterative process as exemplified by similar types of studies, copies of the topic guide with these addition questions can be found in Appendix 11 (386,389).

3.11 Recruitment process

Direct and indirect methods were used to try to recruit participants and included details of how to contact the doctoral student (stated as the lead researcher in the study protocol). Indirect methods included displaying posters in student's employing mental health trust outpatient clinics or posting on social media. Direct methods included mental health trust pharmacy manager to send out email and poster to relevant staff within the trust (see study protocol, Appendix 9, for further detail). Informal carers of patients who formed part of a caring dyad with patients were recruited via the patient - the patient was asked to nominate someone who provided a significant amount of care or support for them. The patient was then provided with information to give to this person. Individuals who contacted and expressed an interest in taking part in the study in response to those recruitment methods were contacted by the doctoral student to check if they were eligible to take part, discuss the study and answer any questions they might have. If they were still interested in taking part then a letter of invitation and participant information sheet was sent to them by their preferred method (email or post). If the potential participant did not respond then a follow-up reminder was sent two weeks later. If the potential participant confirmed that they were happy to take part then they were contacted to arrange a suitable date and time for the interview and asked if they wished this to happen face-to-face or by telephone.

It was made clear at all points (including in the participant information sheet, in discussion about the study, prior to providing consent, at the start of the interview) that they could withdraw from the study at any point during the data collection process. Participants were informed that they had until the point at which their data was anonymised to withdraw all or any of the information provided or discussed in the interview. Participants were also informed that if they chose to disclose information with implications for safety of any individual this would be discussed with the supervisory team. Had the doctoral student had any concerns otherwise then they would raise them with the supervisory team, who in any case also reviewed all study data during analysis. More detailed information is provided in the study protocol (Appendix 9).

3.12 Doctoral student's qualifications, occupation, training and expertise, data generation, recording, data processing and transcription, and data storage

The doctoral student has a Batchelor of Science degree in Pharmacy, a Postgraduate Diploma in Clinical Pharmacy, and a Postgraduate Diploma in Psychiatric Pharmacy. The doctoral student was practicing as a Senior Mental Health Pharmacist at the time of the study. She has received training in research methods as part of postgraduate diplomas in pharmacy practice and psychiatric therapeutics, qualitative research methods and specifically in carrying out interviews and in using NVivo® as a tool to facilitate analysis of qualitative data (QSR International PTY Ltd 2016). The doctoral student attended the National Institute for Health Research (NIHR) Good Clinical Practice primary care and secondary care training for researchers (NIHR 2018) and attends and for an update of this training every two years.

3.13 Data handling

Interviews were carried out over the telephone, face-to-face at the participant's home, place of work or at the local NHS mental health trust between March 2019 and September 2019 based on the preferences of the individual respondents. Interviews lasted between 18 and 93 minutes.

3.14.1 Recording of interviews

A Phillips DPM8000 pocket memo Dictaphone® (digitally encrypted voice recorder) was used to record the interviews. The Dictophone® was checked immediately prior to each interview to ensure that it was recording. The doctoral student took consent, introduced herself at the beginning of the

interview, outlined the interview process and read the preamble at the start of the topic guide before recording began. The doctoral student asked the participant whether they were ready and happy to start and then switched on the Dictaphone® and started the interview. Recording continued until the interview was finished.

3.14.2 Data processing and transcription

Printed copies and consent-related documents were stored in a site file, which was kept in a locked filing cabinet within the student's employing mental health trust (Leicestershire Partnership NHS Trust) site. Recordings were uploaded as soon as possible on password protected NHS computers and laptop and backed up on a secure NHS server. Only the doctoral researcher had access to the data. Participants' names were not recorded and any information which might identify them, others or their places of work, residence or specific information relating to specific localities was removed from the transcripts during accuracy checking. Participants were allocated a pseudonym determined by the doctoral research which was used throughout the research; names and corresponding pseudonyms were stored securely and separately from the transcripts. Uploaded recordings were checked for audibility and clarity by the doctoral student and then they were then erased from the Dictophone®.

The doctoral student arranged for a professional transcription service to transcribe the interviews. There were confidentiality arrangements in place for use of this service. Recording files were sent to this service using a password protected electronic platform. Each interview was transcribed separately verbatim. The password protected transcripts were sent back to the doctoral student, who checked them with the original recording for accuracy and completeness. Occasionally the doctoral student corrected a mis-heard word or inserted a name or word (e.g., a drug name) with which the transcriber was not familiar.

Verbatim transcription and researcher notation of participants' non-verbal behaviour has been cited as being central to the veracity, reliability and validity of qualitative data collection (390–392). In research underpinned by theoretical frameworks such as all types of TA, the close relationship between the researcher and participant is critical to the research design and philosophical tenets of the methodology (393). A verbatim record of the interview is clearly beneficial in facilitating data analysis as it brings the doctoral researcher closer to the data.

3.14.3 Data storage

Documents were stored in password-protected computer files; printed copies and consent-related documents were stored in a site file, that was kept in a locked filing cabinet within Leicestershire Partnership NHS Trust where the doctoral student was employed. Documents were only removed for data checking and analysis and immediately returned once checked. Audio recordings and transcripts kept on password-protected computer files will remain there for five years after the date of the last publication from the study, as per Aston University research guidelines.

3.14 Data analysis

Data analysis describes the identification, examination, and interpretation of patterns and themes in data and determines how these patterns and themes help to increase the understanding of the phenomenon being studied (394). Analytical rigour is required to prevent bias and ensure that findings reflect the data. Data was coded both with and without the use of computer assisted qualitative data analysis software. Coding was carried out by the doctoral student.

There are challenges in analysing narratives from semi-structured interviews because of the incongruence between the practical process of data analysis while ensuring quality and maintaining both ethical or theoretical standpoints (395). Delineating the boundaries of a story in relation to interview data is often challenging in qualitative research (396). The narratives that were analysed in this research were co-constructed with participants. The way data is analysed and findings are produced depends on the particular perspective of the researcher and disciplinary framing (397). The purpose of this study was to document and analyse research participants' views, experiences, and perceptions. Therefore, analysis required a repeated process of immersing and re-immersing in the co-constructed narratives to ensure that participants' stories were dominant and the patient's lived experience remained central to the study. This involved reading and re-reading the transcripts, extended engagement with the narrative content to identify themes and subjecting the results of the analysis to critical review by PhD supervisors.

3.15.1 The process of framework analysis

This research was underpinned by reference to the literature and pre-existing knowledge, experience and understanding of the doctoral researcher. It was appropriate that a framework analysis approach

was undertaken using the topic guide to form the initial coding framework (341,398–400). Framework analysis has five main stages (341,401,402):

- *Familiarisation with the data*: listening to recordings, reading transcripts, going over the reflective diary and field notes and, studying any other data sources. The doctoral researcher conducted all the interviews and this was also part of the familiarisation process.
- Identifying a thematic framework from the literature, underpinning theoretical framework and coding that took place as part of the familiarisation stage; this evolved as the analysis progressed. The patient is at the centre of this research, the thematic framework and all data was coded in a way that acknowledged this.
- Indexing: ascribing all *"significant statements"* (316) to the appropriate part or parts of the framework.
- Charting: synthesising and arranging the data thematically.
- Mapping and interpreting: a process whereby broader themes are identified from the data and in relation to the framework categories.

3.15.2 Data handling and analysis using NVivo® (computer assisted qualitative data analysis software)

NVivo® (QSR International Pty Ltd. 2016) was used by the doctoral student to support data analysis. NVivo® facilitates data handling and analysis including identification of representative illustrative quotations (316). Computer software such as NVivo® is only an aid to the organisation of the material and is not in itself an interpretive device (403) as the researchers role within the interpretation remains central.

3.16 Research ethics

The four principles of medical ethics have been described as: beneficence, non-maleficence, respect for autonomy and justice (404). With regards this research, to meet the need of beneficence the study had to be carried out in a way that offered benefits to all participants. Avoidance of causing harm to participants or others was required to meet the need of non-maleficence. Respect for autonomy was met by providing sufficient and appropriate information to allow participants to give informed consent at each stage. There were two components to meet the need for justice: first, the study design and conduct ensured compliance with relevant policies and legislation and second, all participants were treated in the same way. The doctoral student is a pharmacist and is therefore guided by the

requirement to adhere to the GPhC Standards for Pharmacy Professionals (405). The ethical issues raised by study are considered with respect to these principles.

3.16.1 Beneficence and non-maleficence

Research participants were patients, informal carers, pharmacy professionals and care professionals. Participants were informed in the participant information sheet (Appendix 10) that findings from the research *"will be used by the research team to improve health services for people with SMI*" thereby offering opportunities for beneficence. Maleficence was also included in the participant information sheet, for example, *"You may feel that some of the questions we ask about your personal health or medication are stressful or upsetting"* and that should this occur then they were free to refuse provide a response or withdraw.

The study was designed to ensure that participants' identities remained confidential; patients were only identified by their gender, ethnicity, age, their mental health and physical health diagnoses and current medication. Informal carers were identified by their gender, ethnicity, age, relationship to, and their knowledge of, mental health and physical health diagnoses and current medication for the person they were a carer for. Care professionals and pharmacy professionals were identified by their gender, ethnicity, age, current role or position, duration, and level of involvement with individuals with SMI and professional qualifications and professional experience.

In all cases any identifiers were removed following transcription. In the participant information sheet and before the start of each interview participants were reminded that if they chose to disclose an issue which in the opinion of the doctoral student might compromise patient-safety or the safety of any individual then this would be discussed with the supervisory team. Healthcare professionals in the UK have a legal duty of candour (Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20 (406)) in addition to the requirements of their professional code and standards. Informing participants that information might be shared satisfied non-maleficence as well as the doctoral student's own obligation to act with candour. Participants chose what they wanted to disclose to the doctoral student thereby, satisfying autonomy and possibly beneficence.

3.16.2 Aspects of recruitment and selection during phase 2 of this research which show respect for autonomy of participants

Provision of:

- information and opportunity to ask questions,
- written consent to participating having anonymised data shared and published,
- reassurance that responses would be kept confidential,
- consent to any information which might compromise patient safety being discussed with the research team if required, following the principle of non-maleficence.

Also,

- Participants could withdraw from the study at any time without giving a reason.
- Interview schedule designed to elicit the required information while minimising the cognitive burden. Disclosure of possible patient harm was discussed at supervisory meetings.
- Participants chose the how the interview was conducted to minimise any burden.
- Participants could refuse to answer any question or provide any information asked of them.

3.16.3 Justice and ethics

Conduct of the research was informed by the Code of Practice for Research Degrees (Aston University 2018/2019). It was also carried out in accordance with the requirements of the Data Protection Act (1998) and Aston University Data Protection Policy (Aston University 2018), Guidelines on Research Ethics and Registration of Research projects for Ethical Approval (Aston University 2015) and Research Governance and Integrity Assurance (Aston University 2019) policies. Measures taken by the doctoral student to ensure compliance with these procedures and legislative controls are described in this chapter. Ethics approval was obtained from the West Midlands Coventry and Warwickshire Research Ethics Committee (18th December 2018, REC reference: 17/EE/3057, Appendix 12; approval for substantial amendments: 10th March 2019 and 2nd August 2019; Appendix 13). Approval was obtained from Research Ethics Committee, School of Life and Health Sciences, Aston University (1st February 2019, Aston Health Research, and Innovation Cluster reference: 258-218-DS, Appendix 14 and substantial amendments approved 5th April 2019 and 20th August 2019 Appendix 15).

The doctoral student was trained in qualitative research methods and was supervised by individuals experienced in supervising and carrying out qualitative research including interview-based research.

The doctoral student has completed the NIHR Good Clinical Practice primary care and secondary care training for researchers (NIHR 2018).

The GPhC Standards for Pharmacy Professionals (405) outlines responsibilities which match those inherent in good research governance, for example with regard to taking responsibility for one's own working practices, showing respect for the autonomy of others and ensuring the well-being of all those involved. By following the principles outlined above, these responsibilities were met throughout this study.

3.17 Chapter summary

Phase 1, presented in Chapter Two, of this research was a systematic review of the literature on the role of pharmacy in the management of cardiometabolic risk, metabolic syndrome, and related diseases in severe mental illness. Results from this systematic review informed the development of Phase 2 which are considered in Chapters Four through Eight. This approach was undertaken according to an interpretivism philosophy using a qualitative research methodology. An interpretivist-constructionist, qualitative exploratory study was designed and carried out. Data generated through semi-structured interviews with patients, informal carers, caring dyads, pharmacy professionals and care professionals exploring their views and experiences and the resulting data was analysed using framework analysis.

Chapter Four: Cardiometabolic risk, metabolic syndrome, and related diseases in severe mental illness: the role of pharmacy in the lived experience of patients. Findings from patient interviews

4.1 Introduction

Patients were asked about their lived experience of CMR, MetS and related diseases and their views, experiences, and perceptions of pharmacy and the role pharmacy plays in their care. This was central in understanding for example, where a particular intervention or service development would be best targeted and whether patients with SMI would engage with such a service to help them manage their conditions. The aim was to describe the role of pharmacy for patients with CMR, MetS and related diseases and SMI and where patients identify pharmacy as having the greatest potential role in their healthcare.

The findings from the analysis of the semi-structured interviews with sixteen patients with CMR, MetS and related diseases and SMI is presented in this chapter. Description of the key themes will help in understanding the role of pharmacy in the lived experience of these patients in relation to their specific health conditions. Respondents varied by age, gender, and diagnoses (demographic details of the sample are provided in Table 4.1). Detailed information about methods is provided in Chapter Three. The key points are summarised at the end of the chapter.

This chapter contributes to the research question in the following ways:

- the patient is considered front and centre,

- the theoretical framework identified against which data from all the participants in the study was coded was developed from analysis of the patient data here.

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Table 4.1: Demographic data of patients with severe mental illness and cardiometabolic risk, metabolic syndrome, and related diseases (self-reported)

Participant pseudonym	Gender	Ethnicity	Age range	Physical health diagnosis/es	Psychiatric diagnosis/es
Gemma	Female	White	20-24	Smoking Overweight (BMI ≥30)	Psychosis Borderline Personality Disorder
Erica	Female	White	45-49	Ex-smoker Overweight (BMI ≥30) T2DM	Chronic Paranoid Schizophrenia
Frank	Male	White	45-49	Central Obesity Overweight T2DM Hypertension	Schizophrenia Depression
Florence	Female	Mixed	50-54	Underweight Sedation Lethargy Sleep Disturbances	Schizophrenia Anorexia Nervosa
Trisha	Female	Black British	50-54	Overweight Lupus Rheumatoid Arthritis Spinal Stenosis, Leg Ulcers	Rapid Cycling Bipolar Disorder
Denise (part of a caring dyad)	Female	White Irish	60-64	Obese Prediabetes Hashimoto's Disease Benign Ventricular Hypertrophy	Schizophrenia
Sally (part of a caring dyad)	Female	White	50-54	Obese	Schizophrenia
Gail	Female	White	45-49	Obese T2DM Hypertension (currently on medication for this) Fibromyalgia Arthritis Constipation Irritable Bowel Syndrome	Bipolar Affective Disorder Major Depression Post-Traumatic Stress Disorder
Judith	Female	White	60-64	T2DM High Serum Cholesterol Hypertension (currently on medication) Cataracts Immune Skin Disorder Vertigo	Major Depression with Psychotic Symptoms
Andrea (part of a caring dyad)	Female	White	40-44	Overweight Hiatus Hernia Barrett's Oesophagus	Major Depression with Psychotic Symptoms
Irshad	Male	Asian	30-34	Ex-smoker Obese	Schizophrenia

				T2DM	
Claire	Female	White	50-54	Obese, hypothyroidism	Bipolar Affective Disorder Complex Post-Traumatic Stress Disorder History of Self-Harm
Khadija	Female	Asian/Asian British	40-44	Overweight Ankylosing Spondylitis Chronic Pain Raynaud's Disease Endometriosis Glaucoma Uveitis	Bipolar Affective Disorder
Megan	Female	White	35-39	Obese T2DM Hypertension (currently on medication) Hypermobility Syndrome Psoriasis Asthma Gastro-oesophageal Reflux Disease Keratoconus Asthma Sleep Apnoea	Bipolar Affective Disorder Anxiety
Zubair	Female	Asian/Asian British	35-39	Current Smoker (3 cigarettes per day) Obese Polycystic Ovarian Syndrome	Paranoid Schizophrenia
Stella (part of a caring dyad)	Female	White	55-59	Overweight (but previously obese) Hypertension (currently on medication)	Antibiotic Induced Psychosis

The analysis identified three main themes (see Table 4.2). The first theme related to the psychotropic medication and management of their side-effects as well as information provided about these. The other two themes related to the role of pharmacy and the factors that facilitated or limited support from pharmacists, whether in hospital or community settings.

Tablet 4.2: Themes and subthemes for patients

Theme	Subtheme
Theme 1: CMR, MetS and related diseases, psychotropic medication, psychotropic medication side-effects and SMI	• Prolonged and protracted, repeated, and recursive: the trials of trying different psychotropic medications • Information about psychotropic medication side-effects, screening or management relating to CMR, MetS and related diseases • 'Medicated' hunger • Impact of weight gain • Deeper or different understanding – my learning • Summary of patients' interactions with pharmacists in terms of frequency and depth
Theme 2: The role of pharmacy: barriers	*Actual or experienced* • Lack of communication and information access between services • Saturated with support from other services *Potential or anticipated* • Ability of community pharmacist to engage with patients with mental health problems • Unsure about the expertise, knowledge, and skills of pharmacists • Concern about burden and demands placed on the community pharmacist workload • Lack of privacy and confidentiality in the community pharmacy environment
Theme 3: The role of pharmacy: facilitators	*Actual or experienced* • Conduit facilitating contact between patient and mental health pharmacist e.g., psychiatric nurse, care programme approach coordinator, key worker • Pre-existing 'familiar' relationship resulting in proactive enquiry by patient *Potential or anticipated* • Desire for more information about medication • The pharmacist is someone who is neutral, independent or a patient advocate • Desire for community pharmacists to undertake screening for CMR, MetS and related diseases

Key: *Actual or experienced: barriers and facilitators that were actually experienced*
Potential or anticipated: not actually experienced but anticipated as potential barriers or facilitators

4.2 Theme 1: Cardiometabolic risk, metabolic syndrome and related diseases, psychotropic medication, psychotropic medication side-effects and severe mental illness

4.2.1 Theme 1: Introduction

An enduring tension permeated all patients' descriptions related to their experience of living with their multiple diagnoses and impact of prescribed medication. Respondents' narratives illustrated the experiences of the intersections and entanglements of CMR, MetS and related diseases, psychotropic medication, and their side-effects and SMI. There was no clear delineation between these. For patients, management of CMR, MetS and related diseases, psychotropic medication and their side-effects was a central feature of everyday life whereas SMI was associated with episodic relapses. Patients were trying to understand how these could be managed, how they might reconcile these with their own lives and what it signified for them. All respondents described how their illness and medication had a significant impact on their life. The data shows how patients live with and emerge through these intersections and entanglements.

4.2.2 Theme 1: Detailed description of sub-themes

4.2.2.1 Prolonged and protracted, repeated, and recursive: the trials of trying different psychotropic medication

The experience of being diagnosed and subsequently starting medication was a difficult, prolonged, and protracted process for many patients. The early phase of their illness journey involved numerous hospital admissions, readmissions, or outpatient appointments with psychiatric services. These were accompanied by multiple changes to prescribed psychotropic medication, mainly antipsychotics and other psychotropic medication, and, for some, uncertainty about their diagnosis.

Different respondents explained it using various metaphors. Khadija used the phrase *'trial and error',* which speaks to a sense of passivity on part of the patient but also a *'perceived'* randomness of the judgement of the psychiatrist. Florence described a more tortuous journey reflecting on her *'normal'* life before being *'thrown'* into the mental health system eventually having spent more time in hospital than at home and becoming apathetic to receiving healthcare.

Experiences of psychotropic medication were often described as an almost interminable process with respondents recollections and reflections scattered with painful, distressing, and upsetting

experiences of medication side-effects. For some, knowledge of side-effects was described as a serendipitous discovery as a result of reading and/or recognising their own experience. For many patients changes in their medication regime to tackle these side-effects resulted in relapse in mental illness; this was described as a source of suffering, frustration, and dissatisfaction rather than a road to recovery.

Central to this for a significant proportion of respondents was the experience of CMR, MetS and related diseases as side-effects of psychotropic medication prior to the experience of efficacy. The quick onset and intensity of these side-effects in contrast to the slow, gradual, and delayed abatement of symptoms of SMI. *"Well, my diabetes hadn't always been well controlled anyway but when I started the risperidone things really went off! My sugars rocketed; sky high….it was all a bit of a mess if I'm honest. I was still mentally quite unwell but remember it quite well."* (Erica).

4.2.2.2 Information provided about psychotropic medication side-effects, screening or management relating to cardiometabolic risk, metabolic syndrome, and related diseases

Many patients reported not having received any information that really mattered to them or that they felt was meaningful related to psychotropic medication side-effects, screening or management relating to CMR, MetS and related diseases. A few patients expressed frustration and anger about this whilst others acknowledged that they were too unwell to remember whether this had actually happened or not. Others spoke of not knowing whose responsibility it was to provide this information or undertake related screening or management.

Information about psychotropic medication side-effects

Where a patient information leaflet (PIL), usually a manufacturer's leaflet, had been provided this was dismissed as unimportant, unhelpful, or difficult to read. Some respondents said they were unable to comprehend the information in the leaflet as they could not concentrate enough to read it.

Florence spoke about the negative impact of receiving printed information in isolation.

> *"You get a printout, you go to your room, you read it on your own, and you think, f**k no, I am not taking that, I'm sorry, these are the side-effects…and then you just put it down and you start thinking of very creative ways of not taking these meds, and it's just a crazy world of, do I take them or not for the patient. For the consultants, the nurses and everyone that's involved in caring for the patients it's not productive."*

Frank spoke about his observations that some people were more prone to experience side-effects after being made aware of them. *"I don't like to know the side-effects of medication. Because I've seen it happen with quite a few people, who've gone on to a new medication and the ones that are told what the side-effects are, they think they've got the side-effects. And the people who didn't know, who weren't told what the side-effects were, they didn't have them."*

The lack of tailoring information to needs of patients made some feel 'not seen'. Megan explained:

> *"When I first went on olanzapine, I was just put on it, well……I wasn't told anything about how it's quite well known that it causes appetite increase and weight gain. And I wasn't given any sort of personalised stuff or discussion, like in my family, quite a lot tend to get diabetes quite young anyway. So, you know, no one's ever really talked to me or told me that it may have a great effect, that it could be worse for me than it would be for somebody who doesn't have that kind of family history. Makes me feel, a bit unnoticed, if I'm honest about it, like my needs or that who I am don't really matter."*

Information about side-effects and screening

Sally described being treated with clozapine for three years of treatment with clozapine. Prior to this Sally had been prescribed different antipsychotics and described her experiences of various physical health side-effects placing emphasis on the experience of weight gain with olanzapine. Sally attributed the lack of information received as being part of the 'patriarchal' approach to her care.

> *"With the olanzapine I put on seven stones. And they didn't weigh me and they didn't do anything about it, and I had to say, 'I can't go on, because I'm putting on so much weight', but there was no check and they didn't tell me before I started that this would be a side-effect. But this was a while ago, like ten years, and there was no physical checks or information at that time you just did what you were told to do, that's how it was back then."*

Sally was asked to whether she had received information from any healthcare professional since starting clozapine and she described the occurrence of weight gain and requirement for screening for CMR, MetS and related diseases as serendipitous occurring as if by chance rather than being made fully aware prior to their occurrence.

> "*No….I looked it up on the internet after I experienced significant weight gain, but no, not medically, nobody has really talked about the side-effects. Of course, I know about the weight gain now because it happened to me – I've put more on since starting clozapine! So, they sent me a letter out of the blue to say because, because I'm on clozapine, I have to have an annual health check…and every time I go, they do my blood pressure, my pulse and my weight and*

take some bloods to check for diabetes I think, my psychiatrist has been exceptionally good at the physical health aspect now."

Zubair explained that it was possible that the lack of information provision may be due to the healthcare professionals overseeing her care being concerned about jeopardising her adherence, but, that this led to her feeling distrustful of the care she was receiving and more importantly she said she felt she had a right to know. Zubair highlights an issue raised by a few other patients relating to the feeling that the lack of provision of information was indicative of the 'control of care' by the psychiatry team.

"When I was first put on this (depot) I was angry with them, because…. they're supposed to explain to you and they are supposed to check, aren't they? Things like check your weight and things?…And I've had so many side-effects and I've wanted to stop the medication so many times, and they say, 'you can't stop it, you have to stay on this medication for two years'…I think they worried that if they had told me then I wouldn't have started it, but how can you trust them if they won't tell you? Tell me! It's like they always want to be in control."

Responsibility for the provision of information about side-effects, screening, and management

In regard to responsibility:

"I don't know if it's the doctor's duty, whether it's the psychiatrist's duty, whether it's the pharmacist's duty or the manufacturer's duty to give me as much information as possible about the medication that I may take. Well, I would say that doctors in my experience very rarely have spoken about side-effects or screening of any medication that I have taken, and the psychiatrists also." (Claire).

As a result of this lack of information, many participants in the study said they used the internet and online patient chat groups as sources of information about CMR, MetS and related diseases. Some felt that they were still unable to have open conversations with their psychiatry teams despite having difficult experiences of side-effects. *"I rang up and I ask about it and I was treated like I 'm a nuisance."* (Zubair).

Ultimate desires

Most patients said that in their view information exchange and decision-making about treatment would involve proximity, preferably in the form of a face-to-face interaction, an empathetic approach, open dialogue and negotiation, and an unhurried interaction with a care professional. This was particularly important when they were taking more than one psychotropic medication. For many this

was what 'good' care should look like. Central to this was the importance of care professionals listening and accounting for individual's needs, wants, and desires. Many patients did not realise there was a need for screening for CMR, MetS and related diseases until they had received an appointment or notification or when they sourced their own information. For respondents it was not only information provision about medication and the need for screening but also a discussion about these issues that they sought to be better informed, empowered and supported in maintaining their decision-making capacity.

4.2.2.3 'Medicated' hunger

Overwhelmingly, patients discussed the impact of antipsychotic medication on hunger and subsequent often, rapid, weight gain. Consistently, this 'medicated' hunger was described as immediate, voracious, ravenous, persistent, and uncontrollable. In addition, participants described never feeling full no matter how much food or type of food they consumed. Importantly, this experience was described as different to their 'normal' hunger and patients articulated that they experienced this behaviour as excessive. 'Medicated' hunger connects the experience of taking antipsychotics to that of rapid and extensive weight gain.

Gemma relates her experience of the intense nature of the hunger. *"I eat during the night... I'm like: 'Give me food!' I was so f***ing ravenous, that's my problem. I'm up several times during the night."* Khadija describes how she would *"….eat anything and everything I could find in the fridge and the cupboards in a short space of time just so I could try and feel full up."* However, despite eating copious amounts of food Khadija described the hunger like a *"bottomless pit."*

Stella explained the difference between 'medicated' hunger and 'normal' hunger having previously experiencing this while on an antipsychotic. *"It just made me eat and eat and eat and eat and eat. And now, I'm on a different antipsychotic, zuclopenthixol, and I still get hungry but it feels like normal hunger, not like before."* Another characteristic of this 'medicated' hunger was the type of food desired or consumed: *"Oh the sweet food, I try to avoid it, but sweet is my type of thing, it's my big problem and yeah olanzapine was the worst one for this."* (Andrea).

When asked about how antipsychotics made people put weight on, Zubair spoke about a slowing down of metabolism. *"….the medication makes you put on weight and it means that your metabolism isn't working like it used to its much slower than it used to be."* Stella found it difficult to comprehend

and was surprised by the sudden and rapid weight gain *"….before I knew I was overweight. It was so, so, so quick!"*

The realisation and bewilderment associated with extensive weight gain after a period of being mentally unwell only served to make this experience worse, patients spoke of not being 'present' during the process of weight gain. *"A couple of months before I got discharged, I went to put my jeans on and I just couldn't do them up. When I went into hospital, I was a 32 waist, when I came out of hospital after three years, I was a 40. I didn't really notice that this had happened until I tried my jeans on. I was quite unwell for quite a lot of that time in* hospital." (Frank).

The experiences described by patients illustrate an important juxtaposition: the experience of taking psychotropic medication that simultaneously attenuates and slows down thoughts associated with SMI and causes sedation whilst at the same time causing ravenous voracious hunger that leads to rapid weight gain.

4.2.2.4 Impact of weight gain

Weight gain led to experiences of limitations in physical mobility and a sense of 'heaviness' and feeling restricted. Denise described how gaining weight hampered her ability to do everyday activities like tidying her house and that it *"slows me down and I get a little bit out of breath going for long distances and have to stop and sit on a bench I'm putting strain on my knee joints."*

Discussions of experiences of recovery from initial episodes and relapses in mental health were accompanied by an emerging acceptance of a new self-identity. This included many dimensions including aspects associated with CMR, MetS and related diseases, psychotropic medication, psychotropic medication side-effects and SMI. These discussions were accompanied by a sense of loss for the person they used to be often illustrated by no longer being able to wear the clothes they used to.

Weight gain or fear of weight gain also impacted adherence, Sally: *"I kept saying to the doctors, I can't go on, I can't carry on putting on more and more weight. But nobody did anything about it, and I can't remember how it ended. I stopped it……nobody was interested in the weight gain at that time."* Denise explained that to try and attenuate weight gain *"I skip a dose on a Sunday."* Primacy was given to the of fear of putting on weight over any therapeutic benefits for Florence: "*It was olanzapine, and,*

ironically, it helped me the most, but because it made me want to eat, even with having an eating disorder, it absolutely was not going to happen. I can honestly say that was one of the reasons I came off it and won't ever go back on to it I don't think."

Within our understanding of SMI and CMR, MetS and related diseases the experience of weight (gain) extends far beyond its conceptualisation as a side-effect of psychotropic medication. We see here it associated with a feeling of heaviness and impacts on ability to be physically mobile and feeling restricted. It also acts a reference point for identity of self before being diagnosed with SMI and its persistence serves to reinforce this. There are important impacts on the relationship patients have with psychotropic medication.

4.2.2.5 Deeper or different understanding – learning to manage

There are two main connected threads in the accounts of patients in this study: awareness and hope. Reflections on previous experiences relate to the difficulties and hardships associated with CMR, MetS and related diseases, psychotropic medication, psychotropic medication side-effects and SMI. These reflections were in addition to broader consequences including stigma. The lack of awareness of these aspects was a challenge and provoked feelings of bewilderment. Many spoke of how this was a particular issue early on after receiving a diagnosis or in treatment. The experience of illness brought about awareness and facilitated recovery, untangling of some of the entanglements.

Denise described one of the things she was doing to manage her prediabetes daily was counting calories and that this *"…helps to keep a lid on that."* Megan, who had longstanding obesity and recently diagnosed with T2DM, explained how she was managing: "*I've been trying to kind of learn, because anything with carbohydrates raises my blood sugars then I can feel hungry again quite quickly. I am making quite good choices but it's how much I do that, which is what would make it be sustainable."* Megan's comments also illustrate an awareness of how her own actions might undermine her efforts to make changes to her diet.

Several patients mentioned that they understood the need to undertake physical activity to manage their weight and that doing so had additional benefits for their mental health. Irshad spoke about a Bollywood dancing programme he was taking part in in his area and Zubair had just started to go swimming on the recommendation of her GP *"I have a real good feel good factor when I go swimming and I am starting to lose a little bit of weight."*

Stella was able to make changes to achieve a desirable outcome having lost 16.5 pounds using a fitness app.

> *"I was hearing things and seeing things, and to top it up, they put me back on olanzapine. I have put a little bit more weight on but these last couple of weeks and I've just fought the hunger, I haven't had anything. I just have a glass of water if I feel hungry. And now this last couple of weeks I've gone back to using the app and I'm just eating what I've planned for my meals and no in-between biscuits or anything like that, no alcohol or no takeaways or anything."*

These narratives provide insight into the complexities of how patients place value on aspects of their lives as lived compared to how it might be lived differently. A life of taking psychotropic medication for SMI is associated with the ambivalence of hopes and fears as well as promises, gains, and losses, but so too can a life be without this medication. The conflict between the therapeutic benefit and the impact of side-effects is a central element of a tension which that was apparent for all the patients in the research.

4.2.2.6 Summary of patients' interactions with pharmacists in terms of frequency and depth

Patient interactions with pharmacists providing support for CMR, MetS and related diseases in patients with SMI were encapsulated as three 'scenarios' based on the frequency and depth of such interactions. Pharmacists were the only type of pharmacy professional patients discussed.

- Scenario 1: Frequency of interaction was high and depth of interaction was low.

  These occurred at least every two to four weeks and were described as being superficial or transactional in nature. Examples included the dispensing of medication or Medicines Use Reviews (MUR) with community pharmacist.

- Scenario 2: Frequency of interaction was low and interactions were in-depth.

  Such interactions were described by patients as occurring only once or twice in their illness continuum. Interactions occurring, either, as a result of proactive enquiry with a community pharmacist by a patient, or a meeting with a mental health pharmacist facilitated by a conduit. Interaction was described by patients as having made a significant impact on their

CMR, MetS and related diseases, for instance, detailed discussion about the relative side-effects of psychotropic medication relating to CMR, MetS and related diseases which increased their understanding or led to switching medication.

- Scenario 3: Frequency of interaction was low and depth of interaction was low.

  This occurred when information about the administration of non-psychotropic medication such as simvastatin was provided. Interaction was initiated by member of the community pharmacy team when the patient collected dispensed medication.

Further analysis of the data allowed for an understanding of the possible connection between the actual experiences of pharmacy and views on the potential future involvement. Patients who had experienced an in-depth interaction expressed enthusiasm for pharmacy undertaking screening for CMR, MetS or related diseases in the future. Where patients had experience of receiving any type of advice from a pharmacist about medication or where someone close to them had received advice or intervention then they expressed a desire for face-to-face conversations with pharmacists about medication side-effects.

Regardless of their experience or current input patients in the study who felt they already had enough appointments (were saturated) such as diabetes or clozapine checks expressed no need to receive anything else further. It might be that this group of patients see the position of pharmacist's authority in their care as being anomalous or peripheral. The nature and quality of the relationship with pharmacists were highlighted as being significant, as Claire clearly articulated, *"I think it's going to be down to developing personal relationships with patients, and that's going to take time. And it's also going to take the patient accepting that that's what the pharmacist wants to do and understanding why they're doing it."*

4.3 Themes 2 and 3 Introduction

Community pharmacists and mental health pharmacists were the only type of pharmacy staff or professionals mentioned by patients and views and experiences were mixed. Patients' experiences were mainly from primary care (e.g., GP) and secondary care psychiatric services (inpatient and outpatient). Patients' experiences are explained in terms of barriers and facilitators to engaging with pharmacists. Many of these barriers and facilitators relate to patients view of the community

pharmacy as a healthcare destination. This reflects the frequency of contact with community pharmacy.

4.4 Theme 2: The role of pharmacy: barriers. Detailed description of sub-themes

4.4.1 Actual or experienced barriers

4.4.1.1 Lack of information access and communication between services

Continuity of care was considered important by all participants. This was discussed in the context of information exchange or access between services. For example, during transition between secondary care and primary care such as discharge from an inpatient ward to a GP, or where care was 'shared' between secondary care and primary care such as between a psychiatric outpatient clinic and a GP. Communication of information between different services and pharmacy was not considered to be seamless.

> "*We just need that link, there's no proper link, between the GP, the CPN (Community Psychiatric Nurse), hospitals and the psych ward and the pharmacy, they all seem separate, they're not joined up at all. There have been times when my community pharmacy hasn't had any of the details about my discharge medication or changes to my medication regime from the hospital."* (Florence).

Patients reported having to fill this information void themselves with the biggest source of frustration relating to changes in their medication regime. The community pharmacist's lack of access to and therefore lack knowledge of information about diagnoses and indications for psychotropic medication were also highlighted as being problematic. For example, some patients mentioned they were aware that olanzapine could be used in the treatment of schizophrenia or bipolar disorder. *"Well, the community pharmacist they just don't have that information, do they? How would they know about me then, recognise me as an individual? My diagnosis, my medication, my dose, my weight. Why do **I** have to be the one to explain this to them?"* (Zubair). This appear to leave the patient feeling detached and being a 'stranger' from the community pharmacist.

4.4.1.2 Saturated with support from other services

For some the burden of managing and navigating their way through the intersections and entanglements associated with their condition was all consuming. This included attendance at appointments for CMR, MetS and related diseases and SMI, which often occurred separately from each other. A strong desire was expressed that to lead a fulfilling life and take part in other activities

despite this necessary commitment to attend appointments for health needs. *"All those appointments I need to attend you know - it's like a full time job sometimes but I still want to live and have a life you know."* (Gemma).

Gail had diagnoses of T2DM, hypertension and obesity and SMI and she articulated that her needs were being met *"I think it's all dealt with by the GP surgery and the hospital, so, at the moment, there isn't anything that is outstanding really. I have enough appointments for the diabetes and the rest at the hospital, so I don't really need any more appointments anywhere. It would be too much."*

Patients who were taking clozapine all reported regular attendance at outpatient clinic for screening for comprehensive screening for CMR, MetS and related diseases and were more than satisfied and felt saturated with their needs for care. Patients whose care was 'mandated' such as in the case of clozapine or who had multiple appointments for CMR, MetS and related diseases saw no additional benefit or were not aware of the role of pharmacy other than for dispensing their medication.

4.4.2 Potential or anticipated barriers

4.4.2.1 Ability of community pharmacist to engage with patients with mental health conditions

Concern was expressed by patient respondents about community pharmacists' ability to engage with patients with mental health problems. Their accounts highlighted that this perception hindered patients' willingness to discuss CMR, MetS and related diseases with community pharmacists. Questions were raised about emotional involvement and communication skills.

> *"The reality is that having a mental illness is really s**t…. there are times when I'm ill I'm not so self-aware and so I can talk about quite distressing things and…then you've got a pharmacist sat there with this little pile of poo [laughs] and how are they going to be supported. I suppose for me it's not just about money cost, it's about the emotional cost of people getting involved in other people's messiness. Getting involved in this messiness is not without cost to people*." (Claire).

The phrase *"little pile of poo"* stated by Claire here indicates that she feels that talking about complicated and distressing things may be burdening the pharmacist with a set of complex issues to deal with.

Concerns were discussed by participating patients about the parity given by pharmacists for mental health and physical health. This was framed as questioning why pharmacists had first aid training for

physical health but not for mental health. *"Just in the same way that they (community pharmacists) have like basic first aid training then why couldn't they have training for mental health? Like mental health first aid training or something…. how to respond during a mental health crisis?"* (Gemma). This was viewed by patients as an important barrier.

4.4.2.2 Unsure or unclear about the expertise, knowledge, and skills of pharmacists

For some patient respondents, views of community pharmacists' roles and abilities ranged from being *"… just a pill dispenser,"* (Claire) to *"…once in a while they'll remind you about the advice that's on the label anyway! Like with the simvastatin for my cholesterol, about not eating grapefruit or drinking grapefruit juice."* (Gail). Gail's comments illustrated that she felt that it was of little particular value. These patients viewed community pharmacist's sole expertise as dispensing medication and reiterating advice on the label. Therefore, any relationship with patients was purely transactional in nature: exchanging a prescription for medication.

Expertise and knowledge by pharmacists of psychotropic medication and their side-effects was also questioned *"I just don't know what their qualifications are, what they know, could they tell me about my antipsychotic? I don't know. Would they know that my quetiapine made me gain weight and how I might deal with all of that sort of stuff?"* The repetition here indicated that Khadija felt perplexed by this. Khadija's comments also illustrate that she felt that the psychotropic medication and its related side-effects not only 'belonged' to her but were more complex than might be apparent on the surface, they formed part of her identity and who she was.

Mental health pharmacists' prominence in this conversation was lacking. Common responses resonated with Denise's comment *"Oh. I didn't know that were specific mental health pharmacists. Are there? What do they do?"* Suggesting that knowing that they existed rather than what they did was the key issue.

4.4.2.3 Concern about burden and demands placed on the community pharmacist's workload

The ability of a community pharmacist to be able to dedicate time to a patients' needs was questioned; comments evoked a sense of concern about taking a pharmacist away from their duties or main role as well as whether their own individual needs were important. Gemma was asked whether she would consider asking for support in relation to weight gain *"Well, they don't have time, they can't*

look at every person that comes in and be like 'Oh, you're a bit overweight have you considered x, y and z?'"

Claire describes not wanting to add to the workload and burden of the pharmacist. She explained how she felt that the pharmacist's time might be subject to other demands or commitments based on her observations.

> *"They're always so busy, you can see that they're so busy, and so actually even asking for your prescription I feel, oh flipping heck, I know you're really busy but can I have my meds, there are always boxes everywhere and there's three or four of them and they're rushing about, I'm your typical English woman who doesn't want to be a problem, just give me meds and get on with your work and your day because I'm sure you're doing lots of things for other people, so I don't want to take up their time."*

This sub-theme can be clearly seen to be related to the previous sub-theme - priority is given to the community pharmacist's role in dispensing medication.

4.4.2.4 Lack of privacy and confidentiality in the community pharmacy environment

All community pharmacies, which were described by patients as local independent community pharmacies and supermarket pharmacies, were subject to critical scrutiny as being places that would be less likely to allow discussions to take place with sufficient privacy. Some likened a supermarket pharmacy with the supermarket checkout. Khadija was very firm with her assertion: *"Look, I'm not going to stand there in the middle of the pharmacy talking to someone about my health problems with everyone listening whist they're doing their weekly shop!"*

Gail who regularly collected her medication from her local community pharmacy explained: *"You're in everyone else's earshot. Some of my issues, like my weight or my mental health are very personal you know!"* This comment highlights a view of the 'public nature' of the community pharmacy environment and a discomfort with discussing mental health and CMR, MetS and related diseases in this environment.

A few patients mentioned that they were aware of a consultation room as it had been used for an MUR with the community pharmacist or they had specifically requested to access it in the past. However, many said they were completely unaware of its existence. This 'selective' use of the consultation room and lack of awareness of its existence may contribute to the lack of view of

community pharmacies as a healthcare destination, source of valuable information about prescribed medication or healthcare environment.

4.5 Theme 3: The role of pharmacy: facilitators. Detailed description of sub-themes

4.5.1 Actual or experienced facilitators

4.5.1.1 Conduit facilitating contact between patient and mental health pharmacist

Awareness of the existence of mental health pharmacists was limited. A few patients mentioned seeing a mental health pharmacist on an inpatient psychiatric ward but were not sure what their role was. *"They (the mental health pharmacist) never interacted with me directly, even just to say hello or introduced themself. I don't really know what they did on the wards. I can't remember seeing them in the ward round either."* (Frank). All patients in the study were asked about their contact with mental health pharmacists. Interactions, although very infrequent, were considered by patients to be in-depth, valuable, and significant and positively impacted on their understanding, relationship with and adherence to psychotropic medication. Where this interaction had occurred, it included a discussion about the relative incidence of side-effects of different antipsychotics relating to CMR, MetS and related diseases.

Such interactions were facilitated by a conduit such as a care programme approach (CPA) coordinator, psychiatric nurse or key worker and took place either on an inpatient psychiatric ward or in a psychiatric outpatient clinic. Andrea described how a key worker arranged a meeting with herself and the mental health pharmacist. *"The mental health pharmacist gave me a spreadsheet and explained the difference in how often side-effects occur with aripiprazole, olanzapine and amisulpride. He said that the aripiprazole might help me with losing weight, and, but then the olanzapine would be helpful with sleepiness, but also cause weight gain so he explained that."*

Megan explained further *"…. quite a few years ago now, I had a meeting arranged for me with the mental health trust lead pharmacist ……he was able to give me a lot more information than my psychiatrist had about the side-effects and the screening needed such as blood tests. I felt more confident about doing it and that probably made me adhere to medication for a bit longer than I would have done otherwise."*

Awareness of the existence of mental health pharmacists was limited. Interactions with mental health pharmacists were not described other than via a conduit.

4.5.1.2 Pre-existing 'familiar' relationship resulting in proactive enquiry by patient

Pre-existing familiar relationships with community pharmacists or contact with a mental health pharmacist meant that patients were more likely to seek or had already sought further advice or support from pharmacy. This proactive enquiry was often with the community pharmacist by patients who visited the community pharmacy regularly to collect their medication. Furthermore, as one patient mentioned that they recently asked their key worker if they could arrange another meeting with the mental health pharmacist from the mental health trust again highlighting the importance of familiarity.

Irshad discussed how he was referred by his community pharmacist for smoking cessation scheme, "*So I kind of got to know the pharmacist XXXXX (forename of the pharmacist). So, he was trying to quit smoking himself at the time, we had a good discussion. So, then he told me about the scheme and then I think he made a referral."* This shows how a shared bond between the community pharmacist and the patient makes the community pharmacist more accessible. Another patient mentioned they had asked their community pharmacist for advice about diet as their own partner had experience of having a finger prick test in the community pharmacy to check for diabetes.

Convenience due to the proximity and accessibility (including being able to attend without making an appointment) of community pharmacy and community pharmacists when compared to GP services was emphasised by those who utilised them for more than dispensing of medication. Trisha also described obstacles that prevented her from getting information about the side-effects of psychotropic medication from other sources: *"I asked my community pharmacist after a few years, he told me about the medication and their side-effects, nice chap he is, I know him quite well and he's really good…. I know that I could just look at my prescriptions and just google, but I'm not like that, because I get paranoid."*

These examples illustrate important elements of the relationship that might be required for patients to seek advice in this way: a sense of shared experience, familiarity, continuity, longevity, trust and having had at least one meaningful interaction with a pharmacist.

4.5.2 Potential or anticipated facilitators

4.5.2.1 Desire for face-to-face conversations with pharmacists about medication

The value of having a mental health pharmacist providing advice about side-effects and attending mental health wards or CPA meetings was discussed.

> *"... it would be beneficial for wards to get in people that talked about the meds and side-effects and came in and did group sessions, rather than the very busy nurses, who have no time at all, they're running around, they're doing all these different shifts…. A pharmacist working in the mental health trust who knows what the meds are … to come and explain what these meds do in a professional way."* (Florence).

> *"If I had time with a community pharmacist, I'd probably be more interested in stuff about medications rather than them checking my blood pressure…the nurse can take my blood pressure. Yeah, if I could go and see them about looking at all my different medications rather than just discussing that with the GP….Certainly, I'd find it helpful if they incorporated it more. Like, I'd love it if a pharmacist, maybe a psychiatric type of pharmacist, came to my CPA review meetings to talk about the side-effects and other things like that."* (Megan).

The nature and content of this type of interaction are important. MURs which took place face-to-face were seen as a superficial bureaucratic exercise and were declined by many patients. *"To me that it's a tick box exercise and it's about as much use as a chocolate teapot. I don't see anything useful in the time that I've had an MUR."* (Claire).

When asked further patients did not distinguish whether they were referring to psychotropic medication or medication for CMR, MetS and related diseases *"…well all of them, any of them really including the metformin for my diabetes and losartan for my blood pressure."* (Megan). Direct recognition of pharmacists as professional and experts in medication is provided in these accounts. This sub-theme also relates to one discussed as part of the lived experience earlier: the identification by patients that they have unmet needs for receiving verbal face-to-face information about their medication.

4.5.2.2 The pharmacist is someone who is neutral, independent or an advocate

Identification of community pharmacists and mental health pharmacists as independent and neutral healthcare professionals when compared to members of the psychiatric healthcare team was highlighted by some patients. Furthermore, mention was made of pharmacists that could act as advocates for patients.

For Claire, the pharmacist represented someone who was detached from the traumatic and troubled experiences of inpatient psychiatric services.

> *"…it's almost like the pharmacist would come on board and be my advocate….someone neutral but who has got my best interests at heart, and who is prepared to say well actually this antipsychotic medication might not be so helpful, or even that this is the best medication combination that we think is best for you and don't interfere with each other, you know? And it's just having someone else, another pair of eyes that's seeing something differently outside of the medical model, or maybe it could have we tried, why don't we do that, see whether that works, you know? And that would be a positive for me."*

Claire's comments point towards the pharmacist's role in shared decision making (SDM) relating to medication. As such, a patient's view of pharmacists exercising their own autonomy, acting as a patient advocate in providing information, supporting patients to assess risk and benefits of medication and, this in turn can enhance patient autonomy.

4.5.2.3 Desire for community pharmacists to undertake screening for cardiometabolic risk, metabolic syndrome, and related diseases

Some patients expressed a desire for screening for CMR, MetS and related diseases. Denise recognised the community pharmacist as a viable alternative to the GP. *"If I started to get symptoms of diabetes, like thirst or something like that and I couldn't get an easy appointment with my GP…. the pharmacist might be able to fit you in more readily. Maybe, even if pharmacists offered to weigh you once, if you were obese, to weigh you once a month that might be helpful*."

Sally thought this was a great idea: *"The pharmacists could do the physical checks and then I wouldn't have to go to the hospital clinic. I think it would be nice if it could be done in the community…the pharmacists could pick up on it early, as you start to gain weight….I have to order my prescriptions and go there to collect them every month anyway."*

Both comments highlight the accessibility and convenience of the community pharmacy. For patients, community pharmacies might also have a role in facilitating early intervention and detection of CMR, MetS and related diseases when compared to other healthcare services.

4.6 Discussion

There is much to be gleaned from patients' experiences of CMR, MetS and related diseases in SMI. Of note are the intersections and entanglements of psychotropic medication and their side-effects. Clinical discourse often follows a pattern of symptoms, diagnosis, treatment, and potential improvement. However, the journey as described by patients in this study is far from this and the findings here show that approaching the components of a clinical discourse as clear and distinct is problematic. Treatment with psychotropic medication, mainly antipsychotics, was not viewed as unconditionally good. The search for expedient medication was seen as a struggle for balance between positive effects and undesirable side-effects (407). The patients' reality experiencing of all of these threads, their intersections, chiasma and entanglements is messy and complex and similar to the findings of other studies (408).

Lived experiences are heterogeneous in nature. Identification of potential opportunities for involvement of pharmacy is critical. Key aspects of the patient experiential journey impact on adherence and there are unmet needs that could be met by pharmacy services. Poor rates of adherence to psychotropic medication a major challenge in the management of SMI and could be in part ameliorated through engagement with a pharmacist (409–412).

Research supporting pharmacists' roles in caring for CMR, MetS and related diseases in patients with SMI is sorely lacking (21) (see Chapter Two) and the findings here make an important contribution. The supporting literature cited in the discussion below relates primarily to community pharmacy. Findings here contribute to the paucity of data that currently exists relating to mental health pharmacists who are mainly based in psychiatric inpatient services.

In common with other studies (413–415) patients in this research reported a lack of information about psychotropic medication. These findings also indicate that patients want more than information provision, they want information exchange, in other words, the opportunity to consider, discuss and question, often personalised information. Finding the appropriate time in the illness continuum or journey to discuss side-effects with patients with SMI is important. Medication is likely to be started or changed when a patient is unwell, this may impact on their ability to fully comprehend discussions that take place at those times. Further, this maybe more about 'nudging' the patient by building this appropriate time into a routine interaction, for example, when they are ordering or collecting medication or at a time close to discharge from an inpatient ward.

A recent systematic review (407) reported that patient's information needs may change during the illness continuum of psychotic illnesses. For example, during the early stages, healthcare professionals should take sufficient time to provide, and often repeat, important information. Also, in the longer term, communication should be reciprocal, respectful, and involved a high degree of user involvement both in treatment planning and delivery (407) as per the move towards SDM.

Manufacturers' patient information leaflets (PILs) were not seen to be particularly useful to patients in this study partly due to their lack of digestibility. High quality digestible information might be a useful constituent of information exchange rather than being relied upon as the sole source. Other studies have reported that patients believed receiving of high quality psychotropic medication information was an important requisite for involvement (415).

As a profession, pharmacists and pharmacy technicians need to work to find effective strategies to promote their role as experts in counselling and discussing side-effects of medication with patients with SMI (21). Other research has shown that pharmacists may not be spending an adequate amount of time discussing psychotropic medication related side-effects with patients (416,417). Where pharmacists are involved in the process of selecting, switching or adjusting psychotropic medication emphasis should be placed on the need to elicit and clarify patient's understanding of their conditions and values, preferences and priorities (407,418). Such a process has potential to benefit not only CMR, MetS and related diseases but also adherence to psychotropic medication regimes.

Understanding patients' experiences, as presented here, provide insights for pharmacists to undertake effective information exchange. For example, patients in this study described experiencing some side-effects of psychotropic medication before the relatively slow therapeutic benefit of the medication occurred. A recent study (407) reported that reducing symptoms during the acute phase of psychosis was in the main perceived by patients to outweigh side-effects. The side-effects were not perceived as particularly detrimental. However, when psychotic symptoms diminished, most patients found the side-effects of antipsychotics as having an extremely detrimental on mental health and well-being (407). This highlights the need to ascertain individuals' experience at the time of counselling.

Services and interventions to manage weight in people with mental illness are an important target for pharmacy (419). The experiences of 'medicated' hunger and weight gain (including perceived risk of psychotropic medication to cause weight gain) impact on adherence as well as patient identity (419).

All need to be taken in to account when designing any intervention to engage patients effectively. Another study has found that patients feel unprepared for the hunger experienced with antipsychotics as well as the magnitude and rapidity of weight gain that can occur (2). Appropriate and timely discussion might help prepare patients for these side-effects.

Health promotion and risk reduction interventions delivered by pharmacy could include tools and strategies to help manage this medicated hunger, diet, and weight gain, this might include apps on mobile phones, advice on how manage daily calorie intake or blood sugars. Advice or referral to exercise programmes or combined health behaviour and exercise (healthy lifestyle) programmes (420) more generally could also be useful. Obesity is preventable, and strategies to prevent diabetes and CVD both include the common goal of optimising weight through diet and exercise (421). There is evidence to support the feasibility, acceptability and effectiveness of pharmacist-led interventions (mainly community pharmacists) for a range of CMR, MetS and related diseases including but not limited to smoking cessation (422–424), alcohol use (425) cardiovascular risk (426,427) diabetes (428,429) and weight management (430–434).

Smoking cessation and alcohol reduction services are routinely delivered through community pharmacy (179). Weight loss achieved in those studies (430–434) as similar to that compared with other interventions in other primary care but not sustained in the longer term when compared to control or other interventions. The small number of studies which focused on cardiovascular risk and diabetes (426,427,429) fall low on the evidence hierarchy and were conducted in Australia where health system infrastructure and funding for these services is likely to differ from the UK. One of the studies which focused on diabetes (428) could not find strong evidence for the link between the intervention and outcomes measured. None of these studies have specifically focused on patient with comorbid SMI.

As already highlighted important elements of establishing and maintaining relationships with patients include familiarity and at least one meaningful interaction. Data in this study also points to other elements that might be important that have also been found in other studies (374,435,436), such as longevity, a sense of shared experience and trust (437). Patients also need to feel that pharmacists are willing to engage with them and have the time to do so. These are similar to factors highlighted in work by Philip Ley 'communicating with patients' (438).

There is a tension in developing personal relationships that patients reported wanting. Such relationships require high frequency and in-depth interactions and currently neither community pharmacists nor mental health pharmacists appear to be currently fulfilling this. However, what is also clear is that patients are more likely to know their community pharmacist. The findings in this study highlight an incongruence between SMI patient experience and needs for CMR, MetS and related diseases and the role that pharmacy currently has in their illness continuum, management, and journey.

Identification of the actual and potential barriers and facilitators can help towards effective targeting future service design and delivery of interventions for these patients. Strategies to overcome barriers and enhancement of facilitators could act as a starting point to bridge this gap. In addition, whether pharmacists are the most appropriate healthcare professionals to provide these services.

In order for community pharmacists to deliver effective care for CMR, MetS and related diseases patients in this study saw a need for community pharmacists to have access to some of their clinical data. In April 2017 community pharmacy access to the summary care record was granted (439) which allows read only access to a limited amount of patient data including current repeat prescription and allergies but not patient diagnosis. A notification to a community pharmacy nominated by the patient when they are discharged from secondary care psychiatric services would also be useful for both the patient and the community pharmacy team. A systematic review into patient and public perspectives of community pharmacies also found that a lack of access to medical records and communication difficulties with other healthcare services were significant barriers to patients acceptability of pharmacists' extended roles in the wider health-care system (440).

Patients in this study felt that a lack of community pharmacist's knowledge of specific information such as the therapeutic indication for psychotropic medication or their diagnosis contributed to a feeling of not being recognised as an individual. Further, the patient's role in having to provide this information to the community pharmacist on repeated occasions was a source of frustration for the patient. Evidence from patients here also suggests that this lack of knowledge of patient specific information may be a barrier to patients feeling confident about the community pharmacist as a healthcare professional the community pharmacy as a healthcare destination. This has not been explored in the published literature. The need for community pharmacists to have access to comprehensive patient healthcare records has been recognised (441) and more recently there have been moves towards making this a reality.

There are no published studies that have explored how comfortable patients with mental health diagnoses are discussing their physical health problems with community pharmacists. In this study concerns about community pharmacists' ability to engage with patients with mental health conditions were identified as an important barrier for patients to discuss their physical health. Studies have reported that patients are comfortable discussing CMR, MetS and related diseases such as diabetes with community pharmacists (442) but there are also studies that indicate the contrary (443). Studies have reported that patients are comfortable discussing their mental health with community pharmacists (444) but again there are also studies that indicate the contrary (445).

For some patients in this study, it was not a simple matter of being averse to pharmacists or pharmacy services but rather of not having a clear understanding of how the pharmacist's expertise could be useful to them in managing CMR, MetS and related diseases.

Although it was a shared perception amongst some patients in this research it is not known whether the community pharmacists were actually and uniformly busy over the course of a working day. In the primary care setting pharmacists are the only healthcare profession that patients can observe conducting a large proportion of their role, from dispensing medication to counselling or advising patients over the counter. The work of no other healthcare profession in primary care is as transparent and visible. This may have an impact in undermining the potential that patients feel they can approach the pharmacist to speak to them. This may be moderated by factors already discussed such as when a patient knows their pharmacist. These factors may set out the 'terms' under which the pharmacist may be approached or whether they feel it is appropriate to ask for advice. This is supported by findings from other qualitative research studies (446) conducted in patients with diabetes. Patients in this research felt that community pharmacists were busy places, and this may have had an impact on their willingness to ask for advice. Other research on community pharmacist consultations which reported that the general public viewed pharmacists as too busy to engage with patients (440,447). The findings in this study appear to support this conclusion and that the patient respondents saw pharmacists as lacking individually-available time.

When compared to other healthcare settings where private consultations rooms are used as part of everyday care then patients might obviously recognise their absence in the community pharmacies as a limitation to the possibility of having confidential conversations. Other studies have also found that patients feel that the community pharmacy environment is not conducive to private discussions

(374,440). Lack of an appropriate space in which to have an uninterrupted conversation may also impact on whether patients feel able to request advice or support from the community pharmacist.

There are positive and negative aspects to conduits facilitating meetings between patients and mental health pharmacists. Conduits, such as psychiatric nurses, are much more likely to have a closer therapeutic relationship with the patient and acts to 'open the door'. On the other hand, if mental health pharmacists were more physically and regularly prominent in psychiatric healthcare settings then their role would be more clearly identified and recognised and would not need to be reliant on conduits. In addition, some information may be lost in translation through intermediaries. Also, not known is whether interactions between pharmacists and mental health pharmacists have been negatively impacted or impeded by conduits. Within healthcare the place of such as conduits is not a new one, usually within the context of nurses relaying information between doctors and patients or facilitating transition between services (448). Further work is needed to determine how this triumvirate relationship between the mental health pharmacist, patient and conduit affects the extent to which patients are likely to engage with services provided mental health pharmacy.

Other studies have reported that patients see community pharmacists as isolated from the rest of the healthcare team (440,449). However, data in this study are more nuanced, some patients viewed the position of pharmacists as potential patient advocates and this is underpinned by their neutrality and independence as they were not integrated with the rest of the team.

Patients discussed access convenience and not needing to make an appointment as advantages for community pharmacy compared to their GP. What is not known, however, and could be the focus for further exploration is how the nature and quality of relationship with other services impacts on how the relationship of the patient with the pharmacist, primarily the community pharmacist. For example, if the patient has a difficult relationship with their GP are they are more likely to seek advice from a community pharmacist. One study focused on patient engagement in services provided by community pharmacists relative to those provided by general practitioners (436). They report that lack of trust undermines relationships with community pharmacy. Also, due to lack of familiarity new services may be considered by patients to be 'high risk' (436). This study suggested an increase the quality and frequency of patient interactions with community pharmacists will have a positive impact on this trust (436).

Patients here identified their own abilities to learn and manage CMR, MetS and related disease. The published literature has explored self-management and related issues such as SDM and information exchange. The outcomes of these studies are mixed (450) and little is known about which outcomes are valued by patients (451). Self-management may or may not encourage further autonomy (450). A recent systematic review of pharmacist-led self-management interventions for diabetes reported a significant improvement in HbA1c values (452). The studies in this systematic review included pharmacists from both hospital and community settings and used a number of different approaches including education on diabetes complications, medication, lifestyle, and teaching of self-management skills (452). Systematic reviews report that self-management needs depend on individual patient characteristics and development (453). The focus of self-management support should ideally be how to identify problems and how to take appropriate actions (454). Another important factor for successful interventions might be the depth of interactions over time, with the depth of interactions being more important than the duration of the intervention. Certain patient groups may be more vulnerable to having fewer self-management skills than others. For example, patients with a low level of health literacy may benefit much more from self-management support compared to those who are more health literate (455,456).

However, health literacy is only part of the picture, patient preferences and coping styles (passive versus active decision-making) are also important (457). Heterogeneity amongst patient 'groups' may explain why so many study interventions outcomes in RCTs fail to yield anticipated outcomes. Such study interventions are based on 'set' methods and processes and therefore do not allow for the person-centred care (457). Ultimately, across health research, a key finding is that anything related to behaviour change or self-management if thought of as a behaviour is influenced by a trusting, non-judgemental relationship with a clinician. Further, this should be underpinned by a person-centred approach which enables open communication and dialogue (457). This is particularly the case amongst those diagnosed with a potentially stigmatising diagnosis such as SMI. Whilst pharmacist-led interventions have been shown to be of value peer-to-peer initiatives are also very valuable for these types of education and learning, future research should focus on how pharmacists could facilitate and support peer-to-peer approaches.

The target population for pharmacy for health promotion and risk reduction strategies or interventions might be to prioritise filling gaps in current service provision or those who are otherwise underserved or not supported. For example, this might not include those already receiving care for diabetes from GP or secondary care acute services or whose blood tests are mandated otherwise if

they are on clozapine. Data from this study suggest that patients that fall within these groups may be the least receptive to such interventions as they feel 'saturated' with appointments. This study suggests that there are unmet needs in other patients. The definition of target population should incorporate care already being received rather than just absolute risk. In addition, this might benefit from being stratified targeting those with greatest amount of unmet need that experience the greatest benefit. Given that many patients collect their medication from a community pharmacy, this represents the ideal opportunity to 'capture' patients with unmet needs.

The position and place of pharmacy services in having positive impact on outcomes for patients with unmet needs or who are underserved has been explored in the literature. Research studies have reported benefits for hypertensive patients comparing pharmacist – doctor versus doctor only care models (458), diabetic patients as part of an MDT (459) and patients with long-term multiple conditions including psychiatric conditions (460). All these studies utilised pharmacists' expertise in medication and lifestyle interventions.

4.7 Chapter summary

This research has highlighted a significant fracture between patient experiences, views, perceptions and desires and their experiences of services and care currently being provided by pharmacy. Patients' views of pharmacists, the only pharmacy professional discussed, are mixed. Despite frequent contact with community pharmacy, awareness of community pharmacy services beyond medication supply was limited and patients saw them as isolated from the rest of the healthcare team. But this itself may be seen to have some inherent advantages. Although the depth of interaction was reportedly high, patient accessibility and frequency of contact with mental health pharmacists is extremely limited. For community pharmacists to deliver effective care for CMR, MetS and related diseases for individuals with SMI clinical skills beyond the supply of medication need to be recognised and embraced.

Potential barriers to a different role for community pharmacy include a lack of understanding of pharmacists' training and knowledge by patients, the need for reorganisation of pharmacists' workload to accommodate high-quality services effectively and the provision of appropriate facilities within the community pharmacy environment. Ease of access and convenience of community pharmacies present a major advantage. The patient's lived experience is central to this thesis and this chapter has provided the framework central to how the data from other participants relating to their

illness will be understood. The next chapter explores the views, experiences and perceptions of informal carers who play a critical role in the care and everyday lives of these patients.

Chapter Five: Cardiometabolic risk, metabolic syndrome, and related diseases in severe mental illness: the role of pharmacy in lived experience of patients. Findings from informal carer interviews

5.1 Introduction

Informal carers were asked about their experiences of CMR, MetS and related diseases in the patients with SMI who they cared for and in particular the role of pharmacy. The interviews sought to explore and understand the carers role for patients with CMR, MetS and related diseases and SMI. In addition, they explored the carers' views, experiences and perceptions of pharmacy and the role of pharmacy in providing for the needs of the patient but also their own needs. This exploration provides another perspective on particular interventions or service developments that could support them in helping those they cared for and whether informal carers of patients would engage.

The aim of this chapter is to discuss the findings of the analysis of the semi-structured interviews with eight informal carers (spouses, romantic partners, other family members and close friends) of patients with CMR, MetS and related diseases and SMI. Respondents varied by age and sex and whether they resided with the patient or not (demographic details of the sample are provided in Table 5.1). Detailed information about methods is provided in Chapter Three. Informal carer data was coded against the framework developed in Chapter Four from patient data. Six of the eight informal carers were also part of a caring dyad; dyads were recruited via the patient and this specific aspect is explored in Chapter Six. The key points are summarised at the end of the chapter.

This chapter contributes to the research question in the following ways:

- understanding the role that informal carers play in the management of CMR, MetS and related diseases of patients with SMI and the impact these have on the informal carer,

- understanding what the role of pharmacy is for informal carers of patients with CMR, MetS and related diseases of patients with SMI and therefore for the patients for whom they provide care.

Table 5.1: Demographic data of informal carers of patients with severe mental illness and cardiometabolic risk, metabolic syndrome, and related diseases (self-reported)

Participant pseudonym	Gender	Ethnicity	Age range	Relationship to the patient they care for	CMR, MetS or related diseases and other physical health diagnoses of the patient they care for	Psychiatric diagnosis/es of the patient they care for	Do they reside with the patient they provide care for?
Daniel	Male	White	40-44	Was the patient's fiancé/ romantic partner	Asthma Underweight Smoker	Bipolar Affective Disorder	Did live together at the time of the romantic relationship
Louisa (part of a caring dyad)	Female	White	65-69	Sister	Prediabetes Hypothyroidism Obese	Schizophrenia	No
Scott (part of a caring dyad)	Male	White	55-59	Husband	Overweight Hiatus Hernia	Schizoaffective Disorder	Yes
Naomi	Female	White	50-54	Mother	Morbidly Obese (BMI 53.2) Ex-smoker Gout	Schizophrenia, Obsessive Compulsive Disorder Autism Attention Deficit Hyperactivity Disorder	Yes
Charles (part of a caring dyad)	Male	White	65-69	Romantic partner	Palpitations Overweight Hysterectomy	Paranoid Schizophrenia Obsessive Compulsive Disorder	No
Mikkel (part of a caring dyad)	Male	White	40-44	Brother	Unknown	Unknown	No
James (part of a caring dyad)	Male	White	40-44	Husband	Hyperthyroidism Torn Ligaments in Ankle Overweight	Bipolar Affective Disorder Post-Traumatic Stress Disorder	Yes
Julia (part of a caring dyad)	Female	White	25-29	Daughter	Hypertension Obese Investigations being carried out for Arthritis	Antibiotic Induced Psychosis	No

The analysis identified three main themes (see Table 5.2). The first theme relates to the psychotropic medication, the information provided about these and the management of their side-effects. The other two themes relate to the role of pharmacy and the factors that facilitated or limited support from pharmacists, whether in hospital or community settings.

Table 5.2: Themes and sub-themes for informal carers

Theme	Sub-theme
Theme 1: CMR, MetS and related diseases, psychotropic medication, psychotropic medication side-effects and SMI	• Prolonged and protracted, repeated, and recursive: the trials of trying different psychotropic medications • Information provided about psychotropic medication side-effects, screening, or management of CMR, MetS and related diseases • 'Medicated' hunger • Impact of weight gain • Deeper or different understanding – learning to manage • Summary of informal carers' interactions with pharmacists in terms of frequency and depth
Theme 2: The role of pharmacy: barriers	*Potential or anticipated* • Ability of community pharmacist to engage with patients with mental health conditions • Unsure or unclear about the expertise, knowledge, skills, impartiality, and neutrality of the community pharmacist • Visibility and presence of community pharmacist – out of sight out of mind • Concern about burden and demands placed on the community pharmacist's workload • Hierarchy of healthcare in primary care • Lack of privacy and confidentiality and worries about stigma in the community pharmacy environment
Theme 3: The role of pharmacy: facilitators	*Potential or anticipated* • Desire for pharmacists from any setting to engage with informal carers. • Desire for more information about psychotropic medication • Desire for the community pharmacist to undertake non-invasive screening for CMR, MetS and related diseases • Desire to be a point of contact for pharmacists from any setting • Shared knowledge and understanding will facilitate better care for the patient • The pharmacist, from any setting, could be someone who might support self-management for the patient

Key: *Potential or anticipated: not actually experienced but anticipated as potential barriers or facilitators*

5.2 Theme 1: Cardiometabolic risk, metabolic syndrome and related diseases, psychotropic medication, psychotropic medication side-effects, and severe mental illness

5.2.1 Theme 1: Introduction

Informal carers actively participated in moulding the experiences of those who they provided care for and shared in this experience. Involvement in this journey was both practical and emotional and the lives of informal carers were affected sometimes in deeply profound ways. Informal carers were involved in both 'looking after' from the perspective of doing practical tasks such as collecting dispensed medication from a community pharmacy (caring for) and providing emotional support (caring about).

The impact of a diagnosis of a SMI and CMR, MetS and related diseases, were, for the patient, lifelong and enduring. There were times when the level of impairment and illness were severe and the level of informal care 'work' increased both in magnitude and complexity for instance with relapses in mental illness. In addition, there was ongoing continuous 'work' that was also complex and intense in its own way, like managing a healthy diet or medication.

Descriptions provided here by the respondents, some of whom have had lifelong experiences, also illustrated how the passage of time changed their perceptions, views and understanding within their caring role. *"I know so much more now than I did before, some things are easier. On the other hand, as time has passed my own levels of stress and burden have increased as we've both got older and our illnesses have progressed."* (Charles). Many informal carers had additional demands including their own physical health, mental health, and emotional and social wellbeing as well as other caring responsibilities.

Responses provided by informal carers show that there was no clear delineation between the impact of CMR, MetS and related diseases, psychotropic medication, psychotropic medication side-effects and SMI. *"Having lived with someone who has a serious mental health condition, as well as having physical health complaints, with all the medication and the side-effects that go with that, you know, you can't divide one from the other."* (James).

5.2.2 Theme 1: Detailed description of subthemes

5.2.2.1 Prolonged and protracted, repeated, and recursive: the trials of trying different psychotropic medications

Six carers had relationships with the patient that preceded the diagnosis of SMI and CMR, MetS or related diseases of the patient. All carers provided reflections on their experience of diagnosis of SMI which focused on the process and uncertainty. James, an informal carer, explained how he and the patient he cared for had *"endured different mental health 'labels' that had been applied and 'stuck on',"* other respondents reported that uncertainty impacted on the level of trust of psychiatric services and resulted in reduced agency for the patient. Long delays in diagnosis as well as a perceived haphazard route to getting there meant that carers were grappling with unknowns and this impacted on their ability to establish their own identity as an informal carer.

The informal carers gave primacy to the need to avoid a relapse in mental health to avoid things *"spiralling out of control"* (Daniel). Anguish was expressed as relapses had resulted in suicide attempts and significant impacts on the rest of the family. Scott explained the role of medication and specifically the role antipsychotics played in this: "*They all have, I think, side-effects to some degree and we've tried amisulpride, olanzapine, risperidone, all of them have side-effects of some sort, but any antipsychotic is better than none because if she has none, everything just spirals. I mean, it's barely manageable now."* A desire for a good quality of life and recognition of patients' rights and autonomy were frequently articulated within the context of psychotropic medication side-effects. With this however, guilt followed for some as their role and position in undertaking some level of surveillance of medication adherence also meant that they indirectly were endorsing side-effects like weight gain and 'control' exerted by psychiatric care.

5.2.2.2 Information about psychotropic medication side-effects, screening, or management of cardiometabolic risk, metabolic syndrome, and related diseases

Consistent throughout the interviews were narratives about the scant provision of information from healthcare professionals about psychotropic medication side-effects, screening, or management of CMR, MetS and related diseases. This left informal carers feeling unprepared and ill-equipped. Daniel spoke about his role as the 'holder' of the medication and supervising its administration to ensure a harmonious family life, but his lack of knowledge about the side-effects lead to feelings of uncertainty. *"Treating with medication that I don't understand as if I understand it."* For respondents, the lack of

information led to a degree of distrust of healthcare professionals as it was felt that information was being withheld. Daniel was asked about information he was provided with. *"I was given very little information. They told me this medication would fix my fiancée, that it would help her symptoms. When I did push for more information, I felt like I was very quickly cut off, overlooked, or dismissed. It's difficult to build a trusting relationship if you feel that things are being hidden or are not discussed openly."*

Many informal carers were astonished at the disparity between the magnitude and impact of changes to appetite, hunger, and weight and the paucity of information provided about CMR, MetS and related diseases. Charles spoke about attending a clozapine clinic with his romantic partner *"….when we sit in the waiting room it's really sad to see because nearly all the people who come in for the clozapine tests, they're all overweight, like grossly overweight, and that sort of hammers it home that it is the medication, I mean if it so burdensome and occurs so common then why won't they just tell us, I don't understand?!"*

Similar accounts of the difficulties regarding psychotropic medication were apparent throughout the data. That they were encouraging adherence and simultaneously witnessing the cost of this practice. This also serves to reinforces carer's feelings of betrayal and distrust of healthcare professionals who were supposed to be treating and caring for their loved ones.

Comparison of patients and their informal carers withing caring dyads of prescribed medication revealed variable knowledge amongst carers. Although there was good knowledge about the names of individual medications prescribed and whether they were generally for SMI or for CMR, MetS and related diseases and other physical health condition. There was variable knowledge of medication regimes such as doses and timings of administration, specific indication and side-effects. There was no association between the carers relationship type, whether caring dyads lived together or any other demographic data collected in explaining the variability. However, this is a small dataset and further exploration with formal statistical analysis such as regression analysis would be needed to confirm this.

5.2.2.3 'Medicated' hunger

A few informal carers spoke of the effect of medication on their loved one's hunger. Naomi described the nature of this 'medicated' hunger, which was almost immediate on commencing antipsychotics

"He was constantly hungry, always very very hungry." Mikkel went further …*"she (his romantic partner) becomes uncontrollably hungry and un-satiable, just so un-satiable, so she keeps eating and eating and eating and so yes, she puts on weight very quickly"* emphasising the endless nature of the 'medicated' hunger and the rapidity of weight gain.

There was distress associated with observing patients' behaviours in eating patterns including the time of day. Charles spoke about his romantic partner: "s*he comes down during the night like a zombie and eats lots of food."* Charles' use of the term 'zombie' here points towards a lack of volition on the patients' behalf. Other carers commented on the nature and amount of food being consumed, Naomi said, *"……he'll just eat anything and everything that's in the fridge, a whole big, massive block of cheese, anything he can get his hands on. And it's like a constant cycle of self-destruct, and he knows it, but how you break that cycle? I don't know. It's so upsetting for me."* Naomi's comments about her son here also highlight her sense of helplessness. It also emphasizes the importance that informal carers placed on their desire for their loved ones to exhibit self-control and self-care.

These changes in behaviours around food were unanimously attributed to antipsychotic medication and portrayed as 'medicated' hunger as opposed to 'normal' hunger. Julia explained what happened to her mum *"I would say it's related to olanzapine, so it starts when she starts on olanzapine not any of the other medication she has been on.*" She went on to explain further *"….she's had olanzapine in the past and then it was stopped and she doesn't eat so much, it's just normal."* For some carers, the loss of control of hunger and appetite was felt to be akin to the patient's loss of insight during relapse in mental health*. "It's as if my sister's not in control of her hunger and how it drives her to eat. It's like the loss of control she has over her thoughts and voices she hers when her schizophrenia relapses."* (Louisa).

5.2.2.4 Impact of weight gain

Carers described their upset about the impact of weight gain on a broad range of aspects of life for the patient. Naomi spoke about her son. *"Something happened that was really sad this week, incredibly sad for me. He came down from the shower, and I could see that his toenails were incredibly long. I said to him, 'You need to cut your toenails.' and he said, "I can't reach them'."* Naomi went on *"That is desperately sad, isn't it? That at 26, you can't, physically, cut your own toenails, that your mum's got to cut your toenails because you can't actually reach them.*" This also illustrates the dependency some patients have on informal carers to undertake everyday simple mundane tasks of self-care.

Informal carers questioned the primacy that patients placed on self-appearance over long-term health conditions and the impacts of CMR MetS and related disease such as weight on these conditions. Charles spoke about his romantic partner *"If she could look in the mirror and be satisfied with her image and shape, she would be quite willing to put up with the process of putting a strain on heart, like not being able to bend or stretch properly you know or walking up a hill and getting out of breath. She would be willing to bear that just have to a nice figure. She wants people compliment her on how good she looks.*"

Whilst informal carers acknowledged the impact of weight gain on self-esteem and self-confidence, they placed a greater value on the ability of the person they cared for to undertake physical activity, to go to work and reduce their risk of long-term health problems. *"I think she is very focused on the superficial, how she looks, for her self-esteem and confidence. To me the risk of long-term health issues and the ability to be able to work are a greater priority."* (Mikkel).

5.2.2.5 Deeper or different understanding – learning to manage

Informal carers described how their role had evolved over time. Exposure to a unique set of intersections and entanglements impacted on how informal carers experienced practical, social, and emotional demands. Julia explained that as time had passed her mum's position had moved from one of denial to one of acceptance; that having long-term multiple illnesses required adherence to treatment and self-care by attending appointments, undertaking exercise, and following a daily routine.

A few carers described gradually putting in increasing amounts of effort 'working behind the scenes.' Informal carers were heavily invested in their role at the expense of other social roles and all informal carers described becoming socially isolated. They themselves felt invisible and this feeling was compounded by the stigma experienced by the patient. This highlights how informal carers' identity was moulded by the way they felt about themselves and how they felt they were viewed by others. 'Working behind the scenes' and 'hiding' the demands placed upon them may them, may also lead to an underestimation of the demands placed upon them and undermine opportunities for positive recognition from others including the patient they care for.

Scott described the 'behind the scenes' work he did daily: *"Mainly stay at home and look after the house, do the housework like cleaning and the washing….so she can go to work or go to the gym or do*

some exercise." James described himself as an 'enabler.' Primacy was placed on not undermining the patient's feelings of independence or autonomy, to achieve this, informal carers 'hid' the care they provided. Some informal carers spoke about their own physical and mental health illnesses, experiences of anxiety, depression as well as diabetes and heart problems. A few spoke about the additional impact that additional responsibilities such as looking after young children had on their burden as carers.

Informal carers also reported contributing to and supporting healthier lifestyles for patients with SMI. This included giving advice and encouragement about food choices and preparing meals. They also helped support attendance to physical health appointments at mental health trust and primary care as well as supporting engagement with physical activities as described above.

5.2.2.6 Summary of informal carers' interactions with pharmacists in terms of frequency and depth

Interactions with community pharmacy were encapsulated as three 'scenarios' based on depth and frequency of such interactions with themselves, the patient and the community pharmacy: shared utilisation of pharmacy service, superficial transactional relationship, or awareness of interactions with the patient. These categories were not mutually exclusive. For example, an informal carer might be aware of interactions between the patient and the pharmacy but also on occasion collect medication from the community pharmacy on behalf of the patient. On the other hand, some were aware of interactions but had never had any contact with the pharmacy themselves. Regardless of experience, provision of medication information or support from pharmacy or pharmacists for informal carers for CMR, MetS and related diseases and SMI was absent in the interviews as were accounts of interactions with mental health pharmacists.

- Scenario 1: shared utilisation

  One informal carer described that both himself and his romantic partner used the same pharmacy for obtaining medication. In addition, the community pharmacist at this pharmacy had conducted MURs for himself and this partner separately. He was unaware of what advice or support was specifically given to his partner with regards CMR, MetS or related diseases in patients with SMI or psychotropic medication or psychotropic medication side-

effects. However, this may be an issue that relates to patient confidentiality and what permission the patient had given or information the patient had shared.

- Scenario 2: superficial transactional relationship focused on medication supply

A significant proportion of the respondents described a superficial transactional relationship with community pharmacy. These carers collected dispensed medication from the pharmacy regularly as part of their role or when the patient was unable or asked them to. Pharmacists were not viewed by these informal carers as being an integral part of the current care being received or ancillary to their needs.

- Scenario 3: awareness of interactions between the patient and pharmacy/pharmacist

All informal carers were aware that the patient regularly visited the community pharmacy to collect medication. One informal carer knew that his wife had received specific information as part of a consultation with the mental health pharmacist from the local mental health trust and that this had been arranged by her key worker.

5.3 Themes 2 and 3 Introduction

Community pharmacists were mentioned by all informal carers and two mentioned mental health pharmacists. Views and experiences were mixed. Carers' experiences of healthcare services for the patient were within primary care and both inpatient and outpatient secondary care psychiatric services. Carers' experiences are explained in terms of barriers and facilitators in engaging with pharmacists. Barriers and facilitators are based on the descriptions from the cares' second-hand information from the patient because of their lack of direct experience with pharmacy. Facilitators were only mentioned with respect to mental health pharmacist, none were mentioned for community pharmacists.

5.4 Theme 2: The role of pharmacy: barriers. Detailed description of sub-themes

5.4.1 Potential or anticipated barriers

5.4.1.1 Ability of community pharmacist to engage with patients with mental health conditions

Mental health conditions or diagnoses were viewed as a hurdle to overcome. The question of whether community pharmacists could effectively engage in conversations about CMR, MetS and related diseases in a patient with SMI was raised by some respondents. *"Yes. I mean, it's a minefield because you're talking, especially with mental health, you're talking to people who are living with mental health difficulties and are very sceptical of the objectives of people that are randomly trying to get into their life and interfere in their lifestyle."* (Mikkel). We see here the association being made between the need to establish a long-term relationship before providing advice and support and take in to account that provision of these are patient-led.

Informal carers felt that community pharmacists should undertake training in mental health. Further, that community pharmacists should know who to contact for different situations. The need for pharmacy and pharmacists to network and communicate with other NHS services such as the GP and mental health services were considered as part of this discussion.

5.4.1.2 Unsure about the expertise, knowledge, skills, impartiality, and neutrality of the community pharmacist

All informal carers identified the primary role of the community pharmacist in supplying medication and providing advice about over-the-counter preparations. *"I visit the pharmacy either to ask about whether medication is in, or collect medication for xxxx (patient), yeah, just basically that. I just walk in collect the tablets and walk out. I've not known any different."* (Naomi). The knowledge and expertise of community pharmacists to undertake roles beyond this was questioned. "*To my mind pharmacists dispense medication, they don't dispense advice."* (James).

Two informal carers were suspicious of pharmacists' commercial affiliations and financial motives. *"Of course, there's a tension between commercial requirements and the pharmacy as place to deliver any type of healthcare …. the community pharmacist will only engage in it if there's some potential benefit for them."* (Mikkel). This alongside the view that community pharmacists had isolated roles contributed to questions around how community pharmacists might be seen by other healthcare professionals. *"Sometimes I question how they (community pharmacists) are able to marry up the need*

to make a profit alongside providing care and being neutral and impartial? They operate very much independently and the need to make profit I think effects how others like the GP might see them. Morally difficult I guess." (James). This view of the pharmacy as a 'business' may undermine or mitigate any potential clinical role and facilitators.

5.4.1.3 Visibility and presence – out of sight out of mind

Physical visibility was important to some informal carers *"…. the qualified pharmacist ought to be on the floor talking to patients directly and helping them with their concerns about side-effects and interactions, whereas what you see most of the time is them hidden behind the counter*." (Mikkel). We see here visibility being equated with accessibility and approachability. Mikkel went on to suggest how this barrier might be overcome *"Maybe there could be two pharmacists, one doing the dispensing and counting the tablets and the other one on the floor talking to patients and helping them.*"

This reinforced the view of the community pharmacy as a commercial environment and the primary role of the pharmacist as dispensing medication. *"Sometimes you go in and the shop assistant checks your details and hands over the medicine, there's no real conversation. You might not even see the pharmacist.*" (Naomi). There is a sense of frustration here and a desire for something more than a superficial relationship.

5.4.1.4 Concern about burden and demands placed on the community pharmacist's workload

"At the moment all you see is the pharmacist is running around busy counting pills. It makes you feel that you can't really interrupt them, can you?" (Mikkel). Mikkel's comment resonates with the pharmacist's lack of availability and consequent lack of approachability. The positive aspects of community pharmacy may be attenuated by the busyness that is observed. *"On the one hand they are open most hours and you can just walk in and you should be able to speak to them without an appointment but all you see is the top of their head pop-up once in a while and the phone is constantly ringing."* (Mikkel).

The need to be free and have time to speak to the patient or the carer was seen to be related to the pharmacist placing value and importance on informal carers' needs and demands. Not being distracted by other tasks and having dedicated time was also mentioned by other carers. *"It's already difficult for us, we have so much to do. You need to know that someone is available and free to give*

you the attention you need. Some of these issues about morbid obesity, schizophrenia and autism are quite complex and take time and attention to fully appreciate and understand." (Naomi).

5.4.1.5 Hierarchy of healthcare in primary care

In professional terms the community pharmacist was seen as subordinate to the GP, the community psychiatric nurse and psychiatrist by some informal carers. This was in line with the four sub-themes already discussed where suppling medication was identified as the primary expertise of the community pharmacist. The integrity of advice was considered by informal carers to be dependent on health professional's position in what they saw as a healthcare hierarchy. This in part related to what informal carers saw as *"complicated issues around diagnosis, finding the right medication and the relationship between the mental and physical health. Getting in the middle of all of that and teasing it out isn't easy you know. It can be messy!"* (Naomi).

"If the pharmacist suggested something for xxxx (romantic partner) then you might not rely entirely on their advice. I might go and check this with the GP or the CPN or the mental health team first. Psychiatry meds are complicated things." (Charles). The extent to which the carer would recommend the patient acts on pharmacists' advice depends on their relationship with other healthcare professionals; they would double check it with the GP first. This carer is highlighted what seems to them the anomalous positioning of pharmacist's authority in the primary care team.

5.4.1.6 Lack of privacy and confidentiality and worries about stigma in the community pharmacy environment

A significant proportion of carers had concerns about the confidentiality and privacy within the community pharmacy environment. *"I'm not really sure anyone would want to have a conversation in front of everyone else there that's waiting. There's enough stigma about mental health out there already. You're not likely to open up about antipsychotics or for schizophrenia because there is a fear amongst patients and carers of being judged!"* (James). Informal carers had a heightened awareness of stigmatising attitudes and behaviours from the general public. Further questioning revealed that informal carers did not believe that pharmacy staff or pharmacists held stigmatising views of mental health. *"I would guess they see and come into contact with a wide range of people, I don't feel from my limited understanding of what they do or who they are that they stigmatise mental health issues."* (Mikkel).

Direct comparisons with other primary care services were also made. *"You don't go to your GP and have your consultation in the waiting room, do you? So why would you do this anywhere else?"* (Mikkel). Some respondents, however, knew about consultation rooms that were available in some community pharmacies. Both Charles and his romantic partner had used a consultation room when they each had separate MURs in their community pharmacy.

5.5 Theme 3: The role of pharmacy: facilitators. Detailed description of sub-themes

5.5.1 Potential or anticipated facilitators

5.5.1.1 Desire for pharmacists from any setting to engage with informal carers

Whilst it was apparent that none of the informal carers interviewed had in-depth relationships with community pharmacists or mental health pharmacists, half of them (n=4) felt that such engagement could potentially be useful. Discourse was mainly orientated towards community pharmacists; mention of mental health pharmacy was sparse. This reflects their own and the patient's frequent contact and awareness Informal carers described providing support with various aspects of medication management including arranging and collecting supplies from the community pharmacy, supervising adherence, screening, and managing side-effects of CMR, MetS and related diseases such as assuming responsibility for medicines taking behaviours during periods of mental health deterioration supporting management of diabetes.

Particular aspects of the relationship, with the community pharmacist, were considered important, *"Well they need to first establish a relationship with me so that there is trust, I would need to feel like they understood my position. I would like to discuss what my needs are as a carer if I'm honest*." (Charles). Mikkel described his expectation "*Like what you want from your bank, you want to be able to walk in and talk to somebody you know and who you trust."* (Mikkel). This comment also highlights the need to establish a personal relationship and trust, as seen already in this chapter, with them as an individual.

5.5.1.2 Desire for more information about psychotropic medication

Informal carers had a variety of approaches to understanding patients' psychotropic medication. Some actively sought information from the manufacturers' PILs provided in the patient's dispensed medication or the internet. Others were not interested mainly because they regarded psychotropic medication the responsibility of the psychiatrist. Informal carers felt satisfied with the information

they had received about medication for physical health conditions and that these needs had been met by the GP or physical health specialist teams from secondary care. *"My son's GP gave us lots of really useful advice about the medication for his gout. We had to discuss it a few times but I think I am really clear and understand it well."* (Naomi).

Some were burdened with their own medication, health, and illnesses or financial or domestic tasks as part of their caring roles. *"I just don't have the capacity for any more information. I am just about coping. I just manage the medication as part of the daily routine there's nothing else I really need to know. I just make sure the medication has been taken and that chore has been completed."* (Scott).

For those who were interested, conversations with the community pharmacist were seen as *"…a good place to start. To be honest I've never thought about it before but it would be a good place. I suppose the internet isn't as trustworthy or reliable. It might help me understand more I guess and I haven't had much from the mental health team."* (Louisa). Here, the community pharmacist was seen as potentially filling a gap not otherwise met.

5.5.1.3 Desire for the community pharmacist to undertake non-invasive screening for cardiometabolic risk, metabolic syndrome, and related diseases

A few informal carers were supportive of a community pharmacist undertaking particular types of screening for the patient *"…. but maybe if there was a regular weigh-in or, you know, blood pressure or some kind of little test that wasn't too taxing on the pharmacy and not too intrusive for the patient like taking bloods."* (Naomi).

Louisa discussed why the community pharmacy might be a good place to have this done because *"...it's probably a little bit more accessible than the doctors are and you don't need an appointment. So, if it was for a weight check or something of that nature. It would be advantageous for everyone because they would have a secondary person or place that would be aware of their health needs."* Blood tests were considered be the responsibility of a doctor or nurse. The use of the term 'secondary' by Louisa also implies that both the community pharmacist and other healthcare services would be aware of any needs relating to CMR, MetS and related diseases and that community pharmacy was a back-up.

5.5.1.4 Desire to be a point of contact for the community pharmacist

Whilst informal carers described a superficial relationship with the community pharmacist, reflections during the interviews led to conversation with some respondents about the value of having and being such a point of contact *"I suppose I should be more involved. I should be known to the pharmacy so that, you know, God forbid, anything would happen, with her consent of course, that I wouldn't be a stranger in that sense."* (Louisa).

Being a point of contact with other health services but not community pharmacy was queried by one informal carer. *"That does seem a bit odd if I'm honest! All other members of the team have my contact details, the GP, the psychiatrist. So why should the community pharmacist not have my contact details? They're involved in providing the medication which is an important part of her (the patient's) care."* (Charles). As a result of the research and on reflection these carers acknowledged that community pharmacy might be a part of the care network.

5.5.1.5 Shared knowledge and understanding will facilitate better care for the patient

Informal carers felt that shared knowledge with the community pharmacist about the patient would ultimately contribute to better care. This was in part fuelled by a sentiment that they felt *"locked out*" (Julia) by psychiatric services who did not involve them appropriately or adequately. Such framing by the respondents positioned the carers themselves as having a unique set of skills and knowledge about the patient.

Naomi felt that sharing this information would *"result in better care I think, as the carer I know what goes on a day to day basis, the ups the downs*. *The community pharmacist, I think, they're kind of outside the psychiatric services, a bit more neutral maybe, I don't know. But if there's someone like that who we could link up with that might help. We could discuss the medicines and the finer issues and maybe that could help."*

This informal carer placed the community pharmacist as a back-up, a potential port of call with regards medication whilst still acknowledging that they did not fully understand their position or role. The suggestion that the pharmacist was a back-up or a secondary source of information reinforces the statements relating to their role in screening. This sub-theme also suggests that if community

pharmacists would share informal carers' knowledge and understanding about the patient and work together that there is a potential for partnership between themselves and the community pharmacist.

5.5.1.6 The pharmacist, from any setting, could be someone who might support self-management or self-care for the patient

A few informal carers wondered if either the mental health pharmacist or community pharmacist might help support self-management or self-care of CMR, MetS and related diseases. Concerns around deviations from complete adherence to psychotropic medication due to side-effects were also mentioned. *"She (the patient) constantly worries about her weight and hunger and I don't always know if she skips a dose or takes a lower dose to try to help with that. That worries me."* (Scott).

> *"Could the pharmacist help her (romantic partner) to help themselves or provide me with support to help her help herself? That would be great! They know more about the side-effects of the medication and she visits the pharmacy quite often so they could help with managing the side-effects too, I guess. But maybe also decisions about the right types of food to eat or the types of food to avoid with the hunger she gets with the tablets."* (Charles).

It was felt that medication and management of side-effects was a daily part of their caring tasks and if the parent had more knowledge to enable self-management and self-care this would reduce their own caring burden to allow the patient to have greater autonomy. With regards to autonomy carers emphasised the importance of patients' central role in their own care and need to maintain a sense of responsibility for their own health.

5.6 Discussion

Data analysis shows that informal carers play a critical role in the management of CMR, MetS and related diseases in patients with SMI. The Informal carers interviewed positioned themselves as brokers of unique insights and knowledge about the needs and preferences of patients. Their interaction with healthcare services often required that they mediated and advocated on behalf of the patient although they may advocate for themselves rather than the patient. However, it must be acknowledged to what extent and under what circumstances an informal carer can and should speak for the patient.

The findings from this study are supported by a handful of other studies. Informal carers considered obesity as one of the most serious side-effects of antipsychotic medication and its occurrence is associated with worry and anxiety (461). Data collected on medication prescribed may be a useful indicator of informal carers' knowledge of medication. Importantly, lack of or limited discussion with health professionals or access to useful information about side-effects or how to manage them has also been reported (461,462). This is important because improved understanding medication information might allow carers to feel that they can play an active part in the treatment process. Data from several studies suggest that adherence to medication is improved in patients with schizophrenia who live with their relatives or who are in close contact with informal carers as part of their role is in ensuring that medication is taken by the patient (463,464).

Systematic reviews highlight that the contribution of social and family involvement to adherence to antipsychotics in patients with SMI is significant (465). Greater levels of family and carer involvement and support and positive attitudes towards medication (465) have been reported as good predictors of adherence. However, another study found that informal carers are frequently excluded (464) and passively included (466) from treatment decisions (464).

The findings in this study also highlight an important tension in informal carers' roles in relation to medication management. Ensuring and promoting adherence to psychotropic medication also means that they perceive their role to be that of perpetuating and endorse the resulting side-effects and the 'control' exerted by psychiatric care, this has been recognised in another study (467) Their care and support for healthy lifestyles can be seen as in conflict with promoting psychotropic medication which has a detrimental effect on the very focus of those healthy lifestyle behaviours, this may be perceived by them as being a heavily contested part of their role. This may be an additional aspect to the burden that informal carers experience and although recognised in existing literature (466) requires further in-depth exploration.

Families play an important role in providing care and support. Social support has been identified as one of the most important resources in coping with mental illness and adherence with medication (468). Informal carers reported their role as associated with high demands, requiring many sacrifices. This can, impact negatively on their wellbeing as it may contribute to carers neglecting their own health. For example, informal carers are at increased risk of mental illness (469) and are more likely to report worse general health than non-carers (470).

Studies have found that self-neglect is a particular problem for informal carers with chronic conditions and those who care for patients with multiple LTCs (471). Informal carers included in this research study spoke about their own mental and physical health problems. Informal carers have their own needs and require care. Despite the critical role played by informal carers in optimising recovery their views, experiences, and perceptions of patients with CMR, MetS and related diseases in patients with SMI has received little attention from research. Only a handful of studies have been conducted to purposively seek the perspectives of informal carers on matters related to CMR, MetS and related diseases in patients with SMI (462,472–474).

Informal carers interviewed in this research were concerned about the impact of medication on the physical health of their loved ones and the impact this had on their ability to do other activities. This is similar to the findings of a study (462) that reported that informal carers had concerns and observed that medication side-effects led to weight gain which, in turn, affected the patients' ability to engage in strategies to improve their physical health. Again, in agreement with other studies informal carers were found to give primacy to mental health over CMR, MetS and related diseases (475,476), patients on the other hand view these as being of equal importance (see Chapter Four and Chapter Six). These different points of view may arise from informal carers' worries about the impact of relapse in mental health on themselves and carers might find it difficult to encourage healthy lifestyles for other reasons, for example, the patient might be socially isolated.

This is the first study that has explored barriers and facilitators to pharmacy and pharmacists supporting informal carers of patients with CMR, MetS and related diseases and SMI. Informal carers reported that patients' knowledge gaps about psychotropic medication side-effects, screening, or management of CMR, MetS and related diseases were unlikely to be wholly met by pharmacy services. In addition, most informal carers in this study placed pharmacists subordinate, peripheral or as a back-up to the needs of the patient they care for when compared to other healthcare professionals.

This view is explained in part by the barriers identified by respondents. Carers expressed concerns about the ability of community pharmacist to engage with patients with mental health conditions and being unsure about the expertise, knowledge, impartiality, and neutrality of the community pharmacist. In addition, community pharmacists may not appear to be accessible as they are not visible in the community pharmacy, this is further exacerbated by informal carers' concerns about the burden and demands placed on the community pharmacist workload. Finally, informal carers felt that

there was a lack of privacy and confidentiality and had worries about stigma in the community pharmacy environment.

Other studies have reported barriers to a more in-depth clinical role for community pharmacists in the management of dementia (383), behavioural and psychological symptoms of dementia (477) and pain in patients with dementia (478). Similar to other research, informal carers in this study tended to view the role of pharmacists primarily in terms of medication supply (479,480). This was associated with concerns about the commercial aspects of community pharmacy and the potential conflicts of interest that may arise in balancing engagement in the provision of healthcare services and achieving sales of products. This issue was not raised in discussion of their views of the GP who also frequently have the same employment status; within the context of a GP surgery the financial aspect of how services are remunerated is less visible.

There are some positive facilitators that could be utilised and act as a starting point for future service design. Informal carers want to be provided with more information about medication, if pharmacists are able to establish in-depth trusting relationship with informal carers, then they could potentially fulfil this role. In addition, some would be happy for community pharmacists to undertake non-invasive screening for CMR, MetS and related diseases.

There were also some positive views about community pharmacists supporting the patient and work towards implementing self-management or self-care programmes, this might be related to informal carers' views of unmet needs and a desire to partner up with community pharmacists. Other positive aspects of community pharmacy were also mentioned including convenience and accessibility. If the frequency of contact with pharmacy and informal carers increased then there is a potential opportunity for pharmacists and pharmacy staff/professionals to care for carers and potentially reduce their burden.

Published literature confirms the findings presented here that informal carers of patients with SMI often feel marginalised by service providers (481,482). This is in spite of their desires to be more involved and treated as partners in patient care, where their unique insight as brokers of knowledge about the patient are recognised (483–485).

There are currently no specific guidelines on how pharmacy can best to support informal carers with CMR, MetS and related diseases in patients with SMI. The following recommendations for pharmacy services are made based on the findings presented in this chapter:

- All pharmacists need to understand informal carers' perspectives and recognise their role, knowledge, and expertise of the patient.
- Pharmacists, especially mental health pharmacists, need to engage and establish relationships with informal carers.
- Pharmacists need to increase informal carers' involvement in discussions about medication including side-effects, this should be facilitated by an establishing a familiar relationship and creating an environment where this can happen. This must, however, consider the patient's wishes as they might not want the informal carer involved.
- There is a need to better identify informal carers' particular needs for information and support regarding CMR, MetS and related diseases. Specifically, the provision of medicines information, assisting with medication management, and signposting to services that could further relieve their burdens.
- International and national pharmacy organisations need to establish guidance on strategies or interventions that could be used within pharmacy practice to promote improved CMR, MetS and related diseases. The strategies and interventions should be tailored toward the needs of the relationship between the informal carer and the patient and consider how SMI can affect informal carers influence on patient perceptions of medication and adherence.

5.7 Chapter summary

Informal carers play a crucial role in the care and management of CMR, MetS and related diseases in patients with SMI. There are important medication related issues which are yet unmet that informal carers expressed a strong desire to have fulfilled. There are also important services that informal carers believe that community pharmacy might be able to provide which include non-invasive screening such as weight checks for CMR, MetS and related diseases.

There are many steps that will need to be taken to fulfil these needs including first and foremost taking the time to establish relationships with carers and being available. Then, making carers aware of the skills and knowledge pharmacists have and how they might meet these needs. Barriers that need to be overcome to undertake this work includes providing a private and confidential environment for conversations to take place. Frequent contact, accessibility and convenience are

important facilitators. The awareness and understanding of the place of mental health pharmacists amongst informal carers in this study is scant. Mental health pharmacists need to make efforts to establish and improve their interactions with and include informal carers. The informal carers' experience is critical on its own and to the patients' lived experience. The next chapter explores the unique and unresearched perspective – that of the caring dyad.

Chapter Six: The experiences of the caring dyad: (Un)articulated realities of living with cardiometabolic risk, metabolic syndrome, and related diseases in severe mental illness.

6.1 Introduction

In the previous two chapters the perspectives of patients and informal carers were each explored separately. In this chapter a unique perspective of the caring dyad will be explored. The term caring dyad is defined in this study as a patient with CMR, MetS and related diseases and SMI and their informal carer. Caring dyads were asked about their experience of CMR, MetS and related diseases and their views, experiences and perceptions of pharmacy and the role pharmacy plays in their care. This was central in understanding where a particular intervention or service development could be best targeted and whether caring dyads with would engage with such a service to help them manage CMR, MetS and related diseases. The aim of the interviews was to describe the impact of CMR, MetS and related diseases on the relationship and the role of pharmacy in this relationship.

The analysis of the semi-structured interviews with six caring dyads is presented in this chapter (see Table 6.1 for demographic details of the sample). Patients and their informal carers were interviewed separately from each other, detailed information about methodologies and methods is provided in Chapter Three. This aspect of the research sought to capture the interdependent complexities of caring dyads relationships that contribute to health outcomes that are not fully apparent when studying only patients or carers individually. Key points are summarised at the end of the chapter.

This chapter contributes to the research questions in the following ways:

- understanding the impact of CMR, MetS and related diseases and SMI on the relationship between patient and their informal carer,

- the role of pharmacy from the perspective of the caring dyad.

Table 6.1: Demographic data of caring dyads (self-reported)

Dyad	Participant pseudonym and relationship	Gender	Age range	Ethnicity	CMR, MetS or related diseases and other physical health diagnoses of the patient[b]	Psychiatric diagnosis/es of the patient[b]	Do individuals in the caring dyad reside together?
1st dyad Denise and Louisa	Denise (patient)	Female	60-64	White	Obese Prediabetes Hashimoto's thyroiditis Benign Ventricular Hypertrophy	Schizophrenia	No
	Louisa (sister of Denise)	Female	65-69	White	-	-	
2nd dyad Sally and Charles	Sally[a] (patient)	Female	50-54	White	Obese	Schizophrenia	No
	Charles (romantic partner of Sally)	Male	65-69	White	-	-	
3rd dyad Sally and Mikkel	Sally[a] (patient)	Female	50-54	White	Obese	Schizophrenia	No
	Mikkel (brother of Sally)	Male	40-44	White	-	-	
4th dyad Andrea and Scot	Andrea (patient)	Female	40-44	White	Overweight Hiatus hernia Barrett's Oesophagus	Major Depression with Psychotic Symptoms	Yes
	Scott (husband of Andrea)	Male	55-59	White	-	-	
5th dyad Claire and James	Claire (patient)	Female	50-54	White	Obese Hypothyroidism	Bipolar Type I Complex Post-Traumatic Stress Disorder	Yes
	James (husband of Claire)	Male	40-44	White	-	-	
6th dyad Stella and Julia	Stella (patient)	Female	50-59	White	Overweight Hypertension	Psychosis	No
	Julia (daughter of Stella)	Female	25-29	White	-	-	

[a]Sally was part of two caring dyads within the research study. Two informal carers of Sally were recruited.
[b]Data on mental health and physical health conditions of informal carers was not collected. Any reference to these will be that which is self-reported but not actively sought as part of the research study.

The three themes identified from the data are shown in Table 6.2.

Table 6.2: Themes for caring dyads

Theme	Name of theme
Theme 1	Enhancing closeness within the caring dyad
Theme 2	Dissonance within the caring dyad
Theme 3	Balance within the caring dyad

6.2 Introduction

It was evident that the presence of CMR, MetS and related diseases in SMI had a major impact on the relationship between patients who had LTCs and their informal carers. Data analysis contrasting and comparing transcripts from each individual within the dyad identified three themes enhanced perceived closeness, dissonance and balance within the caring dyad.

Enhanced perceived closeness resulted from caring dyads engaging in mundane activities including physical activity and exercise, using the same pharmacy, and attending appointments together. Informal carers meeting the unmet needs of the patient also enhanced closeness. Dissonance within caring dyads was associated with the patient ignoring advice from their informal carer and informal carers participating in controlling and bullying behaviour and was typically linked to incongruent beliefs about health and wellbeing. Within the caring dyad the roles, identity and balance between both individuals was affected by how needs were framed, met, or compromised; the provision of care in all caring dyads was not unidirectional but each member provided care for the other.

6.2.1 Theme 1: Enhanced closeness within the caring dyad

A significant number of the caring dyads in this study reported enhanced closeness within their relationship as a result of both engaging with healthcare services to implement lifestyle changes. This collaborative endeavour brought with it a sense of 'team', 'togetherness' and openness to the relationship; they were working collaboratively towards managing CMR, MetS and related diseases. Lifestyle changes varied but many respondents identified physical activity. Similarly, the joint engagement with healthcare services was a central element that created greater closeness.

For both patients and informal carers, undertaking regular physical activity, such as walking together was regarded as an essential part of the support enabled by and through the caring dyad.

"And I do actually have great support from my brother. Like yesterday, he came around at like, quarter past six in the morning, and made me go for a walk. Which is great. Which is great." (Sally, patient). *"But she does enjoy walking a lot so she goes out and walks every day and we try and go out and walk together every day, so that's what keeps her agile and mobile and so actually her health is very good, considering the challenges."* (Mikkel, informal carer).

Sally and her romantic partner also used the same pharmacy for medication supply and reviews, which was also a positive shared experience and provided a sense of reassurance for the informal carer. *"We've got a lovely rapport with our pharmacist we've found in xxxx (name of city), he's absolutely wonderful, he'll answer any questions that we have. He's even had us both in individually for medication reviews. It's quite reassuring, for me, in particular seeing the same pharmacist as Sally."* (Charles, informal carer).

A significant proportion of caring dyads reported that attending therapy together fostered a greater level of understanding and that this led to a sense of mutual support and closeness. *"…we are all having family therapy at the moment with my family. We've been learning about the triggers: things lead me to become ill. That's been really useful to share with the family so everybody's kind of aware when things are starting to deteriorate a bit. Doing this has brought us closer together."* (Sally, patient). Mikkel, her brother and informal carer also saw the benefit of therapy for everyone directly involved. *"…she's been given family therapy to help with her relationships with her dad and to help us as a sort of social network, so as a family, her partner, my wife, me, to understand her health better."* (Mikkel).

Paradoxically, the experience of receiving little or no external support for CMR, MetS and related diseases appeared to reinforce togetherness within the caring dyads. An informal carer looking after his sister, stressed that providing the support that was not available from healthcare services created a space for him to play a greater role, increased his understanding and enhanced their closeness.

> *"We work together a lot but she's not receiving any outside help at all from the system, no attention is put on it. So, I work with her a lot on her diet and we talk a lot. Since my mum passed away, she's started cooking for my dad and I've been helping her to do that, like doing a cooking course…that's been really helpful for her to learn and become a bit confident about making food and how food is made and how that impacts on her health. So, we work together." (*Mikkel, informal carer)

When James was asked whether he was aware of any signposting for support with diet and lifestyle for his wife when she attended appointments for screening for CMR, MetS and related diseases he

said: *"Yes she has, but the bits of help and support that she's used haven't been that helpful because we already know what we are doing, you know."* (James, informal carer). Undertaking these lifestyle activities together as a dyad improved the health of both the informal carer and the patient. As well as these bidirectional positive impacts, it also acted to compensate for the inadequacy of healthcare provision.

Participating in everyday mundane activities together as much as those specifically associated with disease management strengthened the relationships between members of caring dyads. In many ways, mundane activities were also essential to disease management. For instance, undertaking exercise or physical activity together facilitated those caring dyads to encourage each other.

> *"It was my daughter that said, 'Well why don't you try My Fitness Pal' and I said 'Right, I'll do it' and obviously we did it together. I stuck with it. I didn't eat anything in between my main meals, nothing at all. I went walking every day and obviously the weight just dropped off. ……the app has been fantastic and doing that sort of thing with somebody else is great because you can boost each other."* (Stella, patient).

The sense of being a 'team' and jointly engaging in lifestyle changes as a caring dyad was also something that often predated the emergence of the caring relationship as Julia explained, *"…. with regards to weight, health, eating healthily and living healthily, me and my mum are and always have been very open about things like that. We used to go to the gym together when I was younger, you know, we did it as a team."* (Julia, informal carer). Furthermore, joint activities were something that could be revisited as a source of affirmation reinforcing closeness and support. Julia went on to say, *"And now this last couple of weeks I've gone back onto it where I'm exercising regularly and just eating what I've planned for my meals. I'm not eating anything in-between like biscuits or anything like that or having any alcohol or takeaways or anything."*

6.2.2 Theme 2: Dissonance within the caring dyad

While some responses to the illness trajectory generated closeness within caring dyads there were also three primary sources of dissonance: incongruence in expectations and beliefs about health, well-being and quality of life, barriers or 'shutting out' an informal carer's attempts to provide care and, controlling or coercive behaviour.

Two particular sets of beliefs generated conflict. First, the prioritisation of mental over physical health by some informal carers. Second, the differences in what constituted health, wellbeing, and quality of

life. All the interviewed patients confirmed that the impact of mental health and physical health were of equal importance. However, for their informal carers this was not always the case. Some carers reported that mental health took precedence.

"To me, my physical health is no less important than my mental health. My mental health is just as important as my physical health. They are so intertwined with each other. When I'm mentally not well, then there's a knock on effect and I'm physically not well and vice versa…. for example, if I stop exercising or stop eating properly my mental health gets worse." (Sally, patient). *"The word that springs to mind is homeostasis you know, if you're well in your mind then you're well on the way to you know, sorting and managing your body's physical illnesses. I think mental health's the most important aspect."* (Charles, informal carer)

Importantly, the impact of the side-effects of medication, an aspect of physical health, was also viewed differently within the caring dyad. Patients focused on the aesthetic consequences of side-effects and the impact on their self-esteem and confidence. Whilst acknowledged and appreciating these impacts, informal carers were far more concerned about the long-term consequences for physical health conditions such as diabetes or heart disease.

This contrast is clearly illustrated by the different perspectives of Andrea and her husband. As Andrea explained, *"Yes, when I had my first crisis of psychotic depression, I was very thin, I was a size six. When I started taking medication, I put weight on, now I've got to about, to size 14, and I don't feel very comfortable with it and I haven't got used to it, I don't like myself and I'm not very confident. I lack self-esteem and I don't feel like getting dressed nicely."* (Andrea, patient). In contrast, Andrea's husband was worried about the impact of long-term physical health conditions as well as how engaging with these were part of his responsibilities. *"Yeah, naturally it's (the weight gain) ...I do think there's an element of just self-consciousness and being uncomfortable with for her. But for me it's a concern because, you know, diabetes and, having worked in hospital, I'm all too familiar with how prevalent that is…it's naturally a consideration and something that concerns me because it would only add to my own caring responsibilities."* (Scott, informal carer).

For some individuals managing their concerns about side-effects related directly to their self-esteem. *"..you just feel so, so bad about yourself when you, your self-esteem really does plummet with the weight gain."* (Sally, patient). But for Mikkel, her brother and carer, there was concern not only for physical health consequences of this side-effect, but also the potential implications for mortality and

morbidity. *"The diabetes, heart, cardiovascular health and weight gain causing shortening of life and the threat of long-term illness related to these are my principal concerns. But, you know, my sister, well, we all have our vanities and she would really like to look slender and like the models, that's her focus."* (Mikkel, informal carer).

The prioritisation of side-effects differed between patients and their informal carers; informal carers took a longer-term view in relation to physical health while those they cared for were more concerned with the impact on day-to-day activities and issues of self-esteem and self-confidence.

Informal carers appeared to project their beliefs on to the person they cared for creating challenges when these beliefs were different. Claire (patient) described what health, wellbeing and quality of life meant to her. *"For me it would be contributing to my community and to the society that I live in, and part of that for me would be that I would be a taxpayer, i.e., I would be working and I would be paying tax that provides the services that people in my community and my society need."* This account was very different from the understanding of her husband and informal carer, James:

> *"She's had a down patch, which I think she's coming out of…… I know she finds it difficult because she can't just jump back into work, anyway me and the consultant won't let her, and rightly so. But you know that does impact on that because she wants to feel as though she's contributing to society and her community ….and me saying to her, Claire well, you are actually contributing, you're contributing in this way rather than that way, you know. But do you have to contribute to society?"*

Such contrasts in the understanding of the situation and the implications this had for appropriate responses was a source of tension within the caring dyads. *"I do feel like we go into battle sometimes…She'll eat biscuits, cakes, chocolate, pizza, you name it, but when it comes to actual proper meals, even things she used to like, she just won't sit down and eat them."* (Louisa, informal carer). Louisa went on to explain *"She (Denise) is aware that she's breathless, and, you know, I'm cruel, I'm very open with her, and I'll say I say to her: 'Well, what do you know, does that not bother you?' because it would bother me, and she says, 'I know, I know, yeah', so I hit that lovely polite brick wall."*

Informal carers discussed how the advice they provided, often repeatedly was not heeded, for example, explaining food labelling to help make healthy choices or the impact of being overweight. *"…she just didn't get it at all, and the amount of times I've tried to explain things to her. Now, she just shuts me out and stops listening an doesn't want to discuss it. I am not sure if she can't process it, she can't understand."* (Julia, informal carer). However, this lack of ability to be able to

process it or being able to understand it could be related to negative symptoms of SMI, or the cognitive adverse effects of medication such as antipsychotics.

The informal carers felt that in response to these issues the person they cared for withdrew from conversations or stopped engaging in discussions. Sometimes this led to a harsh response by the informal carer or the use of behaviour that might be regarded as bullying, coercive, or controlling. For Sally (patient), her romantic partner and informal carer, Charles, attempted to stop her eating at night: *"…. she comes down during the night and she eats lots of food …. I lock the (kitchen) door at night on a regular basis."* Another patient, Denise, reported their informal carer using shame as a tactic, *"And sometimes my sister (Louisa) will take a photo of me to show me how I look and how round I am around the middle. She took one yesterday and said, 'Look, here, this is what you look like, just look. You know, I'm concerned about just how much weight you've put on, aren't you concerned?'."*

The use of bullying often took the form of projecting the impact of physical health morbidity as opposed to death. This was due to incongruence in beliefs and visions of life of the informal carer and the patient.

Louisa (informal carer) explained: *"I try and shock her (Denise) as much as I can, because I say, 'Well, you know, if you have a heart attack and die, that's fine. If you have a stroke, then you're looking at a different life forever'.* Louisa went on further:

> *"I feel the weight gain has impacted on her quite lot but it doesn't seem to bother her, she just is living with the fact of. If we go out for a walk, she'll look for a bench early on, she's breathless, and she doesn't walk as far. I know she's aware she's breathless, and, you know I am mean. I'm very open with her, and I'll say, 'Hey kiddo! You know, our mother at 88 wasn't like this, you're just 64 and you already have so many physical limitations.'"*

Typically, the impact of these tactics on patient was negative. Denise (patient) explained how this made her feel *"Well, it just makes you feel a bit down and, you know, a bit told off. You know these things but you know she (Louisa) is doing it out of concern, because she's concerned…Being told off about it too much stops me from doing things."*

6.2.3 Theme 3: Balance within the caring dyad

What each individual within the caring dyad wanted for themselves, as an individual, was different from how they framed their needs within the context of the dyad. Many of the informal carers in the

study had their own health needs but were explicit in framing their identity as someone caring for another rather than someone with a long-term health condition. For some carers, the caring dyad created a way to redefine their identity, but also as a way of negotiating greater symmetry and partnership within their relationship. Being a 'partner' in care meant they were less likely to focus on their own health concerns. Informal carers in this study expressed a desire become more informed about psychotropic medication and its side-effects to create balance within the relationship.

> *"I paid for the private scan it come up with severe stenosis and chronic fractured spine of the spine and torn ruptured discs and now I've got a heart problem, I've also got an autistic son who lets us give him massages, he lets us touch him, hug him. When I go home, back home to Sally's house I get all of her and sometimes, not very often, I just think it's too much, but then I just think how lucky I am. It's my job to take care of her you know, a few times in the past she said you know, she couldn't live without us."* (Charles, informal carer).

For some informal carers, however, their responsibilities within the caring dyad led to compromising their own needs whether health related or in their personal or professional life. Their role as an informal carer took primacy as James described,

> *"The GP told me that I was suffering from chronic and acute stress. The GP said not a great deal can be done really unless you just pull yourself out of the situation and have three months holiday. I think on the positive side, I'm quite lucky because I've got no illnesses but I'm pushed to the point of exhaustion really, where I could barely eat, like I couldn't eat until about two or three in the afternoon. I've just got to keep plodding on really and just try to ration the effort I put in."*

Julia (informal carer) recalled how her mother, Stella, found things particularly difficult in the weeks preceding her wedding. *"A few weeks before my wedding she (Stella) had a wobble, not quite a breakdown, but she started kicking off about things, and it's almost like she needs to know that even though something's going on with me I'm still going to be there for her, and as much as I accept it and I put up with it because she's my mum and I love her."*

There were also examples in the research of caring dyads where care was more symmetrical and the person with CMR, MetS and related diseases and SMI also provided care for their informal carer. This finding challenges the notion that the provision of care within dyads is entirely unidirectional and instead suggests shifts occur between roles within a caring dyad. The reciprocity of care suggests greater equality within the dyadic relationship and an overlapping of roles and degree of symmetry of work, particularly in terms of emotional labour.

This was particularly apparent when respondents were asked what was important in their everyday life. *"Oh, when I'm able to go to work to do my shift that I need to do and meet people and be able to socialise to talk to them and feel happy and fit. I also love spending time with my children looking after them and looking after the house and my husband. Yes, my husband is my carer as well. So, yeah these are the times when I'm quite happy and content with life."* (Andrea, patient). *"… so, the best quality of life I can possibly think of, being realistic, is that I continue as if everything is good and stable. Things like looking after my dogs and walking with them. Also, looking after my husband, even though he's my carer."* (Claire, patient)

Diagnosis of an LTC for the informal carer may be a factor in facilitating greater symmetry in roles and caring labour within the dyad. *"...we know what we're already doing (in relation to long-term conditions), you know, I've got diagnosed with diabetes and we did all of that then, changed our lifestyle so it's much more healthy, exercising, eating as healthy as we can and we've cut down on, you know, processed food and stuff, we eat a lot more fruit and veg than we used to."* (James, informal carer).

Louisa (informal carer) was made to feel surplus to requirement despite desires to engage with the pharmacist to be better informed about medication. *"I do think that I need to know a little bit more about the medication and side-effects as well. I'm not sure it's going to impact on my sister, but from the point of view of a carer I think it would be more helpful to have that knowledge. I feel surplus to requirement, slightly redundant because of her knowledge. So, she doesn't feel that she needs me for that sort of thing."* Of course, there is a broader issue here of whether informal carers should know and whether the patient gives consent for this information to be shared.

6.3 Discussion

Chapter Five provides evidence that Informal carers play a vital role in supporting patients with SMI. Published literature reports that informal carers often help patients with SMI to engage with treatment, including psychosocial and pharmacological interventions (486,487). Studies have shown that quality of life may increase for those with SMI who have support from informal carers (488,489). As part of their role informal carers are often an important social contact for patients with SMI who experience high levels of social exclusion, isolation, loneliness, and stigma (490). The finding presented in this chapter explored the utility of the caring dyad as a unit of analysis to understand the impact of

CMR, MetS and related diseases and SMI on the relationship within the caring dyad and correspondingly on the management of illness.

The different roles within caring dyads and their dynamic nature had consequences not only for the way individuals lived and managed their conditions but also on their identity and how they negotiated balance within the caring dyad. It provides an important element missing from existing understandings of dyad: the interaction between dyadic relationships and health outcomes. Furthermore, the role of pharmacy for the dyad where the patient has CMR, MetS and related diseases has not been explored within the published literature. The presence of CMR, MetS or related diseases and SMI generated both enhanced closeness and dissonance within caring dyads as well as challenging role identities and balance within the relationship which in turn affect health outcomes.

The experience of receiving little or no external support for CMR, MetS and related diseases appeared to reinforce togetherness within the caring dyad in this research as it was an arena where they were able to work together as a team. The quality of the relationship within the caring dyad may play a key role in illness management. Those dyads in which respondents took part in activities implementing lifestyle changes, attending appointments and the same pharmacy together reported enhanced closeness. Jointly pursuing activities associated with wellbeing also created a sense of individual and collective agency. Caring dyads in this research attributed the improved relationships to spending more time together and learning more about each other's experiences and perspectives on health behaviour change. This was even more apparent in more symmetrical caring relationships were both individuals within the caring dyad had health needs and support was bidirectional. Evidence in this study highlight pharmacists could provide information about medication and their side-effects to informal carers so that they are better informed; in this way supporting the carer to create more balance in their relationship with the patient.

These results are also supported by the theory of dyadic illness management – caring dyads with a better quality relationship may be better equipped to work together to manage health behaviours (30). The findings in this study also show that taking part in mundane tasks contributes to wellbeing but also to a sense of agency for the patient and their informal carer. This is consistent with a previous research on patients and their informal carers/self-selected partners participating in a programme aimed to increase social support for healthy eating and exercise. All participants reported benefits to the quality of their relationships (29).

For others, the impact of supporting and caring for CMR, MetS and related diseases and SMI was negative, leading to carers exhibiting controlling and bullying behaviours, limiting patient's autonomy, and the person with SMI shutting their informal carer out. This paradoxical finding is linked with a tension highlighted in Chapter Five (in which data from informal carers was presented), specifically, the impact that managing medication and illness has in catalysing the transition the role of a close social contact or family member to an informal carer. In Chapter Five this also took the form of responsibilities and expectations by health services around medication use, its monitoring and management of side-effects.

Carers' choice whether to care is affirmed in policy (491,492). The findings here indicate that this may not be translated into practice. Similar to other published literature (493), for informal carers in this study exercising this choice was problematic in the long-term because healthcare systems relied on the care they provide. Furthermore, the recipient of care in the caring dyads in this study was the patient alone. This highlights an important aspect for healthcare services, negotiation of this changing role must be carried out with attention and care. The focus should be to involve informal carers in a way that does not undermine the sense of teamwork within the caring dyad but that integrates the healthcare team as members of this extended team and that identifies and manages any source of dissonance.

Dyadic management has consequences for the individual identity of those involved, as well as the identity of the caring dyad, all of which evolve over time in response to the illness journey. It widely acknowledged that people have multiple identities that may reinforce or conflict with each other (494). This part of the research study has explored the challenges to the caring dyad as a functional social unit from the perspective of both cared for and carer. In exploring the caring dyad consideration must be given to the extent to which decisions by informal carers compromise their own needs and the experience of role conflict and symmetry and asymmetry in the provision of care within the dyadic relationship.

The findings in this chapter provide evidence that situating the experience of patients within the context of the caring dyad provides an important perspective on understanding the complex interactions that underpin the management of multiple LTCs. Further, the experience of informal carers is understood far better as a product of interaction within a dyadic relationship. Comparing and contrasting views of each individual within the dyad provides a better understanding of the co-

construction of illness management within a caring dyad and the limitations of clinical engagement solely with the patient.

The analysis presented in this thesis draws on interdependence theory (495–497) to understand CMR, MetS and related diseases and SMI and their link with closeness, dissonance, and balance within the relationship between the patient who has these diagnoses and their informal carer: the individuals within the caring dyad. The caring dyad, therefore, provides a critical unit for the analysis of health behaviours (498) where the characteristics (beliefs, identity and actions) of the interacting partners affect the outcomes (behaviour or experience) of one or both individuals within the dyad (496).

There is a need for a new theoretical framework to better understand the management of SMI and comorbidity and multimorbidity that incorporate both dyadic interdependence theory and dyadic illness management theory. This framework needs to incorporate the potential negative behaviours and health consequences of controlling and coercive behaviours. Furthermore, fully account for the impact of incongruence in beliefs affect the management of illness and the impact of informal carer burden.

This study illustrates that CMR, MetS and related diseases and SMI is a phenomenon that impacts on dyads whereby a patient experiences this phenomenon and their informal carer recognises that this has occurred. CMR, MetS and related diseases and SMI have consequences for the caring dyad and can lead to enhanced closeness as well as dissonance in the relationship. As such, the caring dyad relationship inevitably shapes both individual and collective identity and balance within the caring dyad as well as the individual and joint experience of illness.

Although less well explored self-regulation within the context of research on caring dyads or informal carers (499) explains how individuals become aware of a health threats and respond (500). Recognition of CMR, MetS and related diseases in SMI is a shared health threat for both individuals within a caring dyad. Therefore, the caring dyad becomes a key unit for illness management and has collective responsibility for this management. But, as an interdependent team many factors, including relationship-level factors such as communication and relationship quality, can affect the ability of the caring dyad to work constructively and collaboratively towards a managing illnesses such as CMR, MetS and related diseases in SMI. The impact of overall burden for the informal carer which has been explored in the published literature (104,107,501,502) may have a role to play.

Considering the potential challenges of CMR, MetS and related diseases in patients with SMI and the potential role of informal carers it is problematic that research and literature has not explored (i) impact of any type of comorbid physical health illness in patients with SMI and (ii) qualitative aspects of the experiences or perceptions of both the individual with SMI and CMR, MetS and related diseases and their informal carer and (iii) the impact on their relationship through dyad research (iv) the role of pharmacy within this.

The methodological approach used here gives primacy to understanding the relationship dynamics within the caring dyad as a way of understanding the consequences this has for the management of illness. Further, these dynamics can be conceptualised as the main route to dyadic health and functionality within the context of illness.

The findings from this part of the research study provide a starting point for further research into dyadic illness management within the context of comorbid physical and mental ill health. In addition, this research provides evidence for formulating more effective interventions targeted at caring dyads rather than patients living with CMR, MetS and related diseases and SMI. Within this, promoting dyadic implementation of lifestyle changes and identification and reduction of factors that lead to controlling and coercive behaviours. Such interventions will need to engage with both individuals within the caring dyad and address the quality of the relationship within their caring relationship.

First, using the caring dyad as the unit of analysis as has been done here provides evidence that supports the need for more formal recognition of the active role that informal carers play in supporting CMR, MetS and related diseases in patients with SMI. This suggests the best way to ensure patient care is to support the informal carer.

Second, informal carers are vulnerable as a consequence of their caring roles (including burden and workload) and the informal carer not functioning has consequence for the potential dissonance in the caring dyad relationship. Interventions focusing on the informal carer could maximise the benefit for the patient as well as the informal carer and help ensure greater symmetry and balance within the caring dyad.

Thirdly, the nature of the support from healthcare services, including pharmacy services, for the carer should be about helping them to manage their caring role by supporting medicines optimisation. Support for the caring dyad as a unit, focusing on medication side-effects, is an aspect of care that

could involve pharmacists and pharmacy teams. Support for the informal carer might aim to help them with practice issues, for example, signposting to further support, screening for CMR, MetS and related diseases, reducing the burden for example by delivering medication. Focusing on the informal carer has the potential to facilitate a greater longevity in their health and wellbeing and role.

Acknowledgement of the caring dyad as a key target for intervention should incorporate the needs of the patient and the carer. Also, support and education about medication, for example, side-effects. Focusing on the caring dyad allows us to better articulate a treatment regime that has the potential to facilitate long-term benefits in outcomes for both the informal carer and the patient.

The management of illness is as much about learning to live a condition as it is the clinical intervention to treat the condition. A greater understanding of how patients live with illness is gained through appreciation of the social context that they are in and the informal carer is an integral aspect of this. Evidence here shows that part of recovery includes patients and informal carers learning to live with illness. Patient outcomes cannot be fully realised or understood without including the caring dyad as a way of mediating, mitigating, and supporting any treatment regime.

In addition, data presented here in this study also shows that informal carers place primacy on mental health over physical health, which reinforcing typical clinical perspective. In contrast clinicians often are concerned for acute health conditions whereas informal carers have concerns for long-term physical health conditions.

These aspects reinforce behavioural interventions that focus on learning to live with illness rather than surviving it. Using the caring dyad as the unit of analysis reinforces the importance that informal carers place on mental health but interprets the physical health issues in patients with SMI such as CMR, MetS and related diseases in a very different way. Management of long-term impacts on physical health requires behavioural modification but must also acknowledge the long-term consequences of the side-effects of psychotropic medication.

Finally, holistic care should not require simply bringing together the individual aspects of physical and mental illness but rather understanding the consequence of their co-existence, intersections, interactions and how this can be managed. The use of caring dyads permits a better understanding of these aspects because it is situated in the lived experience of the patient and how they live.

6.4 Chapter summary

This chapter has established the importance of the caring dyad as an analytical too. It documented how an exploration of the caring dyad reveals more than simply looking at patients with LTCs and their informal carers separately. Using a qualitative dyadic approach revealed more than the sum of two individual versions of the illness experience. Analysing the dyad as a unit using separate interviews enriches the perception and shared experience of the phenomenon under study.

Unique to this approach adopted in this research is the capacity to analytically contrast and compare individual accounts of illness by members of the same caring dyad. Acknowledging a dyadic view led to the generation of unique themes and subthemes that would not have been identified by focusing individually on patients or carers. This methodology holds much promise for deepening and broadening our understanding of the lived experience of CMR, MetS and related diseases in patients with SMI.

The presence of CMR, MetS and related diseases in SMI had a major impact on the relationship between patients who had LTCs and their informal carers. Its presence led to increased closeness and better disease management, generated dissonance and challenged identity and disease management. Comparing and contrasting transcripts from each individual within the caring dyad led to the identification of three themes: enhanced perceived closeness, dissonance in the dyadic relationship and creating balance within the dyad. Patients and their informal carers attending the same pharmacy enhanced closeness of the individuals within the caring dyad. Pharmacists could support informal carers in their desire to become more informed about medication and its side-effects creating balance within the caring dyad. Differences in beliefs about informal carers' engagement with pharmacy was an example of incongruence in beliefs between informal carers and patients. Another group of key stakeholders in the lived experience of patients are care professionals, their perspective is explored in the next chapter.

Chapter Seven: Cardiometabolic risk, metabolic syndrome, and related diseases in severe mental illness: the role of pharmacy in the lived experience of patients. Findings from care professional interviews

7.1 Introduction

A central aspect of the study involved exploring with care professionals their experiences of providing care for CMR, MetS and related diseases for patients with SMI. Care professionals were recruited from both primary and secondary care to provide a broad perspective from different contexts as well as from a variety of disciplines. Understanding their views, experiences and perceptions of pharmacy and the role pharmacy plays helps identify what was important for both the patient and their practice. These data provide another perspective on how current services and interactions with pharmacy sit and are positioned for these care professionals in relation to this particular patient population. The findings can inform current and future practices.

This aim of this chapter is to discusses the findings of the analysis of semi-structured interviews with 21 care professionals, excluding pharmacists, directly involved in providing care for patients with CMR, MetS and related diseases and SMI. These 21 care professionals included 15 mental health professionals mainly psychiatrists and registered mental health nurses and six GPs (demographic details of the sample are provided in Table 7.1). Detailed information about methods is provided in Chapter Three. Care professional data was coded against the framework developed in Chapter Four from patient data. The key findings are summarised at the end of the chapter.

This chapter contributes to the research question in the following ways:

- to understand the role that care professionals play for patients with CMR, MetS and related diseases and SMI,

- to understand the role that pharmacy plays for these care professionals and for their patients with CMR, MetS and related diseases and SMI.

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Table 7.1: Demographic data of care professionals (self-reported)

One secondary care psychiatric service (mental health NHS trust) and three CCGs were represented in the sample.

Participant pseudonym	Gender	Ethnicity	Age range	Role	Duration of involvement in care of those with SMI
Matthew	Male	White	30-34	Psychiatry Junior Doctor	7 years
Shaista	Female	Asian/Asian British	55-59	Consultant Psychiatrist	5 years
Michelle	Female	White	55-59	Senior Mental Health Dietician	28.5 years
Robert	Male	White	45-49	Consultant Psychiatrist	10 years
Asalah	Female	Asian/Asian British	40-44	Consultant Psychiatrist	14 years
Stephanie	Female	White	40-44	Physical Health Nurse/ Registered General Nurse (RGN) working within adult mental health services	3.5 years
Garrett	Male	White	35-39	Psychiatry Junior Doctor	5 years
Emily	Female	White	44-49	Registered Mental Nurse (RMN) (Inpatient)	23 years
Dianne	Female	Black/Black British	40-44	Care Coordinator - Early Intervention Psychosis (EIP) Services	9 years
Rahul	Male	Indian	30-34	General Practitioner (GP)	
Anna	Female	White	50-54	Occupational therapist (OT) – Community Mental Health Team (CMHT)	30 years
Bernadette	Female	White	35-39	RMN (CMHT)	15 years
Hannah	Female	White	45-49	RMN (CMHT)	4 years
Elizabeth	Female	White	30-34	GP	11 years
William	Male	White	50-54	GP	29 years
Alice	Female	White	50-54	Senior Mental Health practitioner	32 years
Ella	Female	White	65-69	Support, Time, and Recovery (STR) worker	20 years
Joann	Female	White	40-44	Senior Mental Health Practitioner with social work	14 years
Murtaza	Male	Asian	30-34	GP	8 years – daily involvement
Tanvir	Male	Asian	30-34	GP	6 years – daily involvement
Cassandra	Female	White	40-44	GP	5 years

The analysis identified three main themes (see Table 7.2). The first theme related to CMR, MetS and related diseases, psychotropic medication, and their side effects and SMI, psychotropic medication and the management of their side-effects. The other two themes related to the role of pharmacy and the factors that facilitated or limited support from pharmacists, whether in hospital or community settings.

Table 7.2: Themes and subthemes for care professionals

Theme	Sub-theme
Theme 1: CMR, MetS and related diseases, psychotropic medication, psychotropic medication side-effects and SMI	• Provision of information about psychotropic medication side-effects, screening or management relating to CMR, MetS and related diseases • Undertaking screening and management of CMR, MetS and related diseases in patients with SMI – professional jurisdictions, role boundaries and root causes of health inequalities • The impacts of the side-effects of psychotropic medication and negative symptoms of SMI • Difficult conversations • Summary of care professionals' interactions with pharmacists in terms of frequency and depth
Theme 2: The role of pharmacy: barriers	*Actual or experienced* • Invisible and visible interprofessional boundaries *Potential or anticipated* • Stigma and the ability of community pharmacists to engage patients with SMI • Willingness and motivation: a two way street • Lack of privacy and confidentiality in the community pharmacy environment • Professional jurisdictions and role boundaries and the position of pharmacy and pharmacists as part of the healthcare team
Theme 3: The role of pharmacy: facilitators	*Actual or experienced* • Mental health professionals' desire for greater involvement of mental health pharmacists • Advantages of community pharmacy *Potential or anticipated* • Evolving and potential roles of GP practice based pharmacists • Digital maturity and connectivity for community pharmacists • Policies and initiatives as drivers for change

7.2 Theme 1: Cardiometabolic risk, metabolic syndrome and related diseases, psychotropic medication, psychotropic medication side-effects, and severe mental illness

7.2.1 Theme 1: Introduction

Care professionals described the challenges and dilemmas of balancing the mental versus the physical health needs of patients. These challenges and dilemmas, experienced frequently, placed them in a situation of having to balance risks against benefits for not only health but also broader impacts on patients' lives including social relationships, employment, and aspirations for their future. A greater emphasis was placed on the need to manage positive symptoms of SMI. This did not mean they undervalued CMR, MetS and related diseases as physical health side-effects of psychotropic medication but these were seen as long-term problems in the background and less of a priority than mental health during relapses in patients with SMI. The capacity to engage in concordant, shared approaches to making treatment decisions with patients were limited by the impact of psychotic episodes and relapses where patients might not be able to make rational decisions. Other limitations included identifying appropriate opportunities during the illness continuum and worries about the impact of full disclosure of information on concordance to medication.

7.2.2 Theme 1: Detailed description of subthemes

7.2.2.1 Provision of information about psychotropic medication side-effects, screening or management relating to cardiometabolic risk, metabolic syndrome, and related diseases

The challenge associated with identifying and maximising the appropriate opportunity for providing information about the side-effects of psychotropic medication to patients was discussed frequently. Contextual factors were considered important: where the patient was on the illness continuum and the degree of insight. Related to this, care setting mattered; being under the care of the CMHT or primary care team was an indicator that the patient's treatment and mental health status were more likely to be stable. Facilitators for effective information provision included face-to-face interactions between clinician and patient. Having a diagnosis of SMI was considered by some to be associated with impaired capacity or health literacy. Others mentioned the nocebo effect (503). While there was an awareness of SDM processes these were not part of current practice by respondents.

A face-to-face conversation with the patient incorporating written information as part of the discharge process was considered ideal because the patient and treatment were stable enough to maximise

impact. Respondents suggested that the degree of patient insight impacted on how this information was perceived and understood *"…where patients have been acutely unwell and are still in recovery their insight might not be complete, your explanation that things might get better or need a bit more time can be met with resistance. It is important at that point to communicate it in a way that is digestible and gives them enough information to feel that it's beneficial to continue."* (Garrett, Psychiatry Junior Doctor).

Clinicians reported that patients often reacted with upset, shock or anxiety to the degree, extent, and speed of side-effects, particularly weight gain, once insight had been regained after a period of loss of insight. This, respondents suggested, impacted negatively on the therapeutic alliance, *"I had one patient who went up three dress sizes in a month. When she got mentally well and stable it was a bit of a bombshell! Honestly, I thought she was going to stop the medication there and then."* (Bernadette, RMN).

The complexity and depth of information provided was usually adjusted *'in situ'* in response to needs gauged during the course of the discussion itself. Discussions were also informed by care professionals' prior experiences. Respondents sought to strike a balance between being authoritative and the need to maintain a patient-centred approach.

GPs in this study spoke about health literacy. *"You've got to think about how literate these people with SMI are, how much they understand about some of these medical words that get banded around. I think that they don't quite understand how severe cardiovascular disease can be."* (Elizabeth, GP). Other GPs and mental health professionals also spoke about health literacy more broadly. *"This is about a patient's awareness and motivation to understand, access, evaluate and apply information and health. We are also asking them to make decisions and make judgements in their everyday lives about healthcare, health promotion, prevention of disease and desires to maintain a quality of life."* (William, GP).

Many felt it was easier to discuss CMR, MetS and related diseases when patients were under either the care of the CMHT or primary care as the patient was usually more mentally stable and were more likely to have regained full insight but were faced with a paradox: *"It's still slightly shutting the door once the horse has bolted in some ways. There are things that you can do but by the time you've got a diagnosis of type 2 diabetes actually, the atherosclerotic pathology is already there."* (Robert, Consultant Psychiatrist).

Many GPs made comparisons between individuals with SMI and the general population. Two GPs said they felt that patients with SMI had lower levels of health literacy due to lower socioeconomic status and the presence of cognitive and functional impairments. Rahul, a GP, expressed his opinion about capacity: *"In severe mental illness they don't have or won't have any capacity to understand, they're not going to understand that their medication can sometimes be bad for the heart or make them put on weight*."

Some respondents suggested that warning patients about side-effects that they have not experienced created a nocebo effect. *"The issue is that you don't want to put that in their mind early on, otherwise they'll come back and tell you they've got that side-effect."* (Tanvir, GP). Concerns were also expressed that the provision of comprehensive information to patients about side-effects would lead to refusal to initiate medication, variable, or non-adherence. *"I guess we are all scared in some way that patients will just walk away from medication."* (Emily, RMN). Some also suggested that they felt conflicted about this issue, that worries about the nocebo effects was at odds with their medical, ethical, and moral obligation to be open with the information they provided about medication.

SDM was mentioned by some GPs and mental health professionals and perceived as having a potentially positive impact. However, understanding of what it really was or how to put it into practice was lacking. It was felt that SDM required a high degree of negotiation and exploration of patient views and feelings. In addition, those who mentioned it felt put off as *"…it would take quite a lot of extra time that I just don't have."* (Rahul, GP). This approach was also felt to conflict with concerns about the impact on adherence of sharing information in full.

7.2.2.2 Undertaking screening and management of cardiometabolic risk, metabolic syndrome, and related diseases – professional jurisdictions, role boundaries and root causes of health inequalities

The delivery of high quality effective safe care within an interprofessional context was highlighted as a big challenge. Interprofessional working was described as a complex endeavour and problems fell into three categories: communication, role overlap and role confusion. Broader issues including the need to address the root causes of health inequalities were also mentioned. The overriding consensus was that provision of care for CMR, MetS and related diseases was a collective activity but the division of labour between staff for specific activities was unequal. Some groups felt that their role was

undervalued this reflected unequal power. Respondents felt that interprofessional working was best facilitated if every team member had their own distinct role and an awareness of the roles of others.

Many spoke about the ambiguity in professional boundaries and this was related to confusion about responsibility for some aspects of work and challenges in the identification of distinct roles. Recent drives to improve care in this area, such as parity of esteem, meant that roles and responsibilities often overlapped, shifted, and changed over time. The challenge of coordinating care was also seen to be magnified by a complex care system. Many spoke of the increasing numbers of heterogeneous groups trying to collaborate sometimes in very erratic ways rather than along clearly defined linear pathways.

> *"Discharging patients with complex and concomitant multiple health needs like heart disease, diabetes and schizophrenia that requires ongoing care to a residential home for example, is littered with potential areas where things get missed or delayed due to poor coordination. This can lead to poor outcomes. This is made worse by the complex health system, care responsibilities pass between professionals, organisations, care sectors, and economic sectors."* (Garrett, Psychiatry Junior Doctor).

Tensions were reported between members of the same team and more prominently across care boundaries for instance between secondary care mental health services and other specialities. Psychiatry junior doctors reported that there was an 'unwritten' rule on inpatient wards that they were largely responsible for the care of CMR, MetS and related diseases for those with SMI, with greater expectations falling on the shoulders of GP trainees and foundation doctors. Psychiatry junior doctors discussed that they had had conversations with consultant psychiatrists who admitted that their knowledge and skills in general physical healthcare were not necessarily up to par as they felt out of touch after years of practice as a psychiatrist.

For those junior doctors on their journey to specialising in psychiatry there was a feeling of *"…becoming less and less aware of your blind spots."* (Garrett, Psychiatry Junior Doctor) and that this was disconcerting and felt perilous. "*We're quite physically isolated in a way from medical specialties and primary care and this can provoke issues in management of cardiometabolic risk and mental health,"* which also led to psychiatric doctors having a "*low threshold for seeking intervention in terms of A&E (accident and emergency) or specialist help for things that maybe could turn out to have been inappropriate or certainly maybe a little bit safe."* (Garrett, Psychiatry Junior Doctor). Psychiatry junior doctors were also worried about their competency and knowledge being questioned if they contacted other or more senior doctors from the acute trust with queries.

GPs felt frustrated and said care was hampered by inadequate information communicated to them from secondary care psychiatric services. For some, it was not clear whether this had arisen due to patient refusal or oversight. *"Yeah, a lot of the time the shared care agreement is incomplete. It's not clear as to whether they just haven't done the blood pressure, bloods, weight, or waist circumference or whether the patient has just refused. We're in the dark.*" (William, GP). Two GPs in the sample said that they felt that their care was undervalued as they felt obliged to undertake the screening that had not taken place in secondary care.

Many psychiatric doctors were critical of health services in not providing a more holistic approach to care and addressing the root causes of health inequalities. *"Creating conditions for good health and wellbeing requires a broad whole person approach, addressing the root causes like poverty, and empowering people to make informed choices. This is not just about us in the mental health treating and giving information about side-effects. It needs targeted system wide action at local, national and global level."* (Robert, Consultant Psychiatrist).

7.2.2.3 The impacts of the side-effects of psychotropic medication and negative symptoms of severe mental illness

The impact of medication side-effects was discussed alongside the impacts and relationship with SMI, CMR, MetS and related diseases as well as other physical health, mental health, social, emotional aspects of patients' lives. Care professionals placed emphasis on the need to use antipsychotic medication to treat positive symptoms of SMI and that this was often their priority. It was not considered easy to always differentiate between the negative symptomatology of SMI and the sedating side-effects of psychotropic medications. Usually, an emphasis was placed upon the implications of the combined effect on a patient's ability to engage with interventions for CMR, MetS and related diseases.

Some mental health professionals mentioned the impact of medication on hunger and appetite. *"These drugs can really drive hunger for some patients, it can be difficult for them to control this."* (Dianne, RMN). All mental health professionals that were interviewed acknowledged that psychotropic medication alleviated symptoms but that they were not curative. Hannah described moments when she felt extremely uncomfortable observing the burden of weight gain in the face of residual symptoms and limited therapeutic benefits for some patients. "*It's not like medication makes that all better …they still hear voices every day and I think to myself, why do we continue to do this to them? I*

watched someone balloon, if that happened to me, I would be thinking 'that's not great, is it?'" (Hannah, RMN).

Factors contributing to the marginalisation of patients were discussed including diagnosis and treatment side-effects such as weight gain and that these ultimately disempowered patients "…*you're not working any more, you've probably lost all of your social network so you're less active and isolated. You've fallen right down the social ladder and, you've hit skid. Who's fighting for them? They haven't got a voice. How are they supposed to ask for help with diabetes or weight?"* (Hannah, RMN).

Garrett described his understanding of the implications and impact on perceived identity and adherence "*They can stop the medication. They're balancing all of that change in their appearance with a change in how they feel about themselves and that's really challenging. The side-effects can be quite debilitating with severe implications for their relationship, how they view themselves and how they view themselves in the context of having a really difficult mental illness."* This highlights the profound consequences of the side-effects of psychotropic medication.

Dianne, an RMN who worked in an EIP team described how patients' experiences of CMR, MetS and related diseases damaged the relationship between the team and the patient. One of her patients, who, overweight before starting olanzapine gained further weight and then developed diabetes and as a result stopped olanzapine. *"During a consultation, the patient exclaimed 'You guys gave me diabetes!'"* For some patients, the medication and its side-effects were synonymous with the clinicians providing treatment.

GPs' discussions focused on the link between psychotropic medication, SMI, LTCs and comorbidity, for example, the co-existence of diabetes and SMI. All the GPs interviewed reported that a significant proportion of their patients with SMI had LTCs and multimorbidity. The negative consequences of these conditions on patients' quality of life were a particular concern. A significant number of GPs reflected on their experiences. *"Our patients with SMI have difficulty in recognising certain physical phenomena as a symptom of comorbid disease. They often find it very laborious to communicate their physical needs and arranging appointments, they often they seek help at a relatively late stage."* (William, GP). Many GPs said that this underscored even more the need for care to be easily accessible.

7.2.2.4 Difficult conversations

Weight gain, being overweight or obese can be seen as illustrative indicators of the lifestyle factors that care professionals described as being subject to *"difficult conversations"* (Emily, RMN). Data analysis identified moral underpinnings within accounts of these symptoms. Weight gain was constructed as a risk to health drawing on the assumptions that patients should and can lose weight through implementation of behavioural change interventions.

There were two ways that moral underpinnings were both resisted and reinforced by clinical staff: 'cautious communication' and 'patients will think we are labelling them as fat'. The use of 'cautious communication' with regards weight, being overweight or obese by care professionals illustrated that they did not view these as value-free interactions but rather conversations that took them off 'safe ground' which might result in conflict with the patient. This appears to reinforce a moral discourse about weight. Respondents concerns that 'patients will think we are labelling them as fat' suggests both resistance and reinforcement of this moral discourse. Respondents concerns about how patients might interpret their conversation as a label that they resisted. Care professionals use of the term 'fat' reinforced a moral discourse about weight.

Reflecting in interviews on the problems of talking to patients about weight gain and being overweight or obese care professionals situated themselves as being caught in a precarious position. Clinical staff reported that they had worries and concerns that conversations about weight would subject patients to judgement and reinforce stigma yet at the same time they also wanted patients to take responsibility. *"You don't want to appear as if you're blaming them. If they feel like you are, or they're pass the buck and blame onto something else that can be quite tricky because really some of it is their responsibility. Sometimes we feel that they don't want to take that responsibility, it's hard, we want to avoid getting in a fight about it."* (Rahul, GP). Weight management was also described as being akin to a struggle with mental health in that it was a long and difficult journey.

Approaching the topic of weight with patients without appearing to lack sensitivity was perceived as a fragile job by the clinicians interviewed in this study. Many laboured on how this might be done. Concerns were also raised that having conversations about weight might discourage patients from seeking support and advice about other health issues. Care professionals oscillated either between initiating such conversation themselves or, only having a conversation if it was initiated by the patient. Those who chose not to initiate the conversation themselves justified this on the basis that they did

not want to be yet another person discussing weight and that such conversations could serve to stigmatise and marginalise patients. *"I need to be quite careful……I don't want to sound like I am being presumptuous that they aren't thinking about it or haven't tried something before I mention it, there are complicated issues around what happened before this point."* (Emily, RMN).

Those care professionals who initiated such conversations reported that they took a careful approach to avoid placing blame on the patient and instead framing weight as a CMR, or risk for MetS or related disease or other physical health issue. This provided a 'safe grounds' for discussion. *"It is easier to talk about weight when the patient can appreciate it, see it or feel the direct impact it might have in a tangible way. This is an open door to that conversation. For example, if they have joint pain and the weight gain has made that worse or the joint pain is stopping them from doing other things*." (Ella, STR worker).

Concerns were also raised by respondents of being seen to be pushing a healthcare agenda that added strain to the therapeutic relationship. This fed into concerns that they did not want to be perceived as authority figures overly focused on weight gain and ascribing weight as the root cause of a myriad of illnesses. Some care professionals recalled experiences early on in their careers where patients expressed frustration with 'simplistic' advice. *"When I first qualified, I had patients who told me that that my advice was useless, that there's no point in just saying lose weight. Patients will tell you how that's really unhelpful and that they've heard it a hundred times before."* (Tanvir, GP).

In the interviews, respondents expressed the desire for patients to take responsibility and this was framed as a need to respect autonomy around decision-making: *"It is important to arm patients with information…I had a patient that regularly visited the local KFC, they were a bit overweight. My role was to advise on the importance of diet and exercise and balance that with the need to respect their capacitous decision to live the type of life they want to live. I don't want to be too pushy to the extent that it's going to damage the doctor-patient relationship."* (Matthew, Psychiatry Junior Doctor).

CMHT professionals visiting patients at home took a practical approach to facilitating this responsibility through empowerment with information about gradual changes to eating or physical activity. This acted to move the focus of the conversation away from weight *"…it's getting them to look at what they buy because some of the cheaper foods will be high in salt, fat and sugar. So, it's about saying to them that's okay that but let's try and reduce how much you buy or swap a few items."* (Alice, Senior Mental Health Practitioner).

Many care professionals discussed in the interviews that they felt ill equipped to support the implementation of lifestyle interventions and that this further contributed to their nervousness about providing advice. Instead, they often chose to signpost other services, such as a dietician, but knew that access was limited by long waiting lists and limited availability. Respondents understood that weight gain, being overweight or obese was a complex phenomenon. *"I don't necessarily feel like I can provide the appropriate advice about eating and food and weight, there are lots of factors like the mental health medication and self-neglect and lack of insight. Even the general public without mental health difficulties find it hard, there's a lot of behavioural and emotional issues around eating."* (Hannah, RMN).

Many accounts included a recognition that encouraging adherence to medication further contributed to the issue of weight gain. Further, that some of the drivers for eating were not within the volition of the patient and broader issues such as social determinants of health and health inequalities needed to be considered.

7.2.2.5 Summary of care professionals' interactions with pharmacists in terms of frequency and depth

Care professionals' interactions with pharmacy were encapsulated by two 'scenarios' based on the frequency and depth of such interactions.

- Scenario 1: Low depth interactions that occurred at high frequency

  Described as lacking in significant impact for CMR, MetS and related diseases in patient with SMI. For mental health professionals that worked on inpatient wards there were daily interactions with mental health pharmacy teams or mental health pharmacists. GPs described fewer interactions, which occurred around two to three times a week with community pharmacists. Mental health professionals working in CMHTs described weekly interactions with community pharmacists and mental health pharmacists. Examples of interactions described include pharmacy technicians topping up stocks on the ward and telephone conversations about prescribing errors or amendments.

- Scenario 2: In-depth interactions that occurred at low frequency.

Described as having a significant impact for CMR, MetS and related diseases in patients with SMI. Such interactions were reported as occurring after a proactive enquiry by a health professional to a pharmacist who they were familiar with because of an existing relationship founded perhaps in sharing a common physical space such as an inpatient ward round or patient review in a GP surgery. Some care professionals described the familiar and existing relationship as being a professional working relationship. Others mentioned their own personal experience of care provided by a pharmacist that had then led to them proactively seeking advice about their patient's care.

7.3 Themes 2 and 3 Introduction

Barriers and facilitators to interactions with pharmacists were discussed by care professionals from two perspectives: their own relationship with pharmacy and their beliefs about relationships of their patients with pharmacy. These were not mutually exclusive. Community pharmacists and practice based pharmacists were the only type of pharmacy staff or professionals mentioned by GPs. Mental health professionals other than psychiatry doctors mentioned mental health pharmacists, mental health pharmacy technicians and community pharmacists. Psychiatry doctors spoke about mental health pharmacists and mental health pharmacy technicians. Shared physical space was considered fundamental and central to discussions about relationships with pharmacists. Discussions about care professionals' views of pharmacists' relationships with patients were understood in terms of the elements necessary to establish and maintain a therapeutic relationship.

7.4 Theme 2: The role of pharmacy: barriers. Detailed description of subthemes

7.4.1 Actual or experienced barriers

7.4.1.1 Invisible and visible interprofessional boundaries

Care professionals based in psychiatric settings, mental health professionals, and psychiatric doctors, said communication with mental health pharmacists was largely task orientated, reactive, and focused. The sole purpose of such communication was achieving a particular outcome in response to a specific medication query to facilitate dispensing medication. Many of these conversations took place over the phone with the mental health pharmacist in a different building and related to urgent and acute high risk medication prescription issues "…*it's all on the phone so you never actually know like who you're talking to or you can't put a face to the name and we're all busy so it's often quite terse because you're in the middle of something."* (Garrett, Psychiatry Junior Doctor).

In addition, these encounters were viewed as a source of potential conflict with many queries relating to omissions on prescriptions, dosage queries, medication interactions, medicines reconciliation and prescribing errors all of which held connotations of fault or error on the part of the doctor. This was further exacerbated where there were *"…multiple calls about the same thing, chasing things."* (Garrett, Psychiatry Junior Doctor).

What were viewed by pharmacists as less urgent issues such as reminders for blood tests for CMR, MetS and related diseases were conveyed by notes attached to a prescription, which *"we tend to ignore if I'm honest. It feels like those electronic reminders and alerts keep popping up all the time. Sometimes it just feels like it is just an extra layer between me and the prescription, which I don't need when it is busy."* (Bernadette, RMN). Two consultant psychiatrists reported proactively initiating and interaction with mental health pharmacists with whom they had already established a professional relationship for specific queries about the management of diabetes.

The notions of team and teamwork were invoked widely in discussions with care professionals working in psychiatry across all settings; this was discussed as being central to collaborative working and delivery of services and care to patients. Contributions of pharmacy services and presence of pharmacy technicians on the wards were noted as being valuable in terms of medication supply and stock control but there were strong opinions about the need and benefit of having a mental health pharmacist consistently present on multidisciplinary ward rounds and reviews rather than an occasional appearance. "*A collaborative approach would be better for the patients and better for our relationship and how we move forward as a team together.*" (Garrett, Psychiatry Junior Doctor).

The possible barriers to having a pharmacist consistently present and visible as part of a team were commonly discussed and included the challenges of professional socialisation and hierarchies heavy workloads and demands. *"Our current mental health pharmacist is expected more in the dispensary in the pharmacy building, her availability to do things on the ward like patient counselling about weight gain with antipsychotics is limited.*" (Robert, Consultant Psychiatrist). Once again apparent were visible boundaries such as separate buildings as well as other competing demands on pharmacists' time. Interviewees believed that primacy was given to mental health pharmacists' dispensary duties over patient work on the inpatient ward. However, given that this sample was from one secondary care psychiatric service then this may be specific to that service.

Knowledge of roles and responsibilities was also mentioned. *"Pharmacists are less of a ready presence in ward rounds so it can be tricky to know what pharmacists can and can't do and exactly what their skillset is."* (Matthew, Psychiatry Junior Doctor). Finally, the effects of organisational structures such as the ratio of mental health pharmacists to patients was noted, *"I don't think there are enough mental health pharmacists for the number of patients we have on our wards never mind our outpatient clinics."* (Robert, Consultant Psychiatrist).

All of the psychiatric doctors mentioned a lack of deep relationships with a pharmacist but also mentioned that a key element of nurturing relationships with a pharmacist and the pharmacy department included having their staff on the ground and part of the day to day running of the ward. As Bernadette stated, *"…unless you are willing to get your hands dirty on the ward then you are not really part of the team!"* (Bernadette, RMN). The sense of shared experience was understood as important at the level of individual respondents but also more broadly.

Many care professionals mentioned that the often invisible disciplinary boundaries that prevented effective collaborative working may recede over time if practice and experience was shared daily. Many of the doctors that were interviewed noted that they would be inclined to share information across the interprofessional boundary. *"It's important not to work in tribal silos because it can be toxic for patients."* (Matthew, Psychiatry Junior Doctor).

Community pharmacists' roles in CMR, MetS and related diseases were seen by GPs to be limited and centred around conversations about medication errors. Pharmacists were seen to be working to strict normative standards and dispensing punitive measures e.g., documentation of medication error. Two GPs said that despite knowing their local community pharmacists for a long time interactions were superficial. Rahul characterised his local community pharmacist as pernickety. *"The pharmacist has to respect clinical autonomy…at the moment it feels like they've got a fixed rigid idea of: 'it says this in the BNF and it has to be this dose'…the sort of person that makes a good community pharmacist is someone who's quite precise and picky and checking things … but it helps to be flexible and respect clinical autonomy."* (Rahul, GP). This may also be an assertion of medical dominance by this GP.

Findings reveal invisible boundaries associated with different disciplinary backgrounds were apparent. For pharmacists, their focus on prescriptions, differences in knowledge about patients due to variable access to patient data between them and other care professionals and different ways of working and communicating between professions all generated invisible interprofessional boundaries. Visible

interprofessional boundaries arose from the physical separation of working in different buildings. Both invisible and visible interprofessional boundaries that existed between care professionals and mental health pharmacists and community pharmacists that appear to serve in positioning pharmacists in traditional stereotyped roles. Namely, detecting prescription errors and dispensing medication. The absence of substantial or significant relationships and interactions contributed to this limited framing of pharmacists. Some care professionals acknowledged the underlying cause of such limitations as well as providing potential solutions.

7.4.2 Potential or anticipated barriers

7.4.2.1 Stigma and the ability of community pharmacists to engage patients with severe mental illness

All care professionals worried about the impact that stigma might have on the effective engagement of community pharmacists with patients particularly in the absence of an established relationship. *"Stigma might deter patients seeking advice about weight or exercise. They might feel ashamed or embarrassed to seek help particularly if they are very overweight and they can't necessarily control their eating due to medication and are making what might be seen to be bad choices."* (Robert, Consultant Psychiatrist). This psychiatrist describes a mix of both treatment stigma and internalised stigma.

A few GPs and mental health professionals queried whether stigma might exist amongst community pharmacists which might help explain the low levels of interaction. *"If these patients are already seeing their community pharmacist regularly anyway then why does there seem to be very little current engagement? It can only make you question if there is some stigma there, what are their (community pharmacists) attitudes and beliefs?"* (Cassandra, GP).

Respondents emphasised the need for the interpersonal skills required to form sound therapeutic alliances with patients with SMI. *"Communication skills form the basis of most interventions if, for example, you are going to try to get a patient with SMI to cut down or stop smoking there's an art to doing that effectively. A lot of which is rooted in how you talk about it."* (Alice, RMN). Such skills were described as the building blocks or *"...nuts and bolts, the basic techniques and principles in which everyone engaging with mental health patients need to be fluent."* (Alice, RMN). It was felt that community pharmacists were currently unlikely to have these skills. No concerns were expressed about stigma or patient communication skills amongst mental health pharmacists.

7.4.2.2 Willingness and motivation: a two way street

Willingness and motivation were seen as key for pharmacy to deliver screening or interventions for CMR, MetS and related diseases. "*The patient has to make a decision to attend the community pharmacy. Pharmacists in all settings have to want and be willing to provide these services."* (Anna, OT). Mental health professions mentioned that within the primary care setting those patients who have the greatest need for support might be the least likely to either attend the community pharmacy or initiate a conversation. *"We all know that patients who need care the most are the least likely to seek it. Conversely, those with fewer needs tend to use services more and more effectively, these are your concordant patients who attend all their appointments; they are motivated to begin with."* (Robert, Consultant Psychiatrist).

Joann (Senior Mental Health Practitioner) discussed how this might be tackled. *"Posters or leaflets might help. Plant the seed. There might be a window of opportunity to start a conversation, either the patient could start this conversation, but a good pharmacist could identify an opportunity. Avolition is a big problem in this group.*" Some GPs in the study commented that there would always be a group of patients with CMR, MetS and related diseases and SMI, who sat on the margins of care. Such patients, she said, that were notoriously difficult to engage with by all health services and would benefit from some sort of tailored outreach programme.

7.4.2.3 Lack of privacy and confidentiality in the community pharmacy environment

All care professionals expressed concern about the lack of privacy and confidentiality that might be experienced in the community pharmacy environment. The retail environment in which community pharmacists practice further contributed to this perception *"… patients might not view community pharmacists as a healthcare professional; they might see them as glorified shopkeepers or owners …"* (Cassandra, GP).

Respondents also perceived patients as expecting a rapid service from community pharmacists and perhaps this was because of the retail environment in pharmacies. This might change the view of the nature of community pharmacists as a profession as they provided a service associated with retail staff rather than a health professionals. The brief superficial transactional interactions that commonly took place in community pharmacies were not viewed as something that patients would see as a consultation where they might receive lifestyle advice. *"One of the issues with community pharmacy is*

that it is viewed as being all about in and out, drop off your prescription and pick up your meds, they, patients wouldn't obviously see is a place or health resource like they see a GP." (Tanvir, GP).

GPs showed the greatest level of awareness of consultation rooms in pharmacies and a few saw this use as key to their signposting: *"If I were to start routinely signposting and referring my patients with SMI to the community pharmacy for a blood glucose check then I would want to be able to assure the patient that they would use the consultation room. Also, that they would see the same regular pharmacist each time they went. This would also help with establishing trust."* (Elizabeth, GP). The importance of trust and familiarity with community pharmacists are highlighted in Elizabeth's comments.

Interestingly, and in contrast to these views, mental health professionals in this study said that the use of a consultation area or room in a pharmacy by patients with SMI was both desirable and undesirable. *"Patients might feel like they are being singled out. This can propagate existing stigma associated with their mental health diagnosis. From my recollection the consultation rooms are often small and a bit enclosed. Being taken away to a small room might make them feel uncomfortable."* (Robert, Consultant Psychiatrist). Mental health professionals stated that patients should be made aware of the existence of these facilities and then given the choice as to how they wished any conversation to take place.

7.4.2.4 Professional jurisdictions and role boundaries and the position of pharmacy and pharmacists as part of the healthcare team

All care professionals interviewed felt that the professional jurisdictions and role boundaries and the position of pharmacy and pharmacists as part of the healthcare team needed greater clarity. Care provided for CMR, MetS and related diseases could be facilitated if this could be resolved. *"It's important to inform teams about the pharmacist's roles; this informs expectations about what pharmacist's responsibilities are. If it's not clear it can make collaboration difficult. We might be missing opportunities to signpost to pharmacists as a result."* (Emily, RMN).

Other respondents' comments held a notion of pharmacists knowing where their place was and in part speak to a traditional view of the medical hierarchy. *"I'm broadly aware of the skillset of a pharmacist but not in terms of the minutia of what pharmacists can do and what is outside their remit, so it's not so much a question of whether pharmacists can be involved in the metabolic monitoring and screening*

of patients because, absolutely yes, but it's where that involvement starts and where it ends and what things pharmacists can do and what things pharmacists wouldn't necessarily do." (Matthew, Psychiatry Junior Doctor).

A few care professionals felt that the disposition of pharmacists was a contributory factor. *"Pharmacists could definitely do with being a bit more assertive and confident. This might help in establishing their presence as part of the team. Being hidden away in the dispensary isn't good. They must be able to take the initiative."* (Tanvir, GP). Tanvir's comments highlight a stereotyped role for pharmacists.

Many respondents felt that such perspectives should be balanced with the need to determine the needs of the team and patients. *"Each team that provides care has unique needs and patient groups. Pharmacists should invest energy and time getting to know and learning about the team they are joining. This will make it easier for them to provide services that add value."* (Asalah, Consultant Psychiatrist).

Respondents also felt that the skills and knowledge required for different areas might vary and that additional training might be required. *"Practising within a primary care team, for example, requires unique skills and expertise that will challenge even the most experienced clinicians. Training might be required."* (William, GP). A few GPs also mentioned the importance of understanding local healthcare infrastructure and essential if pharmacists were to signpost healthy lifestyle programmes.

7.5 Theme 3: The role of pharmacy: facilitators. Detailed description of sub-themes

7.5.1 Actual or experienced facilitators

7.5.1.1 Mental health professionals desire for greater involvement of mental health pharmacists

Regardless of their current role or place of work all mental health professionals expressed favourable opinions towards greater, regular, and consistent involvement of mental health pharmacists. For respondents, mental health pharmacists were seen to have *"…specialist knowledge, skills, training and experience with patients with SMI. They're quite good at paying attention to all the detailed stuff like metabolic bloods and screening, when they are due and all the intricacies of side-effects like diabetes and problems with lipids."* (Emily, RMN).

A number of potential future roles for mental health pharmacists were identified including being an integrated part of the team in inpatient outpatient settings, CPA meetings, MDT meetings and counselling patients on side-effects.

> *"There have always been gaps I feel, no one spends enough time talking about medication or what it means to be on medication, to take it for the rest of your life, what it means to have a diagnosis of bipolar disorder or schizophrenia and how this can affect your life. The impact of the illness and side-effects can change over time – I feel that patients should at least have access to the opportunity for some regular input over a long period of time."* (Emily, RMN).

Emily's comments illustrate her understanding of the role that medication plays for patients and the benefits of the increased involvement of pharmacists in relation to psychotropic medication.

Mental health pharmacists' knowledge of both psychotropic and non-psychotropic medication was highlighted as particularly useful by some mental health nurses and doctors in the study. *"They have knowledge and can access resources about all medication, not just antipsychotics or mood stabilisers, but also about managing diabetes and heart problems."* (Hannah, RMN). *"One of our pharmacists flagged up with us that one of our patients was considered to be at high risk of CVD because they had type 2 diabetes and were over the age of 40 years old and advised starting a statin. This might have been missed otherwise."* (Asalah, Consultant Psychiatrist).

7.5.1.2 Advantages of community pharmacy

Despite the barriers already considered, GPs and CMHT staff said that they felt that community pharmacy had advantages to offer over other primary care services such as the ease of access, convenience, and absence of an appointment system. *"…you don't have to make an appointment to see a community pharmacist."* (Elizabeth, GP). *"Community pharmacists are at the frontline of wellbeing in terms of like prevention sort of and the management of emerging and long-term conditions, like doing blood pressure, and a few of my patients have good relationships with them."* (Ella, STR worker).

For some of the respondents the influence of their own personal views and relationships with community pharmacist influenced their own clinical practice. *"I sent my husband to the pharmacist, told him to go there first, no rush, go and have a check I said to him. I don't think people realise how qualified they are and that they are able to give health promotion advice. They're more clued up in the medication than doctors. I always signpost my patients there."* (Stephanie, RGN). Stephanie elaborated

further *"Well it's about building confidence around those things, like it might help getting a finger prick test for diabetes. So, this might mean that in the pharmacy you'll get a diagnosis or concern flagged up and obviously your GP's going to be there to follow you up."* These comments illustrate the view of a collaborative approach that could be taken in the screening by the community pharmacist and management by the GP.

7.5.2 Potential or anticipated facilitators

7.5.2.1 Evolving and potential roles of general practice based pharmacists

Whilst it was acknowledged that practice based pharmacists had new and evolving roles, GPs were in favour of increased collaborative working with them. Three GPs interviewed said they had already experienced the benefits associated with practice based pharmacists and suggested potential models of care that would benefit patients with CMR, MetS and related diseases in patients with SMI. They stressed the potential of practice based pharmacists supporting medicines optimisation, responding to medicine-related problems and errors during care transitions.

Murtaza said that within the current healthcare climate practice based pharmacists had a lot to offer. *"We take care of an ageing demographic and as a result we manage a large number with multimorbidity, co-existing diabetes and hypertension and SMI for example, and polypharmacy. A large percentage of patients with mental health conditions are taken care of within primary care. The role of a GP practice based pharmacist within this has great scope."* (Murtaza, GP).

Tanvir (GP) discussed the role of practice based pharmacists in medication reviews.

> *"Medication reviews are essential. We don't have enough time to do in-depth medication reviews. Also, checking that the patient is happy, willing, and able to take their medicines. The pharmacist can take a focused approach to specific medication related problems. Our pharmacist was instrumental in one of our patient's care recently – helped towards preventing one of our patients with schizoaffective disorder stopping his insulin."*

William, a GP, reflected on his experiences: *"Having a pharmacist in the surgery to easily contact who is part of the team is invaluable. Our pharmacist has ten minute slots for each patient, does all the bloods, physical health checks and onward referrals for lifestyle interventions. It has been enormous help to our workload."* Additional non-patient facing roles were also identified in the interviews such as the involvement of pharmacists in developing and implementing national strategies and

programmes. Part of what was emphasised by the respondents was the importance of shared physical space reinforcing the previous sub-theme relating to invisible and visible interprofessional boundaries.

7.5.2.2 Digital maturity and connectivity for community pharmacists

Community pharmacists' access to detailed patient clinical data was seen as critical to increased collaboration between GPs and community pharmacists and patients. *"Community pharmacists should be able to see patients' medical conditions, prescribed medications, path lab and blood results, and treatment plans. This would enhance communication between us and enhance our professional relationship as we would all be singing off the same hymn sheet."* (Murtaza, GP). Another GP went on to say that such access would also help ensure continuity of care and to avoid duplication of effort.

Such an approach was also seen by respondents as helpful in other ways. First, *"It might help because it might result in fewer medication-related questions at the patient's first post discharge appointment with the GP."* (Tanvir, GP). Second*, "It is also likely to reduce the constant interruption of the workflow of our reception staff or other staff where the pharmacist might need important patient information before they can dispense the medication. Ultimately this will support more efficient communication."* (Murtaza, GP).

Two GPs discussed the potential benefits for patients related to care transitions for patients. *"If patients are discharged from the mental health trust, they may need clarity about medication changes or need an immediate supply, community pharmacists can help."* (Tanvir, GP). *"If they have this information to hand the patient can see them quickly and find out. This might be particularly helpful during the evening and weekend when we are closed but they're not."* (Murtaza, GP). Again, accessibility and convenience were stressed as important. Other respondents mentioned that access to patient information might increase patient trust and this would have a positive impact on legitimising the place of community pharmacy as an established healthcare professional within the primary care team.

7.5.2.3 Policies and initiatives as drivers for change

National healthcare policies and strategies were recognised by respondents as drivers for change and a potential opportunity for the greater involvement of pharmacists. First, the need for more non-medical prescribers was understood to be driven by *"increased costs of healthcare and shortage of*

healthcare providers including doctors and the need to widen the scope of prescribing. This is an ideal role for a pharmacist." (William, GP).

Second, pharmacists undertaking activities related to public health. *"Well, there are two health checks and screening, one, for the general population and, two, for SMI. Pharmacists working in all settings can support people with SMI with these, they know what the requirements are they can also help by promoting things like exercise and smoking cessation."* (Stephanie, RGN).

Respondents gave examples of pilot projects that had run locally and successfully and these provided examples that demonstrated pharmacists' abilities. *"The mental health pharmacist ran a Med-Ed living with mental health medication course for patients under the community teams. It worked really well. Patients could ask anything they liked. Many asked about the risks of weight gain and heart disease with antipsychotics and lithium."* (Emily, RMN). Emily went on to say that since the end of the pilot there had been many queries from both patients and informal carers about similar courses.

Shaista (Consultant Psychiatrist) spoke about the involvement of a mental health pharmacist in the local implementation of a national CQUIN for physical health in SMI to improve care and support for CMR, MetS and related diseases. *"The pharmacist had dedicated time to lead on this. We did fantastically well through their hard work and their skill set and meticulous and strategic approach ideally suited to that sort of role."* Respondents identified that the pharmacist's involvement and visibility in such schemes has a positive impact on the views of care professionals about their skills and abilities and beliefs in future roles. Also, highlights particular skills that pharmacists have in paying attention to detail.

7.6 Discussion

Contextual factors considered as barriers by respondents to the provision of information about psychotropic medication side-effects, screening or management relating to CMR, MetS and related diseases in patients with SMI included poor patient insight, diagnosis of SMI and its association with impaired capacity, health literacy, socioeconomic status, cognitive and functional impairments, missed opportunities and the nocebo effect. Facilitators included face-to-face interaction between patients and care professionals, stable treatment and mental health and good insight. Other factors which informed discussion and conversation were an 'in-situ' gauging of patient need and care professionals' desires to strike a balance between being authoritative and a patient-centred approach.

A review published in 2018 reported that quantitative and qualitative studies have identified poor insight as the main reason for non-adherence in patients with SMI (504). Further, improved insight is associated with better attitudes towards medication leading to improved adherence and as a result better therapeutic outcomes (504). The findings here suggest that better patient insight facilitates conversations about the side-effects of medication. This in turn may have a positive impact on adherence. Some patients might not want to have conversations or be informed about the side-effects of medication. So, patients must be asked what their desires are about what information they do or do not which to receive.

Robert (Psychiatrist) said that the impact of CMR, MetS and related diseases on physical health morbidity may have already ensued before insight has been fully regained (*"it's still slightly shutting the door once the horse has bolted")* and before the conversation has taken place. Therefore, these conversations should ideally be scheduled to take place at the earliest appropriate opportunity to minimise this effect and implement any relevant interventions.

What is not well recognised or well described in the published literature is the impact of a patients' realisation of side-effects as insight is regained, the impact of this on adherence, on the therapeutic relationship and how this might be best managed by care professionals. This is important as it may represent a critical point in illness continuum and may require specific input. This should be included in guidance about managing SMI.

Whilst there may be connections between impaired capacity, health literacy, socioeconomic status, cognitive and functional impairments and how patients receive information, assumptions that these are inherent to diagnosis of SMI are both stigmatising and unhelpful. Furthermore, this highlights an area of understanding that potentially needs addressing amongst care professionals. Capacity is attached to a particular medical decision and should be assessed for each decision rather than associating it with an illness or a diagnosis. A recent meta-review reported that a significant proportion of patients with a SMI are able to participate in the decision-making process regarding treatment and the degree of impairment that may be inherent to the mental illness does not constitute incapacity to make decisions (505).

A study exploring health literacy of patients with SMI who were attending a rehabilitation programme found greater proportion of those patients who have schizophrenia have inadequate health literacy

when compared to other severe mental illnesses (506). Another study concluded that the relationship between comorbid mental illness, physical health conditions, and measures of multidimensional health literacy was unclear (507). Lacking in the published literature are reports of assessments of the health literacy of patients with concomitant CMR, MetS and related diseases and SMI. Patient reported cognitive impairment was identified as one of the strongest predictors of non-adherence in a recent systematic review (508), however, this cognitive impairment may be as a result of antipsychotic treatment itself and the resulting non-adherence may be unintentional (508).

What is clear from all of this is that information provision should be tailored to the needs of each patient, indeed, this is the foundation of SDM. An integrative review of SDM in patients with SMI reported similar findings to those here; that care professionals understand its value but the perceived need for extended consultation times are a barrier to its use (509). Studies have also found that interprofessional collaboration can address time barriers to facilitate SDM by providing more opportunities for discussion (509). This is an important consideration for the relationship between pharmacy and other care professionals.

Anticipation and worry about the risk of the nocebo effect (503) was at odds with care professionals' medical, ethical, and moral obligation to be open with the information they provide about psychotropic medication. It also provides evidence of paternalism (510). Published literature on SDM indicates that there is an ethical imperative to overcome such paternalism and to involve patients in treatment decisions (510). One study conducted in the UK found that mental health pharmacists support SDM for antipsychotic prescribing and believe that it improves outcomes (511) but did see capacity and insight as a barrier (511). These pharmacists did not perceive extended consultation times as a barrier (511).

Finally, another study (512) explored healthcare providers' perceptions of barriers and facilitators to both SDM and interprofessional collaboration in mental healthcare. Psychiatry care professionals emphasised the importance of increased mental health expertise of GPs and community pharmacists, whereas GPs and community pharmacists were of the opinion that information sharing between providers and healthcare settings was the main issue (512). Further research is needed into the implementation and impact of interprofessional collaboration such as that with pharmacy professionals, as an integrated part of SDM in primary and secondary care with patients with CMR, MetS and related diseases and SMI.

Professional jurisdictions and role boundaries in interprofessional care for CMR, MetS and related diseases was discussed and questioned across all professions and settings. Similar to other studies this was considered a challenge (513,514). Problems identified here fell into three categories also identified in the published literature - unequal power, communication, role overlap and/or confusion (515). The negative effects of working in 'tribal silos' (516) was also mentioned.

Care professionals in this study felt that the provision of care was a collective activity but, as is recognised in the literature (517) power was unequally distributed between those providing that care. The power being held by whoever sat at the top of the perceived hierarchy, within inpatients care by senior doctors (psychiatrists), whilst between primary and secondary care psychiatric by secondary care. For example, psychiatric inpatient care for CMR, MetS and related diseases in patients with SMI falling largely on psychiatry junior doctors' shoulders and GPs undertaking work, which they felt the psychiatry team should have undertaken. In addition, certain groups, for example, GPs felt their role was undervalued again supported by published literature (518).

Reference was also made to hierarchy of healthcare (519) with regards the view of mental health pharmacists by one of the psychiatry doctors, it was felt that clear established professional jurisdictions and role boundaries were needed (520,521). It was also felt that better care and working could be facilitated when every team member had their own distinct role, and an awareness of the roles of other team members (522). However, ambiguity in professional boundaries is not uncommon in the provision of healthcare generally and relates to confusions about responsibility for some aspects of work (520). Published evidence indicates this also exists with regards provision of care for CMR, MetS and related diseases in patients with SMI specifically (523,524).

Challenges were encountered in trying to identify distinct roles, again consistent with published research (525). Care professionals interviewed felt that roles and responsibilities often overlapped, shifted, and changed over time and this in part was driven by changes to policy and strategy.

Boundary work is a concept that can be used to examine some of the challenges that care professionals encountered in clinical practice and desired for pharmacists. This concept sheds light on how professional groups, such as the doctors here, seek to establish a privileged position for themselves by having work clearly demarcated by a boundary (521). Boundary setting for pharmacists could have two opposing functions: it could act as a facilitator to connect multiple parts together such

as screening and management or a barrier which serves to protect doctors' autonomy, professional standing (526,527) and claim authority over certain parts of practice (528) .

Importantly future roles of pharmacists should be informed by the published literature which recognises that boundaries between professions are not fixed and are locally and nationally determined and negotiated (529–531). As roles for pharmacists evolve over time, like practice based pharmacists or mental health pharmacists in CMHT outpatient clinics (532), and specifically within this area this will be particularly pertinent. Within healthcare it is known that boundaries are frequently drawn and redrawn as professions question the jurisdictions of their work (519). The literature suggests that in order to achieve person-centred care renegotiation of professional boundaries (by all professions) may be necessary (533), this is also a recommendation within published guidance (534).

Communication and information sharing across professional boundaries were also identified as being important to interprofessional working, for example, between secondary care psychiatric services and GPs, and between community pharmacists and GPs. This is an area of practice which is consistently highlighted as being problematic (535). Indeed, poor communication between secondary and primary care providers has been identified as a major challenge to the delivery of high quality care for CMR, MetS and related diseases in patients with SMI (536,537). High visibility and structures around screening and better liaison of psychiatric services with primary care has been identified as facilitating good care (538,539). This may also apply to liaison with community pharmacy and may be a role for hospital mental health pharmacists (540). Hospital clinical pharmacists liaising between GP and community pharmacist with regards medicines reconciliation has been explored in an RCT conducted in 2002 with good patient outcomes and medicines optimisation (541).

As discussed widely in the research literature, the association between 'fat' and moral deviance is deeply pervasive (542,543). The use of the term 'fat' situates weight gain, being overweight and being obese in a personal and moral domain rather than a medical domain. Discourse also illustrates that care professionals felt that patients were subject to a double stigma where both the label of 'fat' and 'mental illness' together further exacerbates this. Discussions suggested that care professionals think that patients with SMI resist to having the label of 'fat' applied. However, they are limited by alternative appropriate or useful terminology and language that they can use in conversations with patients. Discourse also demonstrate that weight gain, overweight and obese and SMI indicated a 'spoiled identity' (544,545)**.** The moral discourse was further amplified and strengthened through care professionals feeling ill equipped to support patients.

Health inequalities and stigma that patients with SMI are subject to were mentioned throughout and are well recognised within the published literature (546). The presence of concomitant physical health conditions CMR, MetS and related diseases made this worse, for example, when discussing weight gain, overweight and obese as above. In addition, access to care for these conditions was felt to be negatively impacted on as a result. Psychiatrists and psychiatry junior doctors spoke of the need for a holistic approach and the need to address root causes of health inequalities. Mention was also made of marginalisation and the impact on access to care. Care professionals felt that barriers to engagement with pharmacy included possible treatment stigma, self- stigma of patients and possible stigma amongst community pharmacists. This will be explored further Chapter Eight which presents findings from the interviews with pharmacists.

Views of pharmacy services were heavily impacted on by nature and content of interactions. Shared physical space and face-to-face interaction and shared experiences were highlighted as being critical for impact on CMR, MetS and related diseases in patients with SMI. Face-to-face interactions were also found to have positive impact on patient outcomes in the systematic literature review presented in Chapter Two (387). Within inpatient psychiatry settings multidisciplinary ward rounds and ward reviews were considered the appropriate context for face-to-face interactions and shared experiences. Interactions communicated over the phone or via notes were felt to lack significance. Again, this is reinforced by the findings of the literature review in Chapter Two which found that the use of reminders by pharmacists had no significant impact on patient outcomes (387). Ward and ward reviews, when done well, are cited as good examples of daily collaborative teamwork (547–549).

Many care professionals in this study felt that invisible boundaries such as the different ways that pharmacists worked and communicated with them may recede over time if working practices and experiences could be shared daily. The positive effects of working in a team cannot be underestimated, high quality care is delivered by higher functioning teams (550). Patients also perceive that the most effective teams are those where healthcare professionals work collaboratively (551). Improved teamwork has been shown to result from the introduction of structured interdisciplinary rounds (552,553). Some of the challenges that are associated with teamwork have already been discussed and include understanding team members' roles and hierarchal structures. Studies conducted within hospital settings have shown that trust between members of teams is facilitated by shared experiences (554). The importance of shared experiences was emphasised by inpatient psychiatric healthcare professionals in this study.

GPs and community pharmacists discussed similar issues relating to primary care settings. Overcoming the visible boundaries of being situated in different buildings was not practical for most community pharmacists. However, GPs felt that improved communication and collaborative work could be facilitated through community pharmacists' access to comprehensive patient data and could help towards reducing the invisible boundaries, in this case differences in knowledge about the health of the patient. Other benefits of community pharmacist access to comprehensive patient data were identified by the GPs interviewed and in common other studies (555,556). In particular, advantages in managing care transitions of care by for instance improved workflow efficiencies as part of discharge procedures.

Such practices have the potential to not only enhance communication between pharmacists and healthcare professionals, but also between pharmacists and patients and this may contribute to nurturing deeper relationships. These advantages were underpinned by the accessibility and convenience for patients of the community pharmacy compared to other services. For example, the community pharmacist having detailed information about the discharge prescription out of hours. This might also result in increased trust in these relationships. Objective studies examining time savings or reduced interruptions in workflow could be valuable to determine how much of an impact access to patient data could bring to collaboration between GPs and community pharmacists.

Discussions about a lack of privacy and confidentiality within the community pharmacy environment for patients with SMI in this study are consistent with the findings of other studies generally (440) and in relation to mental health (557). As was identified in this research, another study has reported that patients should be given the choice about utilising a consultation room (557). Despite concerns about community pharmacy, care professionals recognised the advantages of community pharmacy over other primary care services.

In this research central to these advantages were the ease of access to patients, convenience and lack of an appointment based system all of which are supported by findings of other studies (436). Some of the mental health professionals interviewed saw the potential for a collaborative role whereby community pharmacists might screen for CMR, MetS and related diseases and the GP would undertake the follow up. A recent systematic review reported that GPs' awareness of community pharmacy services was low and collaboration with pharmacists was poor despite the introduction of these services (558). Other literature highlights the lack of high quality evidence focused on GP and

pharmacist collaboration and that specifically related to patient outcomes for CVD and diabetes in any patient population (559). Moving beyond this a protocol for a RCT has recently been published (560) studying an intervention to be delivered wholly by community pharmacists. One of the many outcome measures of this study will be changes in factors associated with CMR. The findings of this study clearly have relevance to the findings in this study and potential ways forward.

Mental health pharmacists were seen to have the greatest levels of expertise, knowledge, skills and training and impact for this patient group. The limited published robust qualitative literature on the role of mental health pharmacists in supporting CMR, MetS and related diseases in patients with SMI (21) was considered in Chapter Two. Care professionals' views and experiences in this study reflect the limited impact of mental health pharmacists. They also recognised potential reasons for this including professional socialisation and hierarchies, heavy workloads and demands, understanding of their roles and responsibilities and organisational structures. As discussed, both visible and invisible boundaries also exist. Going forward mental health pharmacy services should work towards bridging the gaps identified in both the visible and invisible boundaries between care professionals and pharmacists.

Practice based pharmacists as part of primary care services for patients with CMR, MetS and related diseases in patients with SMI were viewed positively and fulfilled GPs expressed desires for shared physical space and face-to-face interactions. Similar to research conducted, practice based pharmacists' work was seen to add value, enhance care and save GP time (561). However, the role of practice based pharmacists is still evolving and not widely accessible to patients when compared to community pharmacists. Access is by appointment only and may be limited by a ten minute appointment that maybe little different to that offered by GPs themselves. Concerns have been expressed about patient safety issues where pharmacists are undertaking work they are not experienced in (167). Views discussed here are based on limited experiences and practice based pharmacists may need training specific to mental health.

National policies and initiatives acted as drivers for change. In common with other studies (562) these were identified and recognised by care professionals as potential opportunities for pharmacists to get involved. Knowledge of pilot projects, such as a national CQUIN and 'Med-Ed' groups, were used to illustrate the skillset and knowledge that pharmacists have. A literature review has reported that pharmacist-led or pharmacist co-led 'Med-Ed' groups have been shown in studies to improve patient outcomes (563). One retrospective cohort study (564) explored the impact of mental health pharmacist-led psychiatric inpatient 'Med-Ed' sessions on readmissions and emergency department

visits. Attendance at one group was reported as having no impact on reducing psychiatric readmission (564). However, patients who attended two or more sessions had fewer emergency department visits (564).

Based on these findings there currently is not one role or type of pharmacist that completely fulfils the desired needs of care professionals or the needs they see for their patients with CMR, MetS and related diseases and SMI. Findings from this analysis also point to an important catalyst for in-depth interactions between healthcare professionals and pharmacists; a familiar or existing relationship with a pharmacist either in the working environment or personal life (565). Existence of such relationships resulted in proactive enquiries about CMR, MetS and related diseases by care professional and signposting patients to do the same. The importance of trust and sensitivity to individual needs were highlighted as essential to good relationships between pharmacists and patients.

7.7 Chapter summary

The view of care professionals in this research is that currently there is not one type, role, or position of pharmacist that completely fulfils the desires or needs of care professionals or those of patients with CMR, MetS and related diseases and SMI. Mental health pharmacists have specialist mental health expertise, knowledge, and training but the frequency of in-depth interactions with patients is limited. Community pharmacists have frequent contact, are accessible and occupy a convenient location, but lack the specialist knowledge and training that care professionals believe is important. Practice based pharmacists roles are still new and require further exploration in terms of their sustainability and impact.

Respondents emphasised shared physical space, in-depth interactions and relationships with pharmacists as inextricably linked and are critical for themselves and for their patients, for themselves and for their patients. Shared space is likely to remedy some tensions resulting from the visible and invisible boundaries between care professionals and pharmacists. Access to comprehensive patient data could act to do the same and nurture deeper relationships between community pharmacists and GPs. The last substantive chapter explores the perspectives of pharmacists in providing care to patients with CMR, MetS and related diseases and SMI.

Chapter Eight: Cardiometabolic risk, metabolic syndrome, and related diseases in severe mental illness: the role of pharmacy in the lived experience of patients. Findings from pharmacist interviews

8.1 Introduction

The last key group whose views, experiences, and perceptions are explored in this thesis are members of the pharmacy profession. The aim of these analyses is to describe the views, perceptions and experiences of the pharmacy profession with regards to the lived experience of patients with CMR, MetS and related diseases and SMI and where they see themselves in this lived experience. In addition, the interviews considered both their current experience of providing services to members of this patient population and their potential role in the future.

Pharmacists were the only pharmacy professional recruited to the study. The aim of this chapter is to discuss the findings of the analysis of the interviews with eleven pharmacists who were involved in providing care for patients with CMR, MetS and related diseases and SMI. These 11 pharmacists included five mental health/psychiatric pharmacists, one GP practice based pharmacist and five community pharmacists (demographic details of these participants is summarised in Table 8.1). Views, experiences, and perceptions of the pharmacists were also shaped by their previous roles across both primary and secondary care as well as during postgraduate training and education.

Detailed information about methods is provided in Chapter Three. The data was coded against the framework developed in Chapter Four from the analysis of patient data. In addition, attention was given to the implementation strategies used by pharmacists (see Chapter Two). Key findings are summarised at the end of the chapter.

This chapter contributes to the research question in the following ways:

- pharmacist data has been coded using the framework developed for patients (Chapter Four) thereby putting the patient at the centre of this research,

- the focus of the thesis is the role of pharmacy within the lived experience of the patient.

Table 8.1: Demographic data of pharmacy professional participants (self-reported)

The study recruited pharmacists but no other type of pharmacy professionals. Three different secondary care psychiatric service (mental health NHS trusts) and six different CCGs are represented in this sample).

Participant pseudonym	Gender	Ethnicity	Age range	Current role/position	Duration/ frequency of involvement in care of those with SMI	Post-graduate qualifications/ professional experience
Brigette	Female	White	50-54	Senior Mental Health Pharmacist: Inpatient Adult Mental Health (AMH), LD, Mental Health Services for Older People (MHSOP)	23 years - daily	• Diploma in Psychiatric Pharmacy • Member of the College of Mental Health Pharmacy
Azzam	Male	Asian/ British Asian	40-44	Mental Health Pharmacist: Inpatient AMH, LD, MHSOP	Five years – daily	
Tahira	Female	Asian/ British Asian	50-54	Senior Mental Health Pharmacist: Inpatient AMH,LD,MHSOP Outpatient Independent Prescriber	17 years – daily	• Diploma in Psychiatric Pharmacy • Accredited Member of the College of Mental Health Pharmacy • Independent prescriber - Mental Health.
Varun	Male	Asian/ British Asian	30-34	Community Pharmacist Manager of Community Pharmacy/ Superintendent Travel clinics	Five years – occasional	• Qualifications in aesthetics • Certificate in Clinical Pharmacy • Independent Prescriber - GP Practices
Alicia	Female	White	50-54	Mental Health Pharmacist: Forensic	25 years – daily	• Postgraduate Diploma in Clinical Pharmacy
Alyssa	Female	White	45-49	Senior Mental Health Pharmacist	25 years – daily	
Serena	Female	Asian/	35-39	Practice Based Pharmacist Independent Prescriber	One year – three to four times a week	• Clinical Diploma in Prescribing

		British Asian		Advanced Clinical Practitioner		• Community Pharmacy • Advanced Clinical Practitioner Other previous roles: • Care Quality Commission • Pharmacy Lecturer • Primary Care Pharmacist • Drug and Alcohol Services
Hazel	Female	White	50-54	Professional Pharmacy Consultant Relief Community Pharmacist Visiting Pharmacy Lecturer at University	30 years - occasional	• Postgraduate Diploma in Clinical Pharmacy
Thalia	Female	Asian	25-29	Community pharmacist	Three years - occasional	
Wasim	Male	Asian/ British Asian	30-34	Community Pharmacist Relief Pharmacist GP Pharmacist Academic Pharmacist	Five years –daily contact with SMI patients	• Independent Prescriber in Mental Health
Anahita	Female	Persian	30 34	Community Pharmacist	Two years - occasional	• Diploma in Clinical Pharmacy • Diploma in Psychiatric, Pharmacy • Independent Prescriber • Masters in education • Hospital • Community • Industrial Pharmacy Mental Health Academia • GP practice

The analysis identified three main themes (see Table 8.2). The first theme related to the psychotropic medication and management of their side-effects as well as information provided about these. The other two themes related to the role of pharmacy and the factors that facilitated or limited support from pharmacists, whether in hospital or community settings.

Table 8.2: Table of themes and sub-themes for pharmacists

Theme	Sub-theme
Theme 1: CMR, MetS and related diseases, psychotropic medication, psychotropic medication side-effects and SMI	• Screening and interventions for CMR, MetS and related diseases in patients with SMI • Referral of patients for healthy lifestyle management • Interventions delivered to healthcare professionals[a]. • Summary of pharmacists' interactions with patients and care professionals in terms of frequency and depth
Theme 2: The role of pharmacy: barriers	*Potential or anticipated* • Crossing the mental health/physical health divide *Actual or experienced* • Patient's perceptions of pharmacist's roles • Invisible and visible interprofessional boundaries • Lack of confidence in delivering interventions for prevention and treatment of CMR, MetS and related diseases and lifestyle modification • Patient trust is not conferred it must be earned[b]
Theme 3: The role of pharmacy: facilitators	*Actual or experienced* • Patient trust is not conferred it must be earned[b] *Potential or anticipated* • Policies and initiatives as drivers for change • Digital maturity and connectivity • Desire for engagement and involvement of informal carers • Advanced roles for pharmacy technicians

[a] *This subtheme specifically relates to implementation strategies used by pharmacists (as per the literature review conducted in Chapter Two).*

[b] *This subtheme sits both in barriers and facilitators and is discussed as one subtheme to allow for comparison and avoid repetition.*

Key: *Potential or anticipated*: *not actually experienced but anticipated as potential barriers or facilitators.*
Actual or experienced: barriers and facilitators that had actually been experienced.

8.2 Theme 1: Cardiometabolic risk, metabolic syndrome and related diseases, psychotropic medication, psychotropic medication side-effects in severe mental illness

8.2.1 Theme 1: Introduction

Pharmacist's time spent face-to-face with patients was limited and their data appear to lack an appreciation and understanding of some of the deeper issues that impact on patients such as the tensions and everyday challenges that patients experience. Face-to-face interaction with patients included the provision of education and educational materials; interactions with healthcare professionals included formulation of guidelines and policies and audit and feedback. Pharmacists were regularly signposting and referring patients to other services for lifestyle interventions.

8.2.2 Theme 1: Detailed description of sub-themes

8.2.2.1 Screening and interventions for cardiometabolic risk, metabolic syndrome, and related diseases in patients with SMI

Mental health pharmacists reported that they delivered individual patient education on inpatient psychiatric wards. This was done when they were able to attend ward rounds or reviews as part of an MDT or in response to a referral or request by a member of the inpatient psychiatric healthcare team. Mental health pharmacists reported that where possible they provided patients with support for aspects of CMR, MetS and related diseases. This support ranged from screening, through to identification of high risk, abnormal parameters, or diagnosis of disorder such as MetS and clinical interventions. This occurred every few weeks or several times a month.

> *"When I am able to attend the ward rounds, I will always try and spend time after the ward round following up on patients who have recently been commenced on antipsychotics. If they are well enough and they want to I will sit with them and have a conversation about the monitoring and things they can do for their lifestyle. Also, before I attend the ward rounds, I will check all the bloods and flag up if an intervention is needed, like a referral to the diabetes team."* (Azzam, Mental Health Pharmacist).

All mental health pharmacists in the study said that there were unmet needs due to missed opportunities at milestones during the inpatient stay *"...if the patient is well, we should be providing individual patient counselling when decisions are being made about medication so that they are fully informed and they can be involved as far as possible. All patients should have a pre-discharge meeting with the pharmacist. At that point they are more likely to be well enough to retain and understand."*

(Brigette, Mental Health Pharmacist). This respondent is making direct reference to patient involvement speaking directly to the concept of SDM.

Community pharmacists described their occasional involvement, every few months, in providing education about smoking cessation and aspects of weight management. These activities occurred after a proactive enquiry by a patient or where they themselves had a personal interest in mental health and approached a patient. Three community pharmacists described that they had provided advice and educational materials to patients who had reduced their consumption or stopped smoking and that this was hugely rewarding. *"A few patients who collected their prescriptions regularly from our pharmacy have asked for support with their smoking, after some detailed discussions they told me they had SMI. I supported them with advice and nicotine replacement, like gum and patches. They have managed to cut down or stopped smoking altogether."* (Thalia, Community Pharmacist).

Educational materials were provided in the form of PILs. Community pharmacists used manufacturers' PILs and directed patients to manufacturers websites or mental health charity websites such as Mind. Mental health pharmacists preferred specialist psychotropic medication websites such as Choice and Medication or the Royal College of Psychiatry. *"Patients find manufacturers' leaflets and information too complex. The font size on PILs is too small and difficult to read, the language used isn't easy to understand. Many patients have told me that they just don't take any notice of the manufacturers' information."* (Tahira, Mental Health Pharmacist).

Two mental health pharmacists discussed providing weekly face-to-face 'Med-Ed' and 'Living with Mental Health Medication' interactive group workshop style sessions that included providing educational materials. These were part of a local initiative organised within their secondary care psychiatric hospitals and described as fixed term running for one or two years. *"We discuss the pros and cons of taking and not taking medication like antipsychotics, the benefits of these sessions are that you can deliver information to more people at one time, patients become more aware of what pharmacists can do and there's often a sense of shared experience between members of the group."* (Brigette, Mental Health Pharmacist).

Due to the largely positive feedback received from patients these pharmacists felt that these sessions should be integrated into their core service provision in their secondary care psychiatric service rather than being a short term pilot.

The mental health pharmacist independent prescriber and the practice based pharmacist in the study explained that they had their own caseload of patients with SMI most of whom had CMR, MetS and related diseases. They described providing comprehensive care and regular contact with the same patient over long periods of time allowing them to develop relationships.

> *"The first few appointments are once a week or once every two weeks during which we develop rapport, trust and familiarity. I'll undertake full screening for CMR, MetS and related diseases, bloods weight ecetera. Then we go from there and tackle one problem at a time depending on what is needed or what the patient wants. It's a long road and takes time. Education and educational materials are provided throughout where appropriate."* (Serena, Practice Based Pharmacist).

These pharmacists mentioned that they included measurement of waist circumference and weight/weight change, cardiovascular and diabetes risk assessment using formal risk assessment tools/calculators, follow up of patients after implementation of an intervention, utilisation of behaviour change approaches such as motivational counselling where possible or appropriate. When patients attended with family or informal carers then they actively involved them, although this was an infrequent occurrence.

8.2.2.2 Referral and signposting patients for healthy lifestyle management

All pharmacists described regularly referring or signposting patients to other services for healthy lifestyle management. This was undertaken when patients asked pharmacists in the study said they were not able to provide this support themselves due to limitations in their knowledge, confidence, experience, or time. Referrals were made to a variety of services mainly smoking cessations services and local healthy lifestyle groups. The 'Make Every Contact Count' initiative was also frequently mentioned in this context. The advantages of this service initiative were commonly described: *"You can refer inpatients, who give their consent, to this service and they will do the rest. They contact the patient and follow them up after they have been discharged."* (Brigette, Mental Health Pharmacist). *"This service provides a comprehensive set of lifestyle interventions. They will visit patients in their own home. They take a behaviour change approach to lifestyle change."* (Hazel, Community Pharmacist).

8.2.2.3 Interventions delivered by mental health pharmacists to other healthcare professionals

Mental health pharmacists described their involvement in delivering interventions to other healthcare professionals relating to CMR, MetS and related diseases in patients with SMI. These included having a

central role within secondary care psychiatric services in developing and writing local policies and guidelines, local and national audit and feedback, and educational meeting as well as courses and workshops delivered to a range of healthcare professionals including doctors, pharmacists, and nurses.

It was routine practice, respondents reported to prompt for screening for and management of CMR, MetS and related diseases for patients with SMI on their wards using reminders. This involved attaching an electronic note attached to an electronic prescription or, less frequently, patient's electronic health record. The note was intended for other healthcare professionals, mostly doctors, as a prompt to undertake screening or follow up. Respondents said these reminders were the sole strategy for a significant proportion of the interventions implemented by mental health pharmacists working within inpatient psychiatric settings.

8.2.2.4 Summary of pharmacists' interactions with patients and other care professionals in terms of frequency and depth

The description by pharmacists' of their interactions with patients and other care professionals can be encapsulated as three 'scenarios' based on the frequency and depth of interaction.

- Scenario 1: In-depth interactions that occurred at high frequency.

  Such interactions where mental health pharmacists had direct face-to-face interaction with patients in 'Med-ed' or 'Living with Mental Health Medication' sessions, were reported to take place on a weekly basis. Pharmacists who had their own caseload of patients: the practice based pharmacist and the mental health independent prescriber working in outpatient clinic also described similar interactions. In addition, the practice based pharmacist in the study described case discussions with GP practice staff. Of note however, both the 'Med-Ed' and 'Living with Mental Health Medication' initiatives were short term. These interactions were reported by pharmacists in the study as having a significant impact for patients; either because they had received feedback from patients themselves or there had been improvements in clinical outcomes such as improvements in blood pressure or diabetes control.

- Scenario 2: In-depth interactions that occurred at low frequency.

  Mental health pharmacists interacted directly with patients either as part of their role in inpatient MDT ward rounds and reviews or as a result of referral or proactive inquiry made by a mental health professional with whom they had had an existing professional relationship with. These interactions took the form of conversations about CMR, MetS and related diseases and SMI. Mental health pharmacists also described their involvement in the delivery of educational meetings and training including audit and feedback to care professionals as having significant impact. Patients asked community pharmacists, with whom they already had a pre-existing relationship with, to discuss psychotropic medication. Also, community pharmacists who themselves had an interest in mental health asked patients about the same. These types of interactions were reported by respondents to occur at least every few weeks or every few months.

- Scenario 3: Low depth interactions occurring at high frequency.

  Mental health pharmacists in the study described responding to enquiries daily or every few days from other mental health professionals to signpost or provide patient information about CMR, MetS and related diseases for patients with SMI. This type of interaction also included signposting care professionals to guidelines and policies relating to CMR MetS and related diseases. Roles associated with the provision of medication were also discussed and would fall into this type of scenario and would also include medicines optimisation for CMR, MetS and related diseases e.g., optimising the dose of anti-diabetic medication.

In addition to these three clearly defined scenarios other interactions were more difficult to evaluate in terms of depth due to lack of follow up by pharmacists. This included the use of reminders and actively referral and signposting of patients to other services. The descriptions above highlight the complexity around pharmacist interventions both in nature, type, and frequency. Barriers and facilitators describe below reflect that pharmacists' descriptions of their involvement in CMR, MetS and related diseases in patients with SMI reflected far less time being spent in face-to-face interactions with patients and more on indirect activities such as policies, audits.

8.3 Themes 2 and 3 Introduction

Barriers and facilitators were discussed by pharmacists from two perspectives, relationships with patients and relationships with care professionals. These were not mutually exclusive. Pharmacists did not mention any interactions with other pharmacists. Mental health pharmacists spoke about interactions mental health professionals and patients. Community pharmacists spoke of GPs and patients. Discussions about relationships with patients was underpinned by the need for trust. Respondents reported that relationships with doctors were hampered by invisible and visible interprofessional boundaries. Pharmacists expressed a lack of confidence in particular areas of care for CMR, MetS and related diseases but were enthusiastic and motivated to meet high standards of care, including interaction with informal carers, and undertaking new or extended roles. A lack of resources was a frequently cited limiting factor for adopting such new roles.

8.4 Theme 2: The role of pharmacy: barriers. Detailed description of sub-themes

8.4.1 Potential or anticipated barriers

8.4.1.1 Crossing the mental health/physical health divide

Community and practice based pharmacists expressed varying degrees of reservations and uncertainty about providing advice about medication used for SMI. *"I wouldn't really know what to say to a patient if they asked what to do if they wanted to stop or switch their olanzapine because they were experiencing intolerable excess weight gain and hunger."* (Thalia, community pharmacist). Paralleling this, most mental health pharmacists expressed reservations about providing specific aspects of care for CMR, MetS and related diseases. *"Well, I might feel a bit lost in assessing or calculating someone's cardiovascular risk, I might miss something, then even if I did then where would I start with recommending starting a statin if it was needed?"* (Alicia, Mental Health Pharmacist). In both cases respondents felt that their day-to-day practice and current knowledge was insufficient for what might be required.

In addition, the intersection between SMI and CMR, MetS and related diseases might present unique challenges. *"Managing someone who has schizophrenia who stops their insulin because of deteriorating mental health is very challenging. Understanding the relationship between their deteriorating mental health and diabetes and how these impact on their attitudes towards medication is really tricky. There isn't much guidance available to support this sort of situation."* (Brigette, Mental Health Pharmacist).

Respondents understood that there was no expectation that they had detailed specialist knowledge of unfamiliar areas of practice. However, they expressed a desire for education and training in key concepts to gain familiarity and improve their confidence. *"It would boost my confidence; SMI is a specialist area and I feel like I would and should at least need to have a grasp of the basics."* (Thalia, Community Pharmacist).

8.4.2 Actual or experienced barriers

8.4.2.1 Patient's perceptions of pharmacist's roles

Most community pharmacists, the practice based pharmacist and a few mental health pharmacists in this study believed that public perception of community pharmacists was limited to trusting them to safely supply medication and they have no other role in providing services. A few community pharmacists said they thought the public saw them as shopkeepers. A small number of community pharmacists reported that some of their patients would only accept very limited advice about medication and this marginalised their role. *"Some patients don't want to me to advise on anything else except the name of the medication and dose. It's almost as if the advice given by the community pharmacist is not heard by the general public because they think that the GP is the main person who can give advice. Our role as healthcare professionals is marginalised."* (Wasim, Community Pharmacist).

In the interviews mental health pharmacists and the practice based pharmacist suggested that patients placed a higher degree of trust in them and their roles beyond medication supply and were comfortable in interacting with them. They felt that patients viewed their roles as working alongside doctors and nurses and that this 'clinical context' legitimised these roles for patients.

"Patients see our roles as more clinical and more specific. Working in a hospital is seen as a more clinical environment, this creates a different dynamic when you speak to patients, especially if they have seen you in the ward round in the MDT." (Brigette, Mental Health Pharmacist). *"The GP surgery is seen by patients as a healthcare destination. So, my role there puts me in an ideal position as patients see me within that framework, it's already in their mind. This is not true of the community pharmacy environment which may be seen as a shop."* (Serena, Practice Based Pharmacist).

The practice based pharmacist, during their interview, mentioned that their role was still new and work was needed for it to become embedded in routine practice and fully established with patients.

All pharmacists agreed that psychiatry was seen by most patients to be a specialist area of care and therefore community pharmacists might be seen ancillary to their needs as community pharmacists were viewed as non-specialists.

8.4.2.2 Invisible and visible interprofessional boundaries

Mental health and community pharmacists that were interviewed were aware of the negative impacts of interprofessional boundaries with other members of the healthcare team. These were felt most extensively with doctors. A significant proportion of these pharmacists' interactions related to prescribing and doctors undertook all the prescribing in their work environments. The only exception to this was where pharmacists undertook roles as independent prescribers where some of the negative impacts were reduced or not experienced; these pharmacists felt that these roles conferred a greater degree of autonomy.

Pharmacists reflected on the tensions created by these boundaries on the care they provided for patients *"…when you call the doctor to get a prescription changed and are flatly refused. This is frustrating where there's no reasoning or evidence to refuse and you are acting in the best interests of evidence based medicine and patient care."* (Thalia, Community Pharmacist). Some respondents felt more attention was placed on their profession rather than the importance of their advice, *"I emailed the doctor highlighting their patient's HbA_1c was way over the threshold, I recommended a referral to diabetes team. They replied and said that this was not a domain that pharmacists should be involved in."* (Azzam, Mental Health Pharmacist). This may also be related to the balance of power in this relationship and the confidence of the pharmacist to challenge what does not appear to be person-centred care from the doctor. Ultimately, it may be indicative of medical dominance.

Pharmacists discussed ways to limit these negative impacts and a desire for greater collaboration and opportunities to establish healthy communication channels and relationships. Within the inpatient psychiatric setting mental health pharmacists saw their place in the clinical MDT taking an active role in ward rounds and reviews. However, many felt that opportunities to participate as a member of the MDT was limited; a problem that they attributed to a mismatch in the ratio of pharmacists to wards and patients as well as the prioritisation of core duties of the dispensary.

> *"I have responsibility for five wards, each has 15 patients – around 60% have SMI. Also, I have to undertake three half days in the dispensary each week. Then, there's all the other stuff like*

> *training, audit etcetera. When I do manage to get to the wards it's often rushed. All you need is for things to get really busy in the dispensary and I get called back in to help – this might in the middle of a ward round. It's an impossible situation."* (Alyssa, Mental Health Pharmacist).

All the community pharmacists in this study reported that their relationships with GPs were solely by telephone interactions discussing routine prescription related queries. This was often a source of tension made more difficult if the receptionist at the GP surgery acted as a gatekeeper limiting their to access to the GP. Many community pharmacists spoke of the need to adopt strategies to avoid damaging their relationship with the GP.

"You choose your words carefully, don't make them (GPs) feel that they're at fault or you are antagonising them … you could say that we are sucking up to them and managing their ego, but I would say I want to keep a good working relationship." (Wasim, Community Pharmacist). Despite the apparent strains in their relationships with GPs a significant number of community pharmacists were determined to seek ways to improve relationships and ideally *"…grasp opportunities to meet face-to-face,"* (Tahira, Community Pharmacist) if such opportunities arose in the future.

A few pharmacists were very affected by the nature of their interactions with doctors. *"At times I have felt quite disheartened by the lack of respect shown by the doctor towards our profession. Otherwise, I think I would be more enthusiastic about undertaking more work, new roles to support care for patients with SMI but the doctors' attitude has dampened it a bit."* (Alicia, Mental Health Pharmacist).

The evidence from the analysis of the interviews suggests that for pharmacists the tensions and negative impacts of invisible and visible boundaries in interprofessional teams resulted in doctors enacting medical dominance over pharmacists. First, through a demarcation of medical territory and denial of pharmacists' skills. Second, through evasion of critical review of prescriptions and dismissal of recommendations. In response to this, pharmacists altered their behaviours and employed their agency in devising strategies to work around problems that doctors seemed to fail to acknowledge and were unwilling decline to resolve or address.

Pharmacists were motivated to bridge these boundaries and provide more care for CMR, MetS and related diseases for patients with SMI. However, broader issues such professional socialisation and hierarchies, heavy workloads, and organisational structures such as the ratio of number of mental health pharmacists to number of patients contributed to their lack of ability to do this effectively. In addition, as one pharmacist said: *"Sometimes I am not surprised that they think that all we do is*

dispense, fill in error forms and police their prescribing as that's pretty much a reflection of their experience with us. Haha!" (Alicia, Mental Health Pharmacist). Alicia's comments acknowledge that a large majority of pharmacists' work, as experienced by doctors serves to reinforce traditional views about the roles of pharmacists as primarily, dispensing and surveillance of prescribing errors. There appears to be a clear need for an increase in the proportion of time spent in patient facing roles.

8.4.2.3 Lack of confidence in delivering interventions for prevention and treatment of cardiometabolic risk, metabolic syndrome, and related diseases and lifestyle modification

All pharmacists in this study expressed a lack of confidence in their ability to deliver interventions for diet and exercise and that they were not doing it in practice. Many worried that this, in turn, negatively impacted patient outcomes. They expressed greater confidence in interventions for smoking, alcohol, and illicit drug use due to the existence of clear guidelines, training, and pharmacotherapy. All pharmacists expressed an understanding of the critical importance of such interventions in improving outcomes and quality of life.

> *"Pharmacy education and training does not prioritise prevention and lifestyle modification. I don't remember it being on our curriculum. At post-grad level health behaviours, physical activity and nutrition are little addressed. When you practice you realise just how important they are and how many diseases are causally related to them or use them as interventions, it's a bit astonishing…. yet I don't feel completely confident in advising on these."* (Anahita, Community Pharmacist).

This indicates that pharmacists' approach needs to be more holistic, and as above, is more person-centred.

A significant number of responses reflected limited resources. *"To be honest I would rather signpost patients to other services, but the accessibility and capacity of these services is often limited and determined by locality and funding."* (Serena, Practice Based Pharmacist). Within the hospital setting mental health pharmacists were aware that dieticians working on the wards prioritised patients who were underweight. *"They are firefighting most of the time, dealing with patients who are severely underweight or malnourished. Weight gain and obesity is not seen as a medical emergency and are therefore prioritised differently."* (Tahira, Mental Health Pharmacist).

Pharmacists also mentioned that there appeared to be a lack of suitable information about CMR, MetS and related diseases that was holistic rather than related to psychotropic medication. *"…there needs*

to be something more general for patients about what annual checks they are entitled to or something more holistic that covers their risks due their diagnosis of SMI." (Azzam, Mental Health Pharmacists).

8.4.2.4 & 8.5.1.1 Patient trust is not conferred it must be earned: this sub-theme relates to both barriers and facilitators

This sub-theme is relevant as both a barrier and facilitator and is therefore discussed as a single sub-theme. Importantly, it overlaps and links with many other sub-themes in this chapter. In considering patient engagement in care for CMR, MetS and related diseases in patients with SMI, all pharmacists in this study mentioned that they felt that from their experiences the most important thing for a patient with a mental illness was a relationship based on trust.

This trust had to be earned over time rather than conferred by a professional role. Factors that might impact on this trust were identified in the interviews. Pharmacists felt that these needed to be proactively addressed by the profession and made evident to patients *"We need to demonstrate and show them (patients with SMI), it's not what you say it's what you do that matters. Our actions matter more than just saying we've ticked a box."* (Alicia, Mental Health Pharmacist).

The most important factors identified by respondents were the visibility, accessibility, and availability of pharmacy. As one pharmacist explained: *"…in my opinion these are like the keys that open the first door to a trusting relationship."* (Brigette, Mental Health Pharmacist). Mental health pharmacists and the practice based pharmacist were aware that from the patient perspective they were the least accessible and visible and that this had consequences for patient views of their availability. In particular, for mental health pharmacists this view may be reinforced if patients are referred to them by someone else. Mental health pharmacists reported that this was a consequence of a lack of ward attendance or roles in CMHTs while for practice based pharmacists patients had to book an appointment via the GP surgery or be on their caseload. All respondents agreed that community pharmacists were the most visible and accessible.

Accessibility and availability were seen to be strongly connected to prompt responses to patient queries. *"I feel that patients expect me to respond quickly when they have a query."* (Tahira, Mental Health Pharmacist). Pharmacists also noted the importance of having time and space and not having a rushed conversation and not being distracted during their interactions.

Acknowledgement of patient concerns was the second factor. *"Patients need to feel heard, if they feel that they are ignored or dismissed they won't engage and open up."* (Alice, Mental Health Pharmacist). Emphasis was placed on the need to understand how patients with SMI might articulate their experiences, feelings and beliefs about their illness and care. The need to show empathy and be an effective listener were mentioned as being important contributors here.

> *"You need to listen carefully to what they are saying. Patients will pick up pretty quickly and close off if you are being insincere. If they are open, you can ask about their feelings, their experiences and how you might help. These all go a long way to showing that empathy that is critical. Sometimes, if it is appropriate talking or sharing a little bit about your own personal experiences and challenges of say of losing weight or stopping smoking can help too as it provides a sense of shared experience."* (Alyssa, Mental Health Pharmacist).

Reference here to the pharmacist using their own experiences is being used as a tool to come across as being less judgmental.

The third factor was the need to respect confidentiality and privacy. This was framed in the context of what patients might view as difficult or sensitive topics*: "A patient with SMI wouldn't really feel comfortable telling you how difficulties and relapses in mental health impacts on their ability to sustain lifestyle changes in the middle of the pharmacy with others listening."* (Anahita, Community Pharmacist).

Mental health pharmacists also mentioned the importance of being completely open and honest with patients about potential side-effects of medication in a way that reinforced SDM.

> *"Many patients will often go and look up the information themselves and may access misinformation, either way you are duty bound to be open and honest about side-effects like weight gain or an effect on their lipids as well as signpost them to reputable sources of information. That way patients will be correctly informed, feel armed and have a better relationship with you in the long-term."* (Alyssa, Mental Health Pharmacist).

The fourth factor was personability and related to social and communication skills. Respondents emphasised the need to show empathy, adopt a non-judgemental approach and avoid stigmatising patients who may already feel marginalised. *"Patients need to feel comfortable enough to ask us anything they want without the fear of being judged or made to feel stupid, like they're asking a silly question. In particular, with regards to excessive weight gain for example in the context of mental illness, where this might be due to medication or difficulties in engaging in exercise."* (Tahira, Mental Health Pharmacist). No one pharmacist role was felt to be stronger or weaker in this area. Pharmacists

in this study did feel that as a professional group, they were good at reading social cues as this was a well-practiced skill used in counselling patients generally. The majority felt that as a professional group they were *"down to earth"* (Alicia, Mental Health Pharmacist) and that this helped towards having conversations with patients as it made them more relatable. One pharmacist phrased this as *"likability and relatability"* (Azzam, Mental Health Pharmacist). However, this must be viewed in the context of reflexivity, pharmacists are not likely to say that they are unliked by patients.

"*If you are counselling someone about the potential impact of olanzapine or any antipsychotics on their hunger or weight it's really important to be able to read and respond to their body language and the response of the patient during that conversation. They may be too polite and not tell you verbally and directly what might be happening for them and you need to probe a bit more."* (Alicia, Mental Health Pharmacist). Emphasis on being able to see the response of the patient speaks to the concept of person-centred care.

The fifth factor, mentioned specifically in relation to community pharmacy, was how services were paid for and remunerated and conflicts of interest. Linking to respondents' concerns about being viewed as a shopkeeper, community pharmacists mentioned that they found themselves feeling conflicted about the need to meet commercial needs whilst at the same time being professionally bound to be ethical. They understood how patients might also feel uneasy about how pharmacists were paid for clinical work and providing services. *"Well, if, for example, you are providing smoking cessation advice they might think you are only doing it so you can make a sale of some nicotine replacement products and they might think you're getting commission or such like. Of course, that's not true, ethically this wouldn't be right but I am not sure that patients fully understand that."* (Wasim, Community Pharmacist).

The final factor was consistency of and continuity of care. Community pharmacists in this study discussed experiencing high rates of staff turnover and hectic and busy rotas that frequently meant pharmacists did not work the same shift patterns. Many respondents said that this could be disruptive when trying to build trust. *"It's like you're both starting from scratch, more so for the patient I guess.*" (Wasim, Community Pharmacist). Continuity of care issues manifested in a different way for mental health pharmacists, as they were not able to attend ward rounds or reviews often enough, they felt they were not always able to follow the patient journey through as patients had often been discharged or transferred to other wards before they got a chance to get to understand their specific needs. Also, *"The rate of turnover of patients on some of our wards is quite high, they might only*

spend a week or two on the ward. If you are only able to go the ward round once every few weeks then you might not even get to see them." (Brigette, Mental Health Pharmacist).

Respondents frequently mentioned the importance of meeting regularly. *"Patients might need to meet you three or four times before they even feel comfortable in engaging in a discussion and opening up."* (Anahita, Community Pharmacist). Mental health pharmacists spoke about their desires to spend more time seeing patients regularly. "*If we saw patients more often, we would be able to provide more individualised and tailored care to meet their needs, it's an opportunity for them (patients) to get to know us and we could get to know them."* (Brigette, Mental Health Pharmacist).

The practice based pharmacist and the pharmacists who undertook roles as independent prescribers spoke about their experiences which were different. *"Most of my patients know me well now as I see them regularly, we have built up a trusting relationship and they and are comfortable in talking openly about medication and the issues that they are experiencing."* (Serena, Practice Based Pharmacist).

8.5.1 Potential or anticipated facilitators

8.5.1.2 Policies and initiatives as drivers for change

A significant number of pharmacists were aware of pressures for pharmacy to be involved in improving care for CMR, MetS and related diseases for patients with SMI; this was driven from the profession, the RPS, government, and NHS England. Benefits cited justifying this shift included improved patient screening, education, outcomes, and satisfaction as well as reduced pressure on primary and secondary cares services and improved profile and professional status for pharmacists. Many pharmacists in this study reported that currently there were inadequate resources for this work.

Pharmacists said that they were open to, and desired to, expand their current roles. *"Providing care in these areas would contribute to job satisfaction as well as help demonstrate the worth and skills of our profession as well as mean that we can spend more time with patients."* (Tahira, Community Pharmacist). Community pharmacists' made this point consistently in the interviews. As Wasim said, *"The key challenge for community pharmacists has always been how to make the transition from what are seen as traditional roles and responsibilities, like dispensing, to integrating more person-centred roles which involve direct interactions with patients. There's a strong push for these services.*"

Mental health pharmacists saw these policies and initiatives as creating the potential for recruiting more pharmacists. *"Basic grade pharmacists (band sixes) could cover dispensary duties. Band seven plus pharmacists would have more time with patients and other members of the team on the wards and also be deployed in community mental health teams and outpatient clinics."* (Tahira, Mental Health Pharmacist). While Alyssa noted, *"Pharmacists running clinics for CMR, MetS and related diseases for patients with SMI has been long overdue and much needed."*

8.5.1.3 Digital maturity and connectivity

A recurrent sub-theme in the transcripts related to the need for digital maturity and connectivity and that this would facilitate effective communication between pharmacy and patients and other healthcare team. Community pharmacy was highlighted as *"…seriously lagging behind other areas of care."* (Thalia, Community Pharmacist). As one community pharmacist aptly put it: *"I should be able to see, document and share information in clinical records about CMR, MetS and related diseases for patients with SMI held by other healthcare professionals including the psychiatry teams."* (Wasim, Community Pharmacist).

As well as being seen as fundamental to safe and effective provision of care having a place in being able to view and document full patient electronic records was seen as being indicative or symbolic of the place of pharmacy within the healthcare team. *"It would reflect the genuine integration of pharmacists and their team into wider NHS."* (Brigette, Mental Health Pharmacist).

Absence of access to these records was seen as a barrier or limitation to community pharmacists' interactions with patients. *"Currently it feels like we speak to patients and other care professionals unknowingly. We don't have an adequate amount of information to have fully informed conversations. Patients find it puzzling and get frustrated when we ask for more information from them, like we are asking for basic information which we should already have."* (Wasim, Community Pharmacist). Having an informed interaction would help, respondents said, to generate trust.

8.5.1.4 Desire for engagement and involvement of informal carers

A significant proportion of pharmacists interviewed said that they had little or no contact with informal carers. They did however say that they recognised the benefits of involving them as a way, for instance, of supporting the implementation of interventions. *"We could start with the basics. For*

example, if an informal carer is looking after a patient with SMI who has diabetes who is on insulin then we could advise on how to monitor blood glucose and administer insulin." (Thalia, Community Pharmacist).

Respondents also recognised the need for informal carers to understand the side-effects of psychotropic medication as they might be the first to become aware of them and be involved in managing the impacts on a day-to-day basis. *"Patients themselves may not fully appreciate that they are eating more than usual and that they've gained a significant amount of weight due to antipsychotics. Carers might be more aware. We can advise on how they might manage this with the patient."* (Wasim, Community Pharmacist).

Many pharmacists mentioned that a stronger link with informal carers might positively contribute to greater trust in their relationship with patients. *"Informal carers might be the only point of social contact for patients. If we make efforts to include them then this might help overcome some of the barriers to establishing trust between us and patients and in turn strengthen our relationship."* (Alicia, Mental Health Pharmacist). Alicia went on to emphasise the role of informal carers when a patients' mental health deteriorated. *"If a patient is experiencing a deterioration in their mental health, then this might impact on their ability for example, to take care of their diet or their hypertension. If the informal carer is educated then this would help towards improving care in those situations. Pharmacists might be able to provide this education and advice to informal carers to help them with this."*

8.5.1.5 Advanced roles for pharmacy technicians

Around half of the pharmacists in this study discussed pharmacy technicians' potential role in screening for CMR, MetS and related diseases identifying three advantages. First, releasing time for other healthcare professionals for example, nurses, pharmacists, doctors to implement interventions and improve outcomes and efficiency. *"Allocating the role of screening to the technician may increase efficiency. Healthcare professionals would have more time with patients tackling anything detected during screening."* (Anahita, Community Pharmacist).

Second, the face-to-face contact that community pharmacy technicians had with patients might provide *"…an opportunity to 'capture' patients who might not otherwise attend other primary care services for screening. Patients have to attend the community pharmacy to collect their medication*

and the pharmacy technician might the only person they exchange words with during that collection." (Thalia, Community Pharmacist).

Finally, one mental health pharmacist mentioned that it would be convenient for patients and secondary care psychiatric pharmacy technicians had been trained and took blood samples to check full blood counts of patients with diagnosis of schizophrenia who were prescribed clozapine. *"This role could be expanded to include all bloods and weight, BMI, blood pressure. Patients have their bloods at the same time they collect medication. Patients have told us it is convenient as they don't have to go for a separate clinic visit."* (Brigette, Mental Health Pharmacist). Respondents also identified a need for additional training, accountability framework and assurance of pharmacy technicians' abilities if this was to be a realistic future option.

8.6 Discussion

Whilst pharmacists are delivering care for CMR, MetS and related diseases directly to patients with SMI this represents a significantly smaller proportion of their time when compared to activities that might be considered to provide care indirectly such as writing policies for other healthcare professionals, undertaking audit and feedback. The literature review carried out in Chapter Two revealed that the most effective interventions were delivered face-to-face. Other studies have also found that he most effective interventions were delivered face-to-face by pharmacists to patients when compared to other methods (566).

Pharmacists here reported that their work kept the patient at the centre of their goals. However, it appears from their descriptions that the primary recipient of their knowledge and skill was another care professional for example in providing doctors with a set of recommendations regarding the patients care. The outcome of this professional activity may not be obvious to the patient. In this context, there is a potential risk that pharmacy professionals may be perceived by patients and other care professionals, as a silent partner in care and, as such, strengthen the belief encountered in earlier chapters that they do not contribute greatly to health outcomes.

Mental health pharmacists described using reminders as the sole strategy for a significant number of interventions for patients on inpatient psychiatric wards. Findings from the literature review show that this approach does not result in a significant improvement in outcomes. Other literature reviews identify alert fatigue as a possible factor and propose a strategic approach to the use of reminders

balancing the impacts on patient safety of interruptions to consultation and omitting essential screening or clinical interventions (567). Mental health pharmacists also spoke of combining audit and feedback with education materials as part of educational meetings for care professionals. The literature review carried out in Chapter Two showed that use of this approach resulted in a statistically significant improvement in some outcomes.

Further consideration of the findings, in light of the literature review carried out in Chapter Two, indicate that there were approaches utilised by pharmacists in this study that may have significant impact on all outcomes. Namely, the practice based pharmacist and the mental health pharmacist independent prescriber working in the outpatient clinic. They used the following implementation strategies: patient mediated interventions, behaviour change, face-to-face education, identification of family support, continuity of care and revision of professional role. Identification of family support, again highlighted by the literature review, by pharmacists occurred infrequently. The other role that was shown in the literature review as having significant impact on outcomes that was being practiced was mental health pharmacists working as part of the clinical MDT. The importance of pharmacist's presence in ward rounds has recently been highlighted by in the Royal College of Physicians Modern Ward Rounds guidance (549), one study has shown that the presence of a pharmacist doubles the number of impactful interventions (568). Surveys report that provision of pharmacy services varies among hospitals in the UK, both in terms of pharmacist-to-patient bed ratio, level of expertise of pharmacists providing services (569). Similar surveys specific to inpatient psychiatric services have not been conducted.

The practice based pharmacist and the mental health pharmacist independent prescriber working in the outpatient clinic represent an important focus for future care. However, it must be noted that they are the least frequently practiced roles and less accessible to patients as the number of patients seen in these contexts is limited to a specific caseload. Efforts and resources should be focused towards making these roles more accessible and visible to both patients and other care professionals as well as more prevalent. In addition, greater emphasis needs to be placed on person-centred care and establishing trust with patients. Community pharmacy represents an important part of healthcare for the care for CMR, MetS and related diseases but is not currently resourced or structured to allow for the potential to be realised. Further, patients may not necessarily view it has a place to access healthcare.

The views on practice based pharmacists must be viewed critically in light of the published literature. Clinical pharmacy services delivered by pharmacists working in isolation may have a negative impact on the quality of care (570). One systematic review of practice based pharmacists highlighted the importance of face-to-face communication and follow up with the patient's GP (165). This points to the need for practice based pharmacists to take an interprofessional approach in GP practices. Another systematic review (164) reported that the maximum benefits of practice based pharmacists for patients will occur if they are fully integrated into GP practices. Integration in this review included aspects of shared vision of collaboratively designed protocols with shared goals and visions of interventions (164).

The WHO recognises that patients with SMI need improved access to healthcare to facilitate recognition, diagnosis, treatment and screening of CMR, MetS and related diseases (295). Indeed, in recognition of this a recently published study protocol outlines a RCT that aims to evaluate effectiveness of a pharmacist-led service for patients with SMI and physical health comorbidities (560).

Of course, comparisons to the literature review in Chapter Two are limited by the small numbers of studies that incorporated specific types of implementation strategies as well as other limitations cited in the literature review, for example, not being able to account for the impact of concurrent healthcare or quality improvement programmes, initiatives.

Comparing and contrasting with the literature review in Chapter Two indicate that the findings from this study address some of the evidence gaps. First, both the practice based pharmacist and mental health independent prescriber that were interviewed spoke about undertaking screening of waist circumference and weight/weight change, cardiovascular and diabetes risk assessment using formal risk assessment tools/calculators. These pharmacists also reported, although infrequently, occasions where they had identified family and informal carers for support as well as utilising behavioural change techniques. Second, the role and involvement of community pharmacy. And finally, although this study did not recruit any pharmacy technicians views of pharmacists indicate their support for the potential role of pharmacy technicians in screening for CMR, MetS and related diseases.

Referral and signposting of patients with SMI for healthy lifestyle management represents an important part of healthcare. Pharmacists consolidate their role in triage and as a gatekeeper for other parts of the health system. If pharmacists integrated this role with risk assessment and then triaged patients this would contribute to greater efficiency through timely and appropriate referrals.

For example, the pharmacist could screen and determine the risk of heart disease and diabetes, patients at highest risk could be referred. This concept is in line with a recent guideline published by NICE after consultation with key stakeholders including patients and pharmacists as key stakeholders (571).

Mental health pharmacists' views indicate their understanding and potential to adopt a SDM approach to psychotropic medication use in individuals with SMI. However, much more needs to be done to facilitate this practice. Translating theory into practice can, however, be a challenge. SDM is now broadly recognised as an integral aspect of person-centred care and has become internationally an ideal form of modern health-care ideal internationally (572,573). SDM is advocated in government policies (574), good practice guidance (575) and healthcare initiatives to promote good clinical practice (576). Research has reported positive impacts on patient satisfaction, treatment adherence, health status and inequalities in health. SDM has received less attention in mental health compared to other specialities and is more rarely practiced (577–579).

Invisible and visible interprofessional boundaries between pharmacists and doctors presented themselves as medical dominance. The term 'interprofessional' refers to a type of collaboration in which professionals work closely together in a collective and interdependent fashion (522). In contrast to other forms of collaborative working in where contributions are sequential or parallel, interprofessional working infers high levels of shared responsibilities, collective decision-making, communication, and reciprocal planning. Each professionals' contribution must be taken into consideration in order to achieve a thorough and complete approach to interprofessional patient care (580).

Interprofessional boundaries between pharmacists and doctors were experienced in a very direct traditional sense of doctors refusing to engage in discussion with pharmacists which resonates with a sense of professional superiority and medical hierarchy enacted by doctors, a form of medical dominance. Invisible and visible boundaries contribute to conflict and tension between pharmacists and doctors and may limit opportunities to build professional relationships. Importantly conflicts with doctors may impact on patient and patient safety as it may delay patients receiving their medication in community pharmacy or delay referral for assessment for CMR, MetS and related diseases. Improved interprofessional collaboration between doctors and pharmacists has been shown to improve patient care (581,582).

Pharmacists experienced a denial of their professional agency and effectiveness when doctors refuse to amend prescriptions leading to conflict. Pharmacists were left to navigate their way through serving needs of patients and meeting their professional responsibilities and commitments without the support of the doctors. The core principle for all pharmacists was to act in the best interests of the patient but behaviour by some doctors leave pharmacists with little room to have reasoned discussions. Interestingly, published literature on this topic suggests that medical dominance is reduced if safety is kept as the main focus (583), most likely this is due respect for a greater involvement of a broader range of health professionals in the decision-making processes that affect patients (584).

Other factors were also identified by pharmacists which may contribute to a greater perceived experience of medical dominance: heavy workloads and demands and organisational structures. Resolving these would go some way to provide opportunities to build perceived healthy professional relationships. In addition, a focus should also be placed on ways to improve pharmacists' professional resilience. Pharmacists' education and training should include activities that foster a greater sense of responsibility and independent decision-making (585). Also, professional confidence to, for instance, refuse supply or question inappropriate medication dosages and not being intimidated. Support within regulations and from organisation should also be forthcoming in this respect. Systematic reviews focusing on interprofessional education have found that there is no rigorous research evidence on its effects (586–593). The evidence relating to the impact of interprofessional education on behaviour, practice, and patients is increasing but currently limited (592).

Such behaviours by doctors also had an emotional impact on pharmacists leading to frustration, anger, and despondency. These responses are similar to those described in responses to conflict between healthcare professionals (594). These may be exacerbated due to a sense of loss of power pharmacists described in trying to resolve medication issues. Evidence suggests that negative emotions may affect cognition which may In turn result in a reduction in problem solving and decision-making (595), which may ultimately impact on care for patients.

These boundaries and assertion of medical dominance may indirectly contribute to reduced performance by pharmacists and effect patient safety and care. In addition, experience of negative interactions and the related emotional responses may result in pharmacists avoiding situations where these are likely to occur (596) and therefore being less proactive with impact on patient safety. However, pharmacists in this study maintained a level of enthusiasm and desire for greater

collaboration and opportunities to establish healthy communication channels and build trust and relationships with patients and other care professionals. Findings in this study here are supported by reviews that report that more focus and effort is needed to improve relationships between pharmacists and doctors (597,598). This is critical for development of new services and roles and patient safety ultimately patient safety. Friction and conflict within interprofessional boundaries are not easily reconciled with the ideals of shared responsibilities, collective decision-making, communication and reciprocal planning necessary for interprofessional working (597,598).

A key predictor of whether a behaviour is performed is self-efficacy; confidence in one's own ability (599). Pharmacists reported a lack of confidence in two areas. First, in delivering interventions for prevention of CMR, MetS and related diseases and lifestyle modification. Second, across the mental health physical health divide and this was linked to education and training; mental health pharmacists in this study said they lacked knowledge and therefore experience and confidence delivering interventions for CMR, MetS and related diseases, whereas community pharmacists and the practice based pharmacist said they lacked confidence in patients with SMI. Frequent mention was made of the need for education and training in these areas. Other studies have reported that pharmacists report low levels of self-efficacy and perceived need for education and training in prevention of CMR, MetS and related diseases and lifestyle modification (600–602) and community pharmacists in patients with SMI (603). The findings here also illustrate that pharmacists do not appear to be delivering interventions for prevention of CMR, MetS and related diseases and lifestyle modification in routine pharmacy practice. Also, supporting literature found was exclusively within the context of community pharmacy (600–603). There is a pressing need for research on the role of mental health pharmacy and hospital pharmacy.

There was no evidence of stigma towards mental illness amongst the pharmacists interviewed. Respondents emphasised the need to show empathy as well as taking a non-judgemental approach and avoiding stigmatising patients. However, pharmacists who have these views might not self-report or be aware that the views they hold are stigmatising. But worries about stigma towards mental health were discussed by care professionals (Chapter Seven) and informal carers (Chapter Five). Objective assessments would be needed to truly determine whether it exists or not. One of the themes identified as part of qualitative research study conducted with 13 patients with mental health diagnoses including schizophrenia and bipolar affective disorder (604) was that self-stigma can impede patients' engagement with community pharmacy. The presence of stigma towards patients with mental illness in the community pharmacy setting has been widely reported (604–609). One study

reported that community pharmacists who hold greater stigmatising attitudes were less willing to provide care for patients with SMI (605). Stigma is thought to result from lack of knowledge, negative attitudes, or prejudices, and resulting discriminatory behaviour. Lack of knowledge about mental health medication amongst community pharmacists is widely reported (606,610–614).

In one study stigma was found to be lower amongst community pharmacists who reported personal experience with mental illness (610). Experiential-oriented educational opportunities may be beneficial in tackling mental health stigma in community pharmacists (610) this may be because this educational approach reduces misunderstanding and fear about mental illness (615,616). However, a recently published RCT reported that exposure of community pharmacist to patients diagnosed with schizophrenia had no significant effect on the baseline stigma score using an objective stigma scoring tool, this tool was developed as part of the study itself (617). Qualitative research with patients and carers about their involvement in pharmacy undergraduate education has been conducted (618). This study highlighted that pharmacists' understanding that each patient is an individual, and listening and giving time might improve the interaction of pharmacists with patients (618). The findings of this research also place emphasis of the importance of pharmacist's understanding of the broader impacts of side-effects of psychotropic medication and weight and conversations about these.

Respondents emphasised earned trust rather than relying on their professional role. Some recently published evidence focused on doctors suggests that public trust in healthcare professionals has declined and that there is a need to earn trust rather than assuming it is conferred (619,620). Conferred trust is trust that is applied to an entire social category and therefore becomes a privilege given by an individual to another group of individuals (621,622). This is given without necessarily having any or having little knowledge about the characteristics of the individual that trust is being given to (621,622). Earned trust, in comparison, is underpinned by lived interpersonal experiences and interactions which occur, as discussed by pharmacists in this study, over a period of time, in which reliability, ability and truth are necessary (621,622). This was illustrated by the emphasis interviewed pharmacists placed on actions being more important than words.

The heightened vulnerability and uncertainty of mental illness and treatment (623) may account for the increased difficulty in establishing trust with mental health patients that pharmacists alluded to. Factors identified from the data that are important in establishing trusting relationships might also be those that are important in providing good and effective care. Other published literature supports the view that visibility (624), accessibility (624,625), and availability (624) are important. This is consistent

with findings in other parts of this research as it was described as the first step to having a face-to-face discussion. Mental health pharmacists discussed the importance of being duty bound to be completely open and honest with patients, where appropriate, about potential side-effects of medication, like weight gain and signpost patients to reputable sources of information – this links trust with patient safety.

As well as visibility, accessibility, and availability six other factors were identified by respondents: acknowledgement of patient concerns, honesty, personality, remuneration (community pharmacy), patient understanding and awareness of pharmacist education, training and regulations and consistency and continuity of care. However, other factors identified as sub-themes, such as self-efficacy, may also be important.

The role and importance of trust in healthcare has been widely discussed and said to be an under-researched area (626). One study reported that trust may play a critical role in medication management in mental health (437) and leads to more open communication about medication (437). The majority of existing research has explored the relationship between doctor and patient relationship and is descriptive in nature (627,628). The issue of trust between nurses and patients trust is often framed as it being a central part of care (629). Further, guidance for nursing staff point to earned trust and emphasise the role of emotional connection achieved through the provision care and this as the principle facilitator for establishing, building and maintaining trust with patients (630).

Trust between pharmacists and patients is less well studied and largely focused on community pharmacy. The widely quoted trope 'pharmacists are one of the most trusted health professionals' citing polls such as Gallup (631,632) needs further critical reflection. Community pharmacists in this study discussed that they felt that they were trusted to dispense medication safely but that patient trust in their abilities to perform other tasks is limited or non-existent. Mental health pharmacists and practice based pharmacist views on patient's perceptions of their role is also limited. So greater clarification of what type of pharmacists are trusted to do what activities is needed.

Communication skills and technical competence were suggested by community pharmacists in one study conducted in the United Arab Emirates as antecedents of trust formation (633). In another study a lack of understanding and trust in the pharmacist's role were suggested as factors that might undermine the new roles by pharmacists (436). Much of this literature reinforces the findings of this

study and could signpost a larger study to identify and model the factors that are critical in trust between patients and pharmacists.

Pharmacists reported they were enthusiastic, willing, and supportive of policies and initiatives that advocated for an increased involvement of pharmacists in CMR, MetS and related disease in patients with SMI. Consistent with other studies, a range of advantages across the healthcare system were associated with such an extended role: reduced pressure on primary care (379,558), improved patient outcomes (634) and increased job satisfaction (635). However, consistent with other studies, respondents were concerned about funding and resources (636) and balancing new roles or making the transition from a traditional dispensing (637).

The call for digital maturity and connectivity, particularly within the context of community pharmacy is not new. Since at least 2015 the RPS has pressured for community pharmacy to have read and write access to patient records (638). In April 2017 community pharmacy access to the summary care record (SCR) was granted (439), this allows read only access to a limited amount of information about a patient such as allergies, adverse reactions, current and past medication history. It is populated with data from the GP record.

Findings of an NHS data analysis carried out by the Pharmaceutical Journal published in 2018 (639) reported that approximately 85% of community pharmacies did not access the SCR at all over a typical week so it might be more than just an issue of connectivity. Further, around one in ten (1,261) of the 11,659 pharmacies that were registered to access SCRs did so more than twice per week (639). An accompanying narrative reported that pharmacists stated they did not need to access it in order to carry out their day-to-day roles (639). These findings are at odds with the findings from the pharmacists interviewed here and requires further research of a large sample of community pharmacists.

Despite the critical role that informal carers play in supporting patients with SMI (106) active engagement was not a routine part of pharmacists' reported practice. A recent review of guidelines and qualitative study with pharmacists and informal carers (640) published in 2016 explored how pharmacy services can more effectively meet the medicines-related needs of carers. This study identified that pharmacists (more than other healthcare professionals) need guidance on how to support informal carers and highlighted (640) key issues relating to the context of care settings. Community pharmacists, unlike other healthcare professionals, may see carers alone, for example, if

the patient is housebound and they commonly work in isolation without an MDT. More recently a realist synthesis published in 2020, reported that informal carers find medication management challenging and burdensome particularly where complex medication regimes are concerned (641). Furthermore, practitioners including pharmacists need to be aware of this potential challenge and its impact on daily lives, and work informal carers to reduce these burdens (641).

In addition, unlike hospital pharmacy teams, community pharmacy teams do not have formal procedures for identifying carers. They also do not have access to systems maintained by other healthcare professionals or organisations to find this information. This was identified in interviews in this study as a barrier to interaction with patients but might equally act as a barrier for interaction with informal carers (477,642,643). Carers may use several pharmacies and patients may have multiple carers. Hospital pharmacists, unlike a community pharmacist, may see patients and carers together thus facilitating the triangle of care.

Effective workflow is a key determinant of efficient delivery of healthcare (644) and proficient support staff enable clinicians to focus on patient care. Pharmacy technicians make up the bulk of support staff within community and hospital pharmacies and traditionally the bulk of their role has consisted of assisting pharmacists in the supply of medication. More recently, pharmacy technicians have taken on new professional roles including final accuracy checking and medicines optimisation.

Evolution of these new roles has occurred in particularly within the UK hospital pharmacy sector as a result of advancements in information technology and the drive for pharmacists to spend more time on person-centred care (645). Indeed, one hospital pharmacist mentioned in their interview that within their hospital trust pharmacy technicians were routinely taking blood samples from patients with a diagnosis of schizophrenia. There is limited evidence on the impact or effectiveness of pharmacy technicians undertaking screening for CMR, MetS and related diseases. In one study conducted in the USA technicians were trained to measure blood pressure to support patients with hypertension (646) but aspects and impact relating specifically to pharmacy technicians were not reported. Although outcomes have not been thoroughly researched reports of pharmacy technician's involvement in taking blood tests also appears elsewhere (647,648).

Consistent with potential advantages cited by respondents in this study, two studies (647,648) reported significant cost savings and an increase in time available to pharmacists for patient-centred work. However, these were pilot studies conducted in specific hospitals without robust study

methodology and not published in peer reviewed journals. Despite repeated attempts no pharmacy technicians agreed to take part in this study. Further exploration of their views on providing care for patients with SMI is needed as there currently appears to be no published evidence.

8.7 Chapter summary

Pharmacists' understanding of the lived experience of patients is limited because of the frequency, depth, type, and nature of their interactions. Specific pharmacist roles are associated with more in-depth interaction: mental health pharmacists working as part of a ward MDTs, mental health pharmacist independent prescribers working in outpatient clinics, practice based pharmacists and some aspects of community pharmacist roles. All of these roles utilise face-face interactions. Some aspects of community pharmacist roles as these utilise face-to-face interactions with patients. These were perceived by pharmacists as being more likely to have a significant impact on outcomes for patients with CMR, MetS and related diseases and SMI. The systematic review reported in Chapter Two showed that face-to-face interactions had a significant impact on outcomes.

However, all pharmacists agreed that mental health pharmacists and practice based pharmacists were the least accessible and visible to patients and other care professionals and this was not an aspect fully considered in the published evidence reviewed. Greater attention should be placed on positioning pharmacists/pharmacist roles that have the greatest impact so that they have more face-to-face interactions with patients and informal carers.

The most important findings from this chapter are that discussions about pharmacists' relationships with patients were underpinned by the need for trust and that discussions about relationships with doctors were hampered by invisible and visible interprofessional boundaries, while relationships with informal carers were limited because by a lack of interaction. Practice based pharmacists and pilot projects led by pharmacists were not commonplace and require further exploration.

Shared physical space and relationships with pharmacists is critical for promoting interprofessional working for care professionals and their patients. Such shared space could alleviate the tensions resulting from visible and invisible boundaries between doctors and mental health pharmacists. Access to comprehensive patient data could also allowing coordinated and patient-centred care and improve relationships between community pharmacists and GPs.

Chapter Nine: Discussion and implications of the findings

9.1 Introduction

This chapter presents a discussion of the novel insights from this research. The major findings will be outlined and explored in the context of previous research and theory. Methodological considerations and reflexivity, including the strengths and limitations of the study, will then be considered. To conclude this chapter, and the thesis, the original contribution that this study makes to the field, implications for clinical practice, future research, and policy will be considered.

The overarching aim of the work presented in this thesis was to understand the lived experience of patients with CMR, MetS and related diseases and SMI and the role of pharmacy within this lived experience. The research design sought to address this aim based on the following objectives:

1. To systematically review evidence relating to the role of pharmacy in CMR, MetS and related diseases in patients with SMI.

2. To explore and document the views, perceptions, and experiences of patients with SMI, their informal carers, caring dyads and pharmacy and care professionals on the role of pharmacy in managing CMR and MetS. This was informed by objective 1.

3. Provide strategic recommendations for clinical practice, policy, and research for pharmacy to improve care for CMR, MetS and related diseases in patients with SMI. This was based on the findings from objectives 1. and 2.

A multi-methods research design was adopted as the most suitable approach to meet these research objectives (see Chapter Three for a full discussion of the rationale). As the first qualitative study to explore the role of pharmacy in the lived experience of patients' physical health, the in-depth framework analysis generated numerous original insights.

9.2 Discussion of findings

This study extends the knowledge and understanding in the existing pharmacy literature by exploring experiences, views and perceptions of patients who have diagnosis of an SMI of support for CMR,

MetS and related diseases and their informal carers and caring dyads. Previous literature examining pharmacist's roles found that face-to-face interactions between pharmacists and other healthcare professionals consistently and significantly improves the process outcomes such as the rate of screening for CMR, MetS and related diseases in this patient population (Chapter Two). The literature review presented in Chapter Two also found that strategies that did not include any form of face-to-face contact were less effective for these same process outcomes. Findings from prior studies highlight the need for robust exploratory qualitative research in patients, informal carers, and caring dyads about the role of pharmacy for this patient group (Chapter Two). This study adds to earlier work by giving primacy to and privileging the patients', informal carers', and caring dyads' perspective on how they experienced delivery of care for by pharmacists for CMR, MetS and related diseases in patients with SMI. This study highlights the need for pharmacists to work together with patients with SMI, their informal carers and caring dyads to manage CMR, MetS and related diseases. Furthermore, pharmacists need to be more visible and present to patients and informal carers both in a literal and a metaphorical sense.

Analysis of patients data identified three themes: 1. CMR, MetS and related diseases, psychotropic medication, psychotropic medication side-effects and SMI 2. barriers to the role of pharmacy and 3. facilitators to the role of pharmacy. This research adds to prior knowledge by identifying that caring for patients by pharmacists goes beyond understanding the disease, providing medications, or information about the side-effects of psychotropic medication. This study points to the need to for care professionals to develop a shared understanding with the person living with CMR, MetS and related diseases and SMI including their views and perceptions.

Understanding that many patients' views and experiences of illness and medication are dynamic, pharmacists and other pharmacy staff and professionals could employ a person-centred approach. It is apparent that pharmacists need to spend more time undertaking patient facing medicines optimisation activities to improve patient outcomes. For many pharmacists, the process of actively increasing engagement with patients may require a new understanding of patient-pharmacist relationships and development of new skills. Interactions and communication should invite the patient to share their perspective, addressing concerns about treatment, regularly monitoring medication and information exchange. Further, primacy should be given to what these mean to the patient as an individual and how these impact on and are managed in their day to day lives. Patients' knowledge and experiences should be recognized as important and valid during routine interactions in an attempt to make such interactions more meaningful and person focused.

Patients used a variety of resources within the healthcare system to manage their CMR, MetS and related diseases. The was reflected in the range of preferred care professionals. This 'go-to' professional differed between patients but included their psychiatrist, community psychiatric nurse, and for very few the pharmacist who patients in the study recognized as a resource for advice and support for CMR, MetS and related diseases. The nature and development of relationships with care professionals was influenced by patient's perceived care needs and perceived role of the care professional as being trusted and able to provide good care as well as ease of access and convenience.

Patients who felt they were saturated and/or their needs met by healthcare services in having multiple appointments or whose physical healthcare was mandated in being on clozapine did not feel they would benefit from any additional support from pharmacists. For other patients in the study there were unmet needs relating to information exchange about CMR, MetS and related disease, psychotropic medication, and their side-effects. Patients in the study mentioned the benefits of having a regular interactions with care professionals and service providers to support and care for them. Given that patients attend community pharmacies regularly to collect dispensed medication then in the future they could access these services in a community pharmacy.

The findings of this study support the position that patient's expectations of pharmacists' roles and that the nature of patient-pharmacist relationship influences perceptions of the quality of interactions and care provided by pharmacists. A significant proportion of interactions between patients and pharmacists in this study clustered toward one type of scenario which lacked depth (high frequency low depth). On the other hand, a few patients had in-depth interactions with mental health or community pharmacists that significantly impacted their care. While policy changes to enhance care for people with LTCs has had a significant influence on pharmacists' expanded roles, each encounter and interaction with a patient is an opportunity to build trust, a relationship, and support the uptake of healthcare services. Compared with patients who reported limited interactions with pharmacists, those who had collaborative and meaningful interactions reported that they not only had a better understanding of CMR, MetS and related diseases, psychotropic medication, and its side but also more confidence and skill managing these.

The themes in this study reflect that patients with CMR, MetS and related diseases and SMI have a desire for and place value on person-centred communication in their interactions, this has the potential to increase patient acceptance of extended pharmacist professional roles. Pharmacists could

invite patients with SMI to share their perspectives on CMR, MetS and related disease. This could increase patient engagement, build trust, and facilitate the tailoring of care and support focused on individual needs. Pharmacy practice has expanded beyond traditional dispensing roles to more collaborative relationships and pharmacists need to consistently provide person-centred care. What matters to patients in their illness management is just as important as telling them the name and dose of medication to take.

Analysis of data collected from caring dyads identified three themes: enhanced closeness, dissonance, and balance within the caring dyad. This research adds to prior knowledge that support for caring dyads goes beyond understanding the experiences of the individual patient. This study points to the need to have an in-depth understanding of the impact of SMI, CMR, MetS or related diseases on the relationship between the patient and their informal carer. For informal carers in the caring dyads in this study caring for a loved one was an integral part of their own life and their relationship with the patient and there were many occasions when the care situation became a dominant part of that relationship.

Informal carers' choice as to whether to care is affirmed in policy within the UK. However, the findings indicated that this is not translated into practice because the care system relied on the support they provide, for example in manage the side effects of psychotropic medication or healthy lifestyle. The findings here indicated that informal carers' roles place them as co-providers of care and further that their own needs may be overlooked or subordinate to the needs and outcomes of the patient. Furthermore, although they are recipients of the care provided to the patient they care for, they are not consistently involved in decisions about treatment. Communication about illness management, well-being and medication within the caring dyad was altered by the experience and presence of side-effects of psychotropic and CMR, MetS and related diseases; pharmacists could support the caring dyad with this communication.

A view of outcomes beyond the patient as an individual may not resolve the problematic position of carers within long-term care policy or indeed the reliance within policy on informal care as a replacement for other forms of care. However, an increased awareness of the interdependence and impact of CMR, MetS and related disease in patients with SMI, especially with regards to closeness, dissonance, and balance within the relationship could reinforce a wider focus on the caring dyad the recipient of care. For example, reciprocity existed in the relationship within the caring dyad and the provision of care was not unidirectional as patients also provided care for their informal carers.

Absence of external support may enhance closeness within the caring dyad, where possible informal carers should be included in decisions about care to account for this. Engagement of caring dyads with pharmacy also resulted in increased closeness within the dyad. Informal carers desires to engage with pharmacists in order to understand psychotropic medication could act to provide an improved balance within the relationship. The caring dyad as a unit of the recipient of care captures the broader impact of long-term care, the absence of which would result in underestimation or misrepresented of evaluation of current interventions or policy.

In this research, patients', informal carers' and caring dyads' experiences, views and perceptions of pharmacy and pharmacists were affected by broader factors associated with the position of pharmacy in the healthcare system. First, the relationships, collaboration, and integration that pharmacists have with other members of the healthcare team such as the challenges that pharmacists face in interdisciplinary work. Second, healthcare organisational structures such as the ratio of mental health pharmacists to mental health inpatients and their active involvement and visibility in MDT teams. And finally, the professional identity of pharmacists, for example, pharmacist self-efficacy. The findings of this study indicate that these broader factors need to be addressed if patients' and caring dyads' needs are to be met.

9.3 Scholarly outputs from this thesis

This thesis has generated a range of academic outputs including publications. In addition, work from this research has been presented at conferences as oral presentations and posters. Details of these can be found on pages four to six of the thesis.

9.4 Implications for pharmacy policy and practice

The findings from this PhD have implications for pharmacy practice and policy in mental healthcare. This study found that pharmacists do not routinely undertake roles in the provision of care for CMR, MetS and related diseases in patients with SMI with sufficient frequency or sufficient depth that is considered meaningful to patients. Pharmacists also have little contact with caring dyads or informal carers of these patients and interactions with other care professionals appears to be constrained by the impact of contextual and relational factors on interprofessional boundaries undermining interprofessional collaboration.

Recommendation from the literature review in Chapter Two included incorporating face-to-face interaction as part of any implementation strategy. The need for face-to-face interactions between pharmacists and patients, informal carers, caring dyads, and other care professionals was also prominent throughout findings presented in Chapters Four to Eight as was the rarity of such occurrences. Central to this research are the patients who already suffer from health inequalities in part due to being marginalised within the care system. The first step for pharmacy practice to impact on this, to increase pharmacist patient facing interactions to facilitate the formation of long-lasting trusting relationships.

A starting point for this could be to build these practices into routine interactions, for example when a patient collects medication from the community pharmacy. In the long-term increased frequency and depth of interactions can only be facilitated by appropriate resourcing of pharmacists to do this. Evidence from this study suggests that such a change will require not only increased numbers of pharmacists but also a change in working practices. Changes in ways of working should incorporate the aspects of social, cultural, policy and healthcare organisational structures documented in this study. These challenges created by include medical hierarchies and the power dynamics and imbalances, labour divisions and boundaries of responsibility between care professions that compromise interdisciplinary working.

Internationally calls have been made for community pharmacists to be more involved in prevention and management of LTCs through the provision of "cognitive" and "clinical" services to support medication use and public health (150,649). Community pharmacy roles to support the patients who are the focus of this study are the NMS, defined public health role with lifestyle advice, discharge from hospital and signposting. The full potential of community pharmacist to contribute to care for CMR, MetS and related diseases in patients with SMI has yet to be realised. Findings from this study reinforce published evidence reporting that progress implementing extended roles for community pharmacy have been *"patchy and lacking in scale; "* (650) and there remains untapped potential (150,651–653).

In the UK, community pharmacy professional organisations and bodies have published a shared vision document (653,654). This document proposes that personalised care for patients with LTCs is a key area that community pharmacy has the potential to address alleviating pressures on other parts of the healthcare system. Translating and implementing this in practice might not be straightforward. Findings from this PhD research identifies a number of challenges to achieving this. Key challenges

include the need to increase community pharmacist numbers, change the skill mix of staff in community pharmacy, promote the active use of patient's electronic health record, ensure broader and systematic integration of community pharmacist within healthcare teams, engineer the NHS and community pharmacist organisational cultures, and increase public awareness of community pharmacy services.

9.5 Further research

1. Develop and test specific models of pharmacy support cardiometabolic risk, metabolic syndrome, and related diseases in patients with severe mental illness.

Such models need to improve patient's experience of care from pharmacy including support, information about psychotropic medication and its side-effects as well as CMR, MetS and related diseases. Primacy needs to be given to the patient perspective and their understanding of good quality care within these models. The findings of this study identify a range things that matter to patients. Such models need to address the barriers and make best use of the facilitators identified in this research. Furthermore, incorporate regular face-to-face interactions with pharmacy staff over a prolonged period of time to facilitate the formation of a trusting relationship and impact on care. An assessment of the quality of such relationships and their impact on outcomes could be measured. Consideration must be given to how models would operate in different contexts, such as secondary care psychiatric settings or community pharmacy, and consider the skill sets of different pharmacists within these settings. Models for pharmacy technician roles although less well explored within this study could focus on screening of CMR, MetS and related diseases for patients with SMI and how the skill-mix might impact on the time available for patient-pharmacist interactions.

2. Exploration of how to support caring dyads and triads in cardiometabolic risk, metabolic syndrome, and related diseases in patients with severe mental illness

The findings from this study provide a starting point for further research into dyadic illness management within the context of comorbid physical and mental ill health. Chapter Six provides evidence for formulating more effective interventions targeted at caring dyads rather than individually for patients living with CMR, MetS and related diseases and SMI and informal carers. Such research might focus on dyadic implementation of lifestyle changes and identification and reduction of factors

that lead to controlling and coercive behaviours. The development of Interventions would need to engage with both individuals and address the quality of the relationship within the caring dyad.

This exploratory study has focused on patients and informal carers as a dyad and has documented key processes that relate to illness management. A larger study exploring this topic is necessary and could include different dyad or triad perspectives, for example, patient, informal carer, and pharmacist or patient and two informal carers.

9.6 Strengths

1. A focus on the experience of patients and carers within the caring dyad

This study provides a significant contribution to knowledge. As far as we are aware, this dissertation reports the results of the first study focusing on the experience of patients with CMR, MetS and related diseases and SMI and the informal carers of those patients in caring dyads. This study highlights the interdependence between the two members of a caring dyad and its impact on illness management. It also highlights that the need for a new theoretical framework to better understand the management of SMI and co-morbidity and multi-morbidity that incorporate both dyadic interdependence theory and dyadic illness management theory. Such a theoretical framework needs to incorporate the potential negative behaviours and health consequences of controlling and coercive behaviours and fully account for the impact of incongruence in beliefs and how this affects the management of illness. Also, how healthcare services can ensure that carers do not feel that they need to exhibit these behaviours.

2. Rigorous qualitative research study in the field of pharmacy

There have been substantial changes to the role of pharmacy pharmacists and pharmacy practice over the last decade (152). While this has received significant research attention there is almost no research focussing on the interaction between pharmacy, in different contexts and patients with living with CMR, MetS and related diseases and SMI.

3. Background and discipline of the doctoral student, supervisors, and co-authors of the systematic review.

The background and discipline of the doctoral student, supervisors and co-authors of the systematic review are relevant to the research. The doctoral student is an experienced pharmacist with 24 years of clinical practice split almost equally between general medicine and psychiatry. The doctoral student is still practicing as a Senior Mental Health Pharmacist in a Mental Health Trust. The supervisory team is multidisciplinary (pharmacy, health psychology, sociology, and public policy) and have extensive experience of conducting applied research within mental health settings. Co-authors of the systematic review have extensive experience working as practising clinical pharmacists within multidisciplinary teams. Detailed analysis of this data was subject to ongoing supervision from the doctoral student's supervisory team that helped ensure the validity of the research findings.

4. A holistic understanding of the patient experience

The aim of qualitative research (655) is to understand what happens, rather than focus on estimates of prevalence; an aim that would necessitate statistically representative sampling and standardised interviews. The sample for this research was composed of different categories of respondents all of whom engaged with patients living with CMR, MetS and related diseases and SMI. Data was gathered from different key stakeholder groups, patients, informal carers, caring dyads and a variety of different care professionals and pharmacist which generated data that was rich, complex, and multifaceted and provided patterned meanings related to the phenomena of interest. Respondent triangulation helped to capture different viewpoints and understandings of the phenomenon under investigation, resulting in a more complete picture (656) as well as enhancing the validity of the collected data

The use of a common interview schedule and coding framework resulted in a holistic understanding of the patient and informal carer experience and their relationship with pharmacy. Patterned meanings and common perspectives were identified across these different categories of respondents. Systematic coding meant that it was easier to identify instances that were incongruent as well as those that were common. Particular attention was paid to identifying such 'deviant' cases.

9.7 Limitations

1. Socially desirable responses

Care professionals and pharmacists may have presented a more liberal image thereby giving a false impression of their actual practice to the interviewer. Studies involving direct observation of clinical practice have a particular advantages over self-reports as they can show the strategies adopted in interactions with clients in greater detail (657) and areas of practice which practitioners may be unaware or do not wish to discuss (658). The only way to ascertain whether interview respondents were accurate would have been to make comparisons between interview and observational data. A considerable methodological literature comparing the advantages of observation and interviews exists (659).

2. Groups of individuals not represented

Despite sampling care professionals with a breadth of experiences and opinions, there were difficulties recruiting from specific disciplines. The study did not recruit any social workers, physiotherapists, GP nurses or pharmacy technicians. There was only one practice based pharmacist recruited to the study.

Respondents with particular ethnicities were not part of the sample, for example there were no respondents with a Chinese ethnic background and only one patient identified as being from Black/Black British ethnic background. There is a possibility that inability to support languages other than English contributed to the inequality in recruitment between ethnic groups that occurred in this study. All informal carers were white.

For people from Black, Asian, and Minority Ethnic (BAME) groups in the UK and other Western countries, significant mental health inequalities prevalent across access, experience and outcome currently exist (660). These disparities have been further highlighted by the recent Independent Review of the Mental Health Act (661). In that review, a call was made for recommendations which would address the root causes of these disparities including a call for research into the underlying contributing factors.

Approximately 13% of the UK population is from an ethnic minority background with eight per cent Asian/Asian British, three percent Black/Black British and two percent mixed/multiple ethnic groups

(662). There was significant under-representation of BAME groups in the research presented in this thesis, in particular for those from Black African and Black Caribbean backgrounds. This is particularly important given the significant over-representation of ethnic minority groups in some parts of the mental health system and the disproportionately high rates of mental health problems seen in BAME people.

Common mental disorders have been found to be more than twice as prevalent in people from BAME backgrounds as the white British population (663) and severe mental illness up to four times more prevalent than in the White British population (664). Importantly, a recent systematic review and network meta-analysis reported non-white ethnicity as a possible risk factor for antipsychotic-induced metabolic dysregulation (91).

Of the eleven pharmacists only two were male and of sixteen patients only two were male. All patients within the caring dyads were female. Further, of the sixteen patients recruited fourteen were female. One patient was aged 20-24 and the remaining 15 patients were over the age of 35 years.

A briefing paper published in 2020 reported that in England, common mental disorders are more common among women than men in every age category. This difference is most pronounced among those aged between 16 and 24 (665). Although the general prevalence of common mental disorders has increased over the last three decades the differences in prevalence between men and women has not changed substantially (665). In the two percent of adults diagnosed with bipolar disorder the rates of diagnosis among men are slightly higher. The highest rates among women were found in ages 16-24 (665). For men, rates were around three percent for age groups between 16 and 44. There was no significant difference in rates of schizophrenia, schizoaffective disorder and other non-organic psychoses between men and women (665).

None of the patients recruited to the study were currently being treated as a psychiatric inpatient. However, it is acknowledged that such patients may have been too unwell to consent. All participants were residents within England

Qualitative research is concerned with assessing validity through the richness of the data collected rather than the number of participants and generalisability. However, the factors highlighted above must be considered as the results and findings might not be transferable to patients currently cared

for by mental health services or other countries of the UK or internationally . A greater breadth of views and richer data may have been collected if a more diverse set of individuals as were recruited participated in the research.

Collectively, as individuals' meanings are informed by the intersectionality of ethnicity, gender, age, culture, time, and context, insights might have been limited by the relative lack of diversity in the sample. As such, any conclusions drawn from this study must be tentatively applied to groups not represented by the study participants, as they may construct CMR, MetS and related diseases and SMI differently.

3. Participant information

Information about medication use and patterns of adherence or concordance was not collected. No data was collected about the severity or duration of mental health or physical disease that might have a consequence on the way that patients, informal carers, and caring dyads functioned.

4. Member checking was not used

One widely used method to increase rigor within qualitative research is member checking (349). The process of member checking, also termed 'respondent' or 'participant validation' involves returning the data such as interview transcripts and/or results to research participants and asking them to provide input and comments. In this way research participants validate the analysis, confirm a common understanding of the data. and reaffirm informed consent. It is often suggested, either implicitly or explicitly, that member checking is a way of limiting subjective bias from the researcher and a useful means of checking the truth of any knowledge (666,667).

9.8 Reflective account

Undertaking research in a reflexive way provides an opportunity to learn about oneself and to engage in transformative process. My own transformation from a neophyte to a more knowledgeable, informed, aware, experienced, and independent researcher has occurred concurrent to this PhD research. Like the stories of the patients who lived daily with CMR, MetS and related diseases and SMI and their informal carers my journey was dynamic and undulating. Many challenges occurred and were addressed while developing and undertaking this research. At the beginning of this journey,

although I was an experienced and expert healthcare professional, I was a novice researcher, constrained by the realms of what I knew and what had been achieved before me. However, during this apprenticeship, I have developed confidence and insights that have inspired me to continually challenge myself as well as the status quo of inquiry. I hope that this has resulted in high quality research that provides an important and a novel contribution to the field in relation to understanding of the phenomenon.

Although I do not refute that the insights identified through the analysis of the data are influenced by my own perspective, the work has been undertaken critically and with methodological rigour. There has been a consistent commitment to conducting an ethical, moral, and relational inquiry of which this thesis is the product. Dedication to the quality of this study has been central and crucial and, therefore, to maintain the authenticity and credibility, reflexive thoughts and processes have been articulated and presented throughout this thesis. Furthermore, rich data excerpts, divergent accounts, counter explanations have been presented to provide transparency.

There are strengths I have been able to draw upon from my clinical background in both general medicine and psychiatry. These provided insights in the specific area of care that would otherwise not have been visible. The drive, motivation and tenacity required to undertake this work has in part come from my experience of working in a clinical environment since I completed my undergraduate degree in Pharmacy.

In addition, I have developed a wide repertoire of knowledge, intuition, and skills that I hope will be key to my future academic and scholarly endeavours. Equally important and synonymous with my transition as a researcher, my practice as a hospital pharmacist has without doubt been informed, challenged, and influenced. I have had the privilege and honoured to be invited into peoples' homes, lives and their stories, those patients and informal carers who have taken part have gifted me their voices on this phenomenon. Exposure to these insights has been evocative, emotive, and caused me to reflect on my own actions, conduct, status and standing as a healthcare professional, a researcher, and a social being. I emerge through this experience more informed and with eyes and mind more open. The privilege of conducting this research, I feel I have begun to understand what being a professional working in psychiatry and the wider healthcare system is about. Furthermore, I comprehend how fundamental it is that pharmacists and other care professionals challenge the status quo and provide and create platforms and opportunities to liberate the voices of our patients, their

informal carers and colleague professionals to continually improve the quality, experiences, and outcomes of care.

9.9 Conclusion

This study has explored patients' lived experience of cardiometabolic risk, metabolic syndrome, and related diseases and severe mental illness and the role of pharmacy within this which was absent from the literature.

This study addressed these deficits by employing a qualitative exploratory research design, using semi-structured interviews, and underpinned by interpretivism. Exploration of he views, experiences and perceptions of patients, informal carers, caring dyads, care professionals and pharmacy professionals on the role of pharmacy shed light research objectives. This study identified that patients experience the intersections and entanglements of CMR, MetS and related diseases, psychotropic medication, psychotropic medication side-effects and SMI. There was no clear delineation between these different conditions and the impact on their lives. Views, experiences, and perceptions of pharmacy care or support for CMR, MetS and related diseases did not meet the desires or perceived needs of patients or their informal carers. In depth meaningful interactions with pharmacists were infrequent. Changes to pharmacy practice and policy could facilitate shared physical space and face-to-face interactions between pharmacists and other care professionals and more importantly patients and informal carers. Ultimately, this would encourage person-centred care with the goal of building trusting relationships which is key in this vulnerable population.

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Appendix 1: Preferred Reporting Items for Systematic reviews and Meta-Analyses 2020 checklist and Preferred Reporting Items for Systematic reviews and Meta-Analyses 2020 checklist for abstracts

Preferred Reporting Items for Systematic reviews and Meta-Analyses 2020 checklist:

Section and Topic	Item #	Checklist item	Location or page where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	Page 39
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist (see below)	-
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	Pages 37 and 41
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	Page 41
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	Page 43 Appendix 4
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	Page 42 Appendix 4
Search strategy	7	Present the full search strategies for all databases, registers, and websites, including any filters and limits used.	Appendix 4
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	Page 44 Appendix 4
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	Pages 45-46
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g., for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	Page 43 Appendix 4
	10b	List and define all other variables for which data were sought (e.g., participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	Pages 43, 45-46

Section and Topic	Item #	Checklist item	Location or page where item is reported
			Appendix 4
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	Page 44 Appendix 5
Effect measures	12	Specify for each outcome the effect measure(s) (e.g., risk ratio, mean difference) used in the synthesis or presentation of results.	Pages 45-46
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g., tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	Pages 45-46
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g., subgroup analysis, meta-regression).	
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	Page 44 Appendix 5
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	N/A
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	Pages 46-47
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	Appendix 7
Study characteristics	17	Cite each included study and present its characteristics.	Appendix 8
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	Pages 48-52 Appendix 5
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g., confidence/credible interval), ideally using structured tables or plots.	Appendix 8

Section and Topic	Item #	Checklist item	Location or page where item is reported
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	Page 46 Pages 50 to 61 Appendix 8
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g., confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	Page 46 Pages 53 to 61 Appendix 8
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	N/A
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	N/A
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	Pages 48 - 52 Appendix 5
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	Pages 48 - 52 Appendix 5
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	Pages 61-66
	23b	Discuss any limitations of the evidence included in the review.	Pages 66-68
	23c	Discuss any limitations of the review processes used.	Pages 66-68
	23d	Discuss implications of the results for practice, policy, and future research.	Pages 61-66 and pages 68-69
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	Page 42
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	N/A

	24c	Describe and explain any amendments to information provided at registration or in the protocol.	N/A
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	See published article (387)
Competing interests	26	Declare any competing interes ts of review authors.	See published article (387)
Availability of data, code, and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	See published article (387)

Preferred Reporting Items for Systematic reviews and Meta-Analyses 2020 for Abstracts:

Section and Topic	Item #	Checklist item	Reported (Yes/No)
TITLE			
Title	1	Identify the report as a systematic review.	See published article (387)
BACKGROUND			
Objectives	2	Provide an explicit statement of the main objective(s) or question(s) the review addresses.	See published article (387)
METHODS			
Eligibility criteria	3	Specify the inclusion and exclusion criteria for the review.	See published article (387)
Information sources	4	Specify the information sources (e.g., databases, registers) used to identify studies and the date when each was last searched.	See published article (387)

Section and Topic	Item #	Checklist item	Reported (Yes/No)
Risk of bias	5	Specify the methods used to assess risk of bias in the included studies.	See published article (387)
Synthesis of results	6	Specify the methods used to present and synthesise results.	See published article (387)
RESULTS			
Included studies	7	Give the total number of included studies and participants and summarise relevant characteristics of studies.	See published article (387)
Synthesis of results	8	Present results for main outcomes, preferably indicating the number of included studies and participants for each. If meta-analysis was done, report the summary estimate and confidence/credible interval. If comparing groups, indicate the direction of the effect (i.e., which group is favoured).	See published article (387)
DISCUSSION			
Limitations of evidence	9	Provide a brief summary of the limitations of the evidence included in the review (e.g., study risk of bias, inconsistency, and imprecision).	See published article (387)
Interpretation	10	Provide a general interpretation of the results and important implications.	See published article (387)
OTHER			
Funding	11	Specify the primary source of funding for the review.	See published article (387)
Registration	12	Provide the register name and registration number.	See published article (387)

Appendix 2: Consolidated criteria for reporting qualitative studies: 32-item checklist

No. Item	Guide questions/description	Page #
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Interviewer/facilitator	Which author/s conducted the interview or focus group?	83,92, 336
2. Credentials	What were the researcher's credentials? e.g., PhD, MD	89
3. Occupation	What was their occupation at the time of the study?	89
4. Gender	Was the researcher male or female?	89
5. Experience and training	What experience or training did the researcher have?	89
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	Page 88 Appendix 9
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g., personal goals, reasons for doing the research	Page 80-81 Appendix 9
8. Interviewer characteristics	What characteristics were reported about the inter viewer/facilitator? e.g., bias, assumptions, reasons, and interests in the research topic	Page 80-81 Appendix 9
Domain 2: study design		
Theoretical framework		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g., grounded theory, discourse analysis, ethnography, phenomenology, content analysis	Pages 75-78 Appendix 9
Participant selection		
10. Sampling	How were participants selected? e.g., purposive, convenience, consecutive, snowball	Page 83-84 Appendix 9
11. Method of approach	How were participants approached? e.g., face-to-face, telephone, mail, email	Page 88-89 Appendix 9
12. Sample size	How many participants were in the study?	Pages 96,126,148,165, 196
13. Non-participation	How many people refused to participate or dropped out? Reasons?	Not possible to give an accurate value for this due the method of recruitment. Participants may have read the inforamtion and not chosen to contact the lead reasearcher.

Setting		
14. Setting of data collection	Where was the data collected? e.g., home, clinic, workplace	Page 89
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	Page 83
16. Description of sample	What are the important characteristics of the sample? e.g., demographic data	Page 97,127, 149, 165, 196-197
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Pages 87-88 Appendix 9 Appendix 11
18. Repeat interviews	Were repeat interviews carried out? If yes, how many?	No repeat interviews were carried out.
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	Pages 89-90 Appendix 11
20. Field notes	Were field notes made during and/or after the interview or focus group?	Pages 75, 80
21. Duration	What was the duration of the interviews or focus group?	Page 89
22. Data saturation	Was data saturation discussed?	Page 87
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	No
Domain 3: analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	Page 91
25. Description of the coding tree	Did authors provide a description of the coding tree?	Coding framework was used pages 92, 234
26. Derivation of themes	Were themes identified in advance or derived from the data?	Both – framework analysis was used. Pages 75-78
27. Software	What software, if applicable, was used to manage the data?	Pages 89, 92 Appendix 9
28. Participant checking	Did participants provide feedback on the findings?	They will be able to provide feedback after dissemination of findings
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the	Yes.

	themes/findings? Was each quotation identified? e.g., participant number	Pages 101-116 Pages 129-142 Pages 151-157 Pages 168-186 Pages 199-214
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Pages 99,128,150,166, 198
31. Clarity of major themes	Were major themes clearly presented in the findings?	Pages 99-116 Pages 128-142 Pages 150-157 Pages 166- 186 Pages 198-214
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Pages 99-116 Pages 128-142 Pages 150-157 Pages 166- 186 Pages 198-214

Appendix 3: Systematic Review Protocol

The role of pharmacy in the management of cardiometabolic risk and metabolic syndrome in severe mental illness: a mixed methods review

Dolly Sud, Eileen Laughton, Robyn McAskill, Eleanor Bradley, Ian Maidment

Citation
Dolly Sud, Eileen Laughton, Robyn McAskill, Eleanor Bradley, Ian Maidment. The role of pharmacy in the management of cardiometabolic risk and metabolic syndrome in severe mental illness: a mixed methods review. PROSPERO 2018 CRD42018086411 Available from: https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42018086411

Review question
What is the role of the pharmacist and pharmacy services in the management of cardiometabolic risk factors (health promotion and risk reduction) and metabolic syndrome in individuals with severe mental illness?

Searches
MEDLINE (Ovid) (1950 to date), Embase (Ovid) (1980 to date), PsycINFO (EBSCO) (1806 to date), British Nursing Index , CINAHL (EBSCO) (1981 to date), AMED (Ovid) (1985 to date), Health Business Elite, Health management information consortium (Ovid) (1979 to present), The Cochrane Library (current date), Health Technology Assessments (current date), Scopus (1970 to date) and Web of Science (1985 to date).

The search strategy will be developed using database-specific search terms with the involvement of a Medical Librarian. Articles must be in the English language. The searches will be re-run just before the final analyses and further studies retrieved for inclusion.

Additionally, other methods will be utilised including search of the Ethos repository of theses, hand-searching key journals and conference proceedings, citation searching of highly cited key papers, scanning reference lists of key papers, contacting authors of relevant conference abstracts and by contacting experts in the field. A grey literature search will also be carried out using Google Scholar, the Grey Literature in Europe website (http://www.opengrey.eu/) and by consulting relevant agencies or organisations.

Types of study to be included
There are no restrictions on the types of study design eligible for inclusion.

Condition or domain being studied
The management of cardiometabolic risk factors and metabolic syndrome in individuals with severe mental illness.

Participants/population
Individuals with severe mental illness (SMI) over the age of 18.

Severe mental illness – bipolar affective disorder, schizophrenia, schizoaffective disorder, psychosis, any psychotic disorder.

Carers of individuals with SMI

Care professionals of those with SMI.

Intervention(s), exposure(s)
Pharmacy staff carrying out any of the following activities to any degree for adults (>18 years) with severe mental illness:

Screening for metabolic syndrome, syndrome X or cardiometabolic disease and any of the associated risk factors including lifestyle advice, diet, smoking, alcohol, exercise, cardiovascular disease, diabetes and prediabetes, weight, BMI, overweight, obesity, lipid abnormalities and blood pressure.

Health promotion or risk reduction intervention for metabolic syndrome, syndrome X or cardiometabolic disease and or any of the associated risk factors.

Medicines related activities for cardiometabolic risk factors or metabolic syndrome.

Comparator(s)/control
Studies will be included regardless of whether there is a comparator/control or not.

Main outcome(s)

Views, perception, opinions, experiences of service users, carers or any healthcare professionals on the role of pharmacists or pharmacy delivering this.

Medicines related activities e.g. optimisation of diabetes treatment.

Additional outcome(s)
Change in rate of screening of cardiometabolic risk factors or for metabolic syndrome (also known as syndrome X).

Change in health behaviour (risk reduction or health promotion).

Diagnosis of metabolic syndrome or identification of individual at high risk of metabolic syndrome.

Diagnosis of diseases related to metabolic syndrome including diabetes, cardiovascular disease, hypertension, obesity, overweight, diabetes/high risk of diabetes/pre-diabetes.

Change in patient or physical health parameter e.g. BP outcome for the above.

Data extraction (selection and coding)
For the first stage of study selection, one reviewer (DS) shall screen articles based on titles only (using Mendeley), and will only eliminate articles that are clearly not relevant to the research questions (e.g. preclinical studies). For the next stage, three reviewers (DS, RM and EL) will independently screen titles and abstracts against the inclusion criteria to identify potentially relevant papers. Reviewers shall be aware of author and journal details. In the third stage, the three reviewers will independently review the full texts of papers which are potentially relevant. Consensus on inclusion in all stages will be reached by discussion between three reviewers (DS,EL and RM), with arbitration by a senior supervisor if necessary. Relevant missing data will be requested from study authors. Any discrepancy will be resolved by discussion between three reviewers and if required arbitration by a senior supervisors (IM or EB or both). If there is any doubt then the study will be included.

Risk of bias (quality) assessment
Risk of bias assessment on the included studies will be conducted by two independent reviewers (DS and EL). Consensus on assessments will be reached by discussion between two reviewers, with arbitration by a senior supervisor if necessary. Risk of bias will be assessed with a modified MMAT (Mixed Methods Appraisal Tool). http://mixedmethodsappraisaltoolpublic.pbworks.com/w/page/24607821/FrontPage. Studies shall not be excluded based on the risk of bias assessments; however, the findings shall provide useful insights into the methods used for data collection and analysis.

Strategy for data synthesis
The exact method of synthesis for the included research shall depend on the nature of the evidence identified.

With regards qualitative data, the choice of method will depend on whether the data are relatively thin or

thick. If the data are found to be thin or descriptive then thematic analyses will be utilised (Thomas and Harden, 2008). Whereas studies with thicker data or richer concepts may be better suited to a more complex in depth analysis such as grounded theory (Barnett-Page and Thomas, 2009). The decision to use one synthesis method over the other shall be made by group consensus as soon as all the studies are selected for inclusion.

If studies are identified with sufficiently homogeneous population or interventions, then their data will be pooled for meta-analysis. The pooled data will then be analysed using an appropriate statistical approach depending on the type of data. This approach will give greater confidence in the conclusions of the review process.

Update of strategy after data have been extracted and reviewed:

A mapping review will be undertaken in order to give an overview of this research area that allows the researchers to pinpoint specific knowledge gaps. Subsequently, review of implementation strategies used to implement study interventions were reviewed using Cochrane EPOC taxonomy

Analysis of subgroups or subsets
None

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Type and method of review
Intervention

Anticipated or actual start date
01 January 2018

Anticipated completion date
31 December 2018

Funding sources/sponsors
LPT NHS Trust Charitable Funds. Aston University.

Conflicts of interest
None known

Language
English

Country
England

Stage of review

Appendix 4: Detailed information about the literature review

Systematic review search strategy

Scoping search

The Centre for Reviews and Dissemination (CRD) database and the Cochrane Database of Systematic Reviews library were initially searched. This was done in order to identify any ongoing or previously published systematic reviews of the role of pharmacy in the management of cardiometabolic risk (CMR), metabolic syndrome (MetS) or related diseases in severe mental illness (SMI).

DS conducted preliminary scoping searches for relevant studies within medical and social science databases (Prospero, Cochrane library, NICE Evidence Search, Turning Research Into Practice) using the following terms:

'pharmac*';

AND 'mental' OR 'psych';

AND 'lifestyle advice' OR diet OR smoking OR alcohol OR exercise OR metabolic OR diabetes.

Using these terms was, however, problematic as the number of results returned was very large and included many papers that were not specific to the question. The reason for this is that the term pharmac* included other areas such as pharmacological and pharmaceutical. The search was repeated to include more specific terms: pharmacy and pharmacist. This returned a smaller number of more specific and relevant papers (243,244,252).

The scoping searches identified that the literature exploring the role of pharmacy role of pharmacy in the management of cardiometabolic risk (CMR), metabolic syndrome (MetS) or related diseases in severe mental illness (SMI; therefore the search was expanded to include any pharmacy related activities by using a broader search terms in accordance with guidance from the CRD (668) and the Cochrane Handbook for Systematic Reviews of Interventions (669). The PICOS (Population, Intervention, Comparators, Outcome, Study design) tool (670) was used to inform the development of inclusion and exclusion criteria and search terms and identify search concepts for the literature search.

Final search strategy

A systematic search for primary research studies in which the study intervention involved pharmacy/pharmacy professionals for CMR or MetS or related diseases in severe mental illness (SMI) was conducted. Any published literature which described an intervention involving pharmacy or pharmacy professionals in CMR, MetS or related diseases were included (in all cases this is described as the study intervention), this could have included for example new pharmacy service or evaluations of existing services. Eleven electronic databases were searched from inception to January 2018; Medline, EMBASE, PsycINFO, British Nursing Index, AMED, Health Business Elite, Health management information consortium, The Cochrane Library, Health Technology Assessments, Scopus, and Web of Science. The search was repeated in August 2020 and no new studies were identified for inclusion. Database-specific search strategies were developed with the input from a medical librarian. Search terms included a combination of Medical Subject Heading terms, keywords, and a comprehensive list of synonyms of the following: "pharmacist" OR "pharmacy" AND "cardiometabolic" OR " metabolic syndrome" and "severe mental illness" with the aim of being as sensitive as possible. The search was not limited by dates of publication or country of origin. The database search was supplemented by search of the Ethos repository of theses; hand-

searches of key journals and conference proceedings; citation searches of highly cited key studies; scanning reference lists of key studies; contacting authors (once) of relevant conference abstracts and studies and experts in the field. The grey literature search was further supplemented by checking the first 100 hits from Google Scholar, the Grey Literature in Europe website (http://www.opengrey.eu/) and by consulting relevant agencies or organisations. The reference manager tool used (Mendeley) also provides a service known as Mendeley suggest which provided a further source of possible studies.

Search terms

Preliminary search terms were generated after scoping reviews and consultation with academic supervisors and the medical librarian. Evaluation was based on whether these search terms provided comprehensive searches which would generate relevant articles. This allowed the search terms to be developed and refined through an iterative process.

The final search terms were:

1. Pharmacy OR pharmacist OR “pharmacy education” OR “pharmacist education” OR “pharmaceutical care”
2. Mental OR psych*
3. Screening OR monitoring” OR Intervention
4. life-style OR “public health” OR health promo*
5. Obesity OR overweight OR weight OR BMI or “body mass index” OR “weight management” OR nutrition OR “weight loss” OR eating OR diet*
6. Cardio* OR cardiac
7. Metabolic OR cardiometabolic OR cardio* OR “syndrome X” OR “cholesterol” OR “triglycerides” OR lipid*
8. Diab* OR glucose OR “glucose regulation” OR “glucose intolerance” OR “hyperglycaemia” or “HbA1c”
9. Exercise OR “physical activity” OR walk* OR jog* OR run*
10. Smoking OR “smoking cessation” OR “nicotine replacement" OR “quit* smoking”
11. Alcohol OR drink* OR “problem drinking”
12. Hypertension OR “blood pressure” OR “BP”
13. 1 AND 2 AND 3 AND 4
14. 1 AND 2 AND 3 AND 5
15. 1 AND 2 AND 3 AND 6
16. 1 AND 2 AND 3 AND 7
17. 1 AND 2 AND 3 AND 8
18. 1 AND 2 AND 3 AND 9
19. 1 AND 2 AND 3 AND 10
20. 1 AND 2 AND 3 AND 11
21. 1 AND 2 AND 3 AND 12

Inclusion and exclusion criteria

The inclusion and exclusion criteria, developed from the scoping searches, for the review are outlined here according to the PICOS criteria (Table 2.2).

Participants

Individuals with SMI who were aged 18 or over were included in the review. Studies were excluded if they did not include an explicit reference to these participants. There were no limits set on study

participants in terms of study setting (i.e., hospital, community, or academic institution) or gender. Studies conducted within the UK, European and international settings were included.

Interventions

To be included the study intervention involved pharmacy or pharmacy professionals in CMR or MetS or related diseases in severe mental illness. Any published literature which described an intervention involving pharmacy or pharmacy professionals in CMR, MetS or related diseases were included this could include for example a new pharmacy service or an existing service was included. This could include, for example, pharmacists/pharmacy professionals/pharmacy students/pharmacy service for undertaking screening (e.g., weight checks), identifying abnormality (e.g., metabolic syndrome), managing cardiometabolic risk factors (e.g., providing support for smoking cessation) or advising on medication (e.g., advising on switching medication with lower risk profile for weight gain). In all cases this is described as the study intervention in our review. The intervention should be for those ≥ 18 years with SMI could be for CMR risk factors or MetS or related diseases as a whole or its constituent parts or specific lifestyle behaviours.

Comparators

Initial searching revealed that studies which included a comparison group appeared to be small in this research area, therefore studies with and without a comparison group were included in the review.

Outcomes

The primary outcome measures were change in rate of screening of cardiometabolic risk factors metabolic syndrome ore related diseases or any of the associated risk factors including lifestyle advice, diet, smoking, exercise, cardiovascular disease; change in health behaviour (risk reduction or health promotion); diagnosis of metabolic syndrome or identification of individual at high risk of metabolic syndrome; diagnosis of diseases related to metabolic syndrome including diabetes, cardiovascular disease, hypertension, obesity, overweight, diabetes/high risk of diabetes or change in patient outcome or health parameter e.g. BP for the above.

Study Design

The decision was ,made to include mixed methods, qualitative and quantitative study designs in the current review. In recent times there has been increasing recognition of the value of qualitative evidence when assessing interventions (234,671). In addition what has become more common health intervention evaluation is the inclusion of qualitative aspects and for the evaluation of complex interventions a 'mixed methods' approach (302,672). In the understanding "*what, how and why*" qualitative evidence is very valuable in reviews of intervention effectiveness (673). Qualitative research data help in the interpretation of systematic review as it enhances the understanding of the what parts are seen favourably/unfavourably and how those who receive the intervention experience it (669).

Language and year of publication

Non English-language papers found during the search process were not included for final review as there were no resources to translate. This was documented along with the reason for exclusion. No limitations on the year of publication were applied.

Appendix 5: Quality assessment using the Modified Mixed Methods Appraisal Tool

Quality assessment – details regarding the mixed methods appraisal tool (MMAT)

The methodological quality of the selected studies was assessed to identify weaknesses and strengths to help interpretation of results. Papers were quality assessed using the Mixed Methods Appraisal Tool (MMAT) (233,269) which is designed to appraise the methodological quality of qualitative, mixed methods and quantitative literature. The MMAT has been shown to have high validity (674) and reliability (675). The scale comprises two screening questions, followed by individual items for different methodologies. Four domains: sampling strategy, appropriate measurement, sample representation and acceptable response rates for the chosen research tool (i.e., questionnaire) were used to assess quantitative studies. Qualitative studies were assessed according to relevance of data source (i.e., focus groups), consideration of how findings relate to the context (i.e., setting), appropriateness of data analysis process (i.e., suitable information provided) and consideration of how the researcher influenced findings (i.e., interaction with participants). Studies were given an overall quality score for each domain met using the following star ratings: Four* = 100%, Three* = 75%, Two* = 50%, One* = 25%, No stars X = 0%

MMAT screening questions:

1. 'Are there clear qualitative and quantitative research questions (or objectives), or a clear mixed-methods question (or objective)?'
2. 'Do the collected data allow for the research question (or objective) to be addressed?'

Quality assessment of studies for this review

The MMAT was employed to review each of the 33 articles. 34 studies were identified (Figure 1) but the results of two of these were combined (238,239) and analysed as one study as the findings were from a single research study. As part of the review process, papers were divided into methodological domains: mixed methods, qualitative and quantitative. The quantitative domain is subdivided into three: randomised controlled, non-randomised and descriptive. The current review contains articles classified into five groups: qualitative studies (n=4), quantitative studies with a nonrandomised design (n=17), quantitative studies with a randomised control design (n=1), quantitative studies with a descriptive design (n=6), and mixed methods studies (n=4). The approach adopted to the classification of articles into these four groups was taken directly from the work on the MMAT as presented by Pluye et al, (233,269). The four articles classified as mixed-methods studies (265–268) did not conform to the classic mixed methods designs as described, for example, by Creswell and Plano Clark (676). The articles did not label themselves as being 'mixed methods', but they included qualitative and quantitative data which were collected and analysed with the purpose of meeting the overall research objective. In these cases , the criteria for the appraisal of mixed-methods studies were applied. In accordance with guidance provided (233) those articles classified as mixed methods were awarded overall quality scores in line with the lowest score of their specific components.

14 of the studies in the review followed a pre-post interventional study design (196,197,254,257–259,241,243–249) and did not conform to the non-randomized control design as described in the MMAT tool as they did not include a control group. This issue is acknowledged by the author of the tool. They make the following recommendations based on other users' experiences; '*remove item 3.3 on the comparability of groups, replace it with another item they judge important, interpret item 3.3 for single group pre-post by checking if the pre- and post-subjects are comparable (e.g., if a high drop-out rate at post) or use the descriptive set of criteria (since no comparison group is a common*

characteristic of descriptive studies). They go on to say that appraisal is a value judgment and the interpretation of the items might vary based on the context of the review (types of studies)'.

After much discussion between the two of the authors (DS and EL) and conformation that this approach was acceptable with another author (RM) it was agreed to use a modified tool as follows:

Original criteria:
'3.2. Are measurements appropriate (clear origin, or validity known, or standard instrument; and absence of contamination between groups when appropriate) regarding the exposure/intervention and outcomes?'

'3.3. In the groups being compared (exposed vs. non-exposed; with intervention vs. without; cases vs. controls), are the participants comparable, or do researchers take into account (control for) the difference between these groups?'

Modified criteria:
3.2. Are measurements appropriate (clear origin, or validity known, or standard instrument?

3.3. In the pre and post study groups are the participants comparable, or do researchers take into account (control for) the difference between or any contamination that may have occurred?

There were several reasons for choosing to take this approach; removing the item altogether would have resulted in assessing those studies against three rather than four items leading to an inequity in the assessment if compared to assessment of those studies that did conform to the non-randomised control design. The question of contamination appeared to be unrelated to that of the measurement chosen. In addition including the question of contamination as a separate item is consistent with a previous version of the tool (674).

Three of the mixed methods studies (261,263,264) including many aspects that were not relevant to the review question and the quality assessment were only applied to those aspects that were relevant to the review question.

Quality assessment – application of MMAT to chosen studies

Table 2 provides detailed information. The overall quality of the reported studies, assessed using the Mixed Methods Appraisal Tool (MMAT) (233,269) generally good, with twelve studies scoring **** (100%), eight studies scoring *** (75%), and thirteen studies scoring ** (50%) or less.

One study (264) did not explicitly state a research question or objective, therefore quality assessment was based upon whether the collected data answered the research questions of the present review. A common weakness across a number of studies concerned the use of qualitative data – authors were not clear about how this particular type of data answered the research question (264–266) Another common weakness was the lack of (262,264–266) or justification for method of synthesis (267); the quality of any study will be fundamentally undermined if an inappropriate choice or method of data collection or analysis is chosen.

Another common weakness was inadequate researcher reflexivity within both qualitative studies (262–264) and qualitative aspects of mixed methods studies (265–268) – there was no examination or critique of how the researcher impacted on the study or the participants.

Relevant national published clinical guidelines were used in several of the studies to allow for the identification of appropriate outcome measures (e.g. blood lipids, weight), however, in two studies

where only a few of these outcome measures were chosen rather than all of those recommended this was not justified (245,267). An inadequate rate of outcome data (< 80%) was reported in several studies (244,252,253,677) only one of these accounted for this with high drop-out rate. In another study inadequate information was provided to allow for attrition to be calculated (247), thus compromising the objectivity of the evaluation of results by potentially introducing bias.

Thirteen of the studies included in this review were uncontrolled quasi (pre–post) studies. There is some evidence to suggest that this type of study may overestimate the effects of quality improvement interventions or intervention implementation (678)

One RCT was identified in the study selection process (252) – in this study participants were unaware of their assignment group at the start of the study. However, as the trial intervention involved receipt of pharmacist input or no pharmacist input, it might be anticipated that the participant would become aware of the group they had been assigned to as time when on. In addition, the investigators were made aware of which study arm the participants had been randomised to. These factors introduce a high risk of bias into this study. In this same study (252) the outcome data was inadequate and the drop-out rate was high – so valid conclusions cannot be drawn from results obtained.

Threats to external validity compromise confidence in stating whether a particular study's results are applicable outside of the study. The risk of selection bias was high in some of the studies (143,238–240,251) given the lack of randomisation and lack of control groups. For these studies, therefore, one cannot reliably determine whether the observed changes resulted from the intervention. A few studies utilised convenience sampling (238–240). The membership of a convenient population may indicate greater access to resources, better knowledge, social support, or even just geographic proximity to the researcher. The method of sampling in the study by Lizer was not clear (244). Five studies (143,240,251,260,265) lacked information about refusal, response rates or follow up engagement.

Demographic data provides important information about research participants and are necessary to determine whether participants are representative of the target population. Demographic data was completely absent in three of the studies (241,259,260).

A threat to the internal validity of a study can occur if contamination occurs between the pre and post groups as was the case in several of the quasi studies (241,244,247,257,259) or differences between active and control groups are not accounted for. One study acknowledged the effect of contamination between groups (107) – (participants were admitted more than once during the study period) but did not account for it in the data analysis/synthesis. In addition, none of our included studies reported undertaking power analysis calculation to determine the minimum number of participants they required.

All four mixed methods studies (265–268) scored poorly (50% or less). These studies were not described by their authors as being 'mixed methods', but all included qualitative and quantitative data which were collected and analysed with the purpose of meeting the overall research objective. Of these only one (267) made reference to the use of mixed data being as being relevant to the research questions. Not unsurprisingly, therefore, all four mixed methods studies scored zero for integration of both qualitative and quantitative data as no integration was undertaken. In the absence of integration, the knowledge harvested is only equivalent to the sum of that derived from a qualitative study and a quantitative study undertaken separately, rather than achieving a *"whole greater than the sum of the parts"* (302). Despite these weaknesses, the reviewers (DS, EL, RM), felt, overall, these studies were sufficiently robust to contribute to our review discussion.

Summary of quality assessment of studies using by MMAT quality criteria scores (first author ((reference))

Study Type \ Score	25% *	50% **	75% ***	100% ****
Qualitative studies	Shanker (264)		McMorris (262) Quirk (263)	Taylor (261)
Quantitative randomised controlled trials	Schneiderhan (252)			
Quantitative non-randomized	Lizer (244)	McCleeary-Monthei (247) Bozymski (253) Pena (677)	Runcie (241) DelMonte (245) Sud (257)	Barnes (196) Taveira (242) Schneiderhan (243) Kjeldsen (249) Ramanuj (248) Cohen (250) Koffarnus (246) Barnes (197) Fischler (254) Sasson (258)
Quantitative descriptive studies	MacHaffie (240)	Gable (143) Raynsford (260)	Lucca (251) Bozymski (256) Sharma △(238,239)	Porras-Segovia (255)
Mixed methods studies	Ohlsen (265) Watkins (266)	Lee (267) Health foundation (268)		

△both publications are from one study so assessed together as per guidance from authors of the MMAT tool.

Detail of the screening questions, quality criteria and scoring of the articles included in the review according to study type.

Qualitative studies: first author (reference) and score (indicated by number of stars)

Study / Question	Taylor (261)****	McMorris (262) ***	Quirk (263)***	Shanker (264)*
Are there clear qualitative and quantitative research questions (or objectives)?	Yes, very clear	Yes	Yes	No
Do the collected data allow for the research question (or objective) to be addressed?	Yes	Yes	Yes	No
Are the sources of qualitative data (archives, documents, informants, observations) relevant to address the research question (objective)?	Yes*	Yes, selection clear, reason for not participating given*	Yes, service users and healthcare professionals of mental health trusts*	Not clear
Is the process for analysing qualitative data relevant to address the research question (objective)?	Yes, method, form, and analysis very clear and well explained *	Partially, the form of the data was not clear	Yes, several sources each very clear and well explained*	Not clear
Is appropriate consideration given to how findings relate to the context (e.g., the setting in which the data were collected)?	Yes, implications for the type of study and wider scope discussed in detail*	Yes*	Yes*	Yes*
Is appropriate consideration given to how findings relate to researchers' influence (e.g., through their interactions with participants)?	Yes, this is referenced*	Yes, limitation acknowledged: facilitator was also the principle investigator increasing the potential for bias*	No, not addressed or discussed	No, not addressed or discussed

7 **Quantitative RCTs: first author (reference) and score (indicated by number of stars)**

Study / Question	Schneiderhan (252)*
Are there clear qualitative and quantitative research questions (or objectives)?	Yes, very clear
Do the collected data allow address the research question (objective)?	Yes
Is there a clear description of the randomization (or an appropriate sequence generation)?	Yes, block randomisation method used*
Is there a clear description of the allocation concealment (or blinding when applicable)?	Partially, however, centralised call in system used to inform the investigator of the subject's random group assignment
Are there complete outcome data (80% or above)?	No, not for all parameters
Is there low withdrawal/drop-out (below 20%)?	No, 22%

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Quantitative non-randomised studies: first author (reference) and score (indicated by number of stars)

Study / Question	Runcie (241)***	Barnes (196)****	Schneiderhan (243)****	Lizer (244)*
Are there clear qualitative and quantitative research questions (or objectives)?	Yes	Yes, very clear	Yes, clear	Yes, clear
Do the collected data allow for the research question (or objective) to be addressed?	Yes	Yes	Yes	Yes
Are participants (or organisations) recruited in such a way that it minimises selection bias?	Yes, all adult inpatients with specified diagnosis on adult inpatient ward between specified dates*	Yes, measures taken to reduce the potential for selection bias*	Yes, all patients under care of a psychiatry clinic*	No, methods of recruitment are not clear so do not know if there was bias or not. Risk of bias not discussed
Are measurements appropriate (clear origin, or validity known, or standard instrument) regarding the exposure/intervention and outcomes?	Yes, protocol developed with expert guidance/advice *	Yes, based on published consensus statements and evidence-based clinical guidelines*	Yes, as per national guideline*	Yes*
In the pre and post study groups are the participants comparable, or do researchers take into account (control for) the difference between or any contamination that may have occurred?	Partially - patients admitted more than once during study period. But no demographic data provided	Yes*	Yes, acknowledged in limitations*	Did not account or control for any contamination that might have occurred
Are there complete outcome data (80% or above), and, when applicable, an acceptable response rate (60% or above), or an acceptable follow-up rate for cohort studies (depending on the duration of follow-up)?	Yes, notes available for 89% of eligible patients*	Yes*	Yes, as analysis of held administrative data*	No, outcome data only reported for 74% of participants

Quantitative non-randomised studies (continued): first author (reference) and score (indicated by number of stars)

Study / Question	DelMonte (245)***	McCleeary-Monthei (247)**	Kjeldsen (249)****	Ramanuj (248)****
Are there clear qualitative and quantitative research questions (or objectives)/	Yes, clear	Yes, clear	Yes, clear	Yes, clear
Do the collected data allow for the research question (or objective) to be addressed?	Yes	Yes	Yes	Yes
Are participants (or organisations) recruited in such a way that it minimises selection bias?	Yes, all patients admitted to inpatient unit*	Yes, all patients admitted to inpatient unit*	Yes, all patients admitted to inpatient ward*	Yes, all patients admitted to inpatient ward*
Are measurements appropriate (clear origin, or validity known, or standard instrument) regarding the exposure/intervention and outcomes?	Partially, however, did not justify clearly enough why only two parameters from national guidance chosen	Yes, based on national recognised guideline*	Yes, based on clinical guidelines developed by expert group*	Yes, based on local trust and published guidelines*
In the pre and post study groups are the participants comparable, or do researchers take into account (control for) the difference between or any contamination that may have occurred?	Yes, discussed that [re and post groups comparable*	No, not addressed or discussed	Yes, issue of longer admission duration in one group discussed*	Yes, issue of closure of one ward and catchment area discussed*
Are there complete outcome data (80% or above), and, when applicable, an acceptable response rate (60% or above), or an acceptable follow-up rate for cohort studies (depending on the duration of follow-up)?	Yes, as analysis of held administrative data*	No, not addressed or discussed	Yes, as analysis of held administrative data*	Yes, as analysis of held administrative data*

Quantitative non-randomised studies (continued): first author (reference) and score (indicated by number of stars)

Study / Question	Sud (257) ***	Koffarnus (246)****	Barnes (197)****	Fischler (254)****
Are there clear qualitative and quantitative research questions (or objectives)?	Yes, clear	Yes, clear	Yes, very clear	Yes, very clear
Do the collected data allow for the research question (or objective) to be addressed?	Yes	Yes	Yes	Yes
Are participants (or organisations) recruited in such a way that it minimises selection bias?	Yes, any patient under the care of inpatient, community, or early intervention team/care in NHS Trust	Yes, all patients screened in a sequential manner for inclusion, with the first 60 patients meeting the criteria in each group included in the study*	Yes, measures taken to reduce the potential for selection bias*	Yes, all patients admitted to inpatient ward*
Are measurements appropriate (clear origin, or validity known, or standard instrument) regarding the exposure/intervention and outcomes?	Yes, based on national quality improvement guideline*	Yes, based on national recognised guideline*	Yes, based on published consensus statements and evidence-based clinical guidelines*	Yes, published expert guidelines reviewed with recognised framework*
In the pre and post study groups are the participants comparable, or do researchers take into account (control for) the difference between or any contamination that may have occurred?	No, not addressed or discussed	Yes, addressed and discussed*	Yes*	Yes, limitations and impact of other factors that may have contributed to the results discussed e.g., artefact of improved documentation*
Are there complete outcome data (80% or above), and, when applicable, an acceptable response rate (60% or above), or an acceptable follow-up rate for cohort studies (depending on the duration of follow-up)?	Yes, all patient data followed up and complete and reviewed by external body*	Yes, as analysis of held administrative data*	Yes*	Yes, all data made available and accessible via electronic system*

28 **Quantitative non-randomised studies (continued): first author (reference) and score (indicated by number of stars)**

Study / Question	Sasson (258)****	Pena (677)**
Are there clear qualitative and quantitative research questions (or objectives)?	Yes, clear	Yes, clear
Do the collected data allow for the research question (or objective) to be addressed?	Yes	Yes
Are participants (or organisations) recruited in such a way that it minimises selection bias?	Yes, any resident admitted to residential home*	Yes*
Are measurements appropriate (clear origin, or validity known, or standard instrument) regarding the exposure/intervention and outcomes?	Yes, appropriate for primary and secondary outcomes*	Yes*
In the pre and post study groups are the participants comparable, or do researchers take into account (control for) the difference between or any contamination that may have occurred?	Yes, no contamination possible as all care from one service.*	No, no discussion of contamination at all. Demographic data for pre and post not reported so could not also therefore account for differences between them as not known.
Are there complete outcome data (80% or above), and, when applicable, an acceptable response rate (60% or above), or an acceptable follow-up rate for cohort studies (depending on the duration of follow-up)?	Yes, as analysis of data from care at one site*	No, outcome data could only be reported for 60% of the patient participants. (Those who were referred and attended for at least one appointment)

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Quantitative non-randomised studies (continued): first author (reference) and score (indicated by number of stars)

Question \ Study	Taveira (242) ****	Cohen (250)****	Bozymski (253) **
Are there clear qualitative and quantitative research questions (or objectives)?	Yes, very clear	Yes, very clear	Yes
Do the collected data allow for the research question (or objective) to be addressed?	Yes	Yes	Yes
Are participants (or organisations) recruited in such a way that it minimises selection bias?	Yes, referral made independent of mental health condition*	Yes, discharged from cardiovascular risk reduction clinic*	Yes, all patients at any of the two sites*
Are measurements appropriate (clear origin, or validity known, or standard instrument; and absence of contamination between groups when appropriate) regarding the exposure/intervention and outcomes?	Yes, recognised risk tool used to calculate cardiovascular risk and patient status at point of referral and impact of this discussed in detail*	Yes, based on national standard*	Yes, in line with national guidelines*
In the groups being compared (exposed vs. non-exposed; with intervention vs. without; cases vs. controls), are the participants comparable, or do researchers take into account (control for) the difference between these groups?	Yes, discussed in detail*	Yes	No, not fully there were significant differences between the groups including numbers compared, frequency of follow up during study period
Are there complete outcome data (80% or above), and, when applicable, an acceptable response rate (60% or above), or an acceptable follow-up rate for cohort studies (depending on the duration of follow-up)?	Yes, all followed up as analysis of held administrative data*	Yes	Not for both groups: 58% follow up in one group and 88% follow up in the other group.

Quantitative descriptive studies: first author (reference) and score (indicated by number of stars)

Study / Question	MacHaffie (240)*	Gable (143)**	Lucca (251)***	Porras- Segovia (255)****
Are there clear qualitative and quantitative research questions (or objectives)?	Yes, clear	Yes	Yes	Yes
Do the collected data allow for the research question (or objective) to be addressed?	Yes	Yes	Yes	Yes
Is the sampling strategy relevant to address the quantitative research question (quantitative aspect of the mixed methods question)?	Partially, sampling bias due to the use of convenience sampling	Yes, all patients under care of a team*	Yes*	Yes*
Is the sample representative of the population understudy?	Partially, no reference to refusal or participation rates or follow up engagement – therefore unknown	Partially, no reference to refusal or participation rates or follow up engagement – therefore unknown	Partially, no reference to refusal or participation rates or follow up engagement – therefore unknown	Yes*
Are measurements appropriate (clear origin, or validity known, or standard instrument)?	Yes*	Yes*	Yes*	Yes, all relevant measurements taken in line with guidelines*
Is there an acceptable response rate (60% or above)?	No, there is no reference to this	No reference to this, cannot tell	Yes, 97% of suspected adverse drug reactions evaluated. 90% of those who gained weight were enrolled onto weigh management programme	Yes, full set of outcome data*

Quantitative descriptive studies (continued): first author (reference) and score (indicated by number of stars)

Study / Question	Bozymski (256)***	Sharma (238,239)***(two papers from same study)	Raynsford (260)
Are there clear qualitative and quantitative research questions (or objectives)?	Yes	Yes, very clear	Yes
Do the collected data allow for the research question (or objective) to be addressed?	Yes	Yes	Yes
Is the sampling strategy relevant to address the quantitative research question (quantitative aspect of the mixed methods question)?	Yes*	No, sampling bias due to the use of convenience sampling	No, inclusion and exclusion criteria not clearly stated. Also, reasons why certain GP practices chose to participate was not explained
Is the sample representative of the population understudy?	Yes, all clients in early intervention care*	Yes, appropriate as used in other studies and formulated by expert group*	Yes. Patients with SMI on mood stabiliser or antipsychotic on GP records*
Are measurements appropriate (clear origin, or validity known, or standard instrument)?	Partly, not clear what the measurements to be measured are based on	Yes, based on a smoking cessation guideline published by Royal College of GPs*	Yes*
Is there an acceptable response rate (60% or above)?	Yes, as analysis of held administrative data*	Yes, response rate 80.4%*	No follow up regarding on whether recommendations/interventions were acted upon or their impact

47 **Mixed-methods studies: first author (reference) and score (indicated by number of stars)**

Study / Question	Ohlsen (265)*	Watkins (266)*	Lee (267)**	Health foundation (268)**
Is there a clear mixed methods question (or objective)?	Yes, clear	Yes	Yes, clear	Yes, clear
Do the collected data allow for the research question (or objective) to be addressed?	Yes	Yes	Yes	Yes
Is the mixed methods research design relevant to address the qualitative and quantitative research questions (or objectives), or the qualitative and quantitative aspects of the mixed methods question (or objective)?	Partially, however, qualitative methods are not explained or discussed	Partially, however, reasons for reporting qualitative aspect is not explained or discussed	Yes	Yes, however, the reasons or justification for using a mixed methods design is not discussed
Is the integration of qualitative and quantitative data (or results) relevant to address the research question (objective)?	No integration of data	No integration of data	Partial reference to this but not clear	No integration of data
Is appropriate consideration given to the limitations associated with this integration, e.g., the divergence of qualitative and quantitative data (or results*) in a triangulation design?	Not relevant as there is no integration of the data	Not relevant as there is no integration of the data	No	Not relevant as there is no integration of the data
Are the criteria for qualitative studies met?	a. No b. No c. Yes, reference to changing referral process, co-working, boundaries, and clarity of roles within the team* d. No, no reference to researcher influence	a. No b. No c. Yes, but very briefly* d. No, no reference to researcher influence	a. Yes* b. Partially, however, no data analysis undertaken c. Yes, context discussed.* d. No, no reference to researcher influence	a. Yes* b. No c. Yes, reference to how the community pharmacists feedback is important in terms of their opinion about patient care* d. No, no reference to researcher influence
Are the criteria for quantitative studies met?	a. Yes, referral from different settings* b. Yes, very clear* c. A single group was used and therefore no contamination* d. No reference to refusal or participation rates There are complete outcome data	a. Yes* b. Yes* c. Yes, discussed as a limitation* d. Yes, 26% drop out accounted for in detail and complete follow-up data on remaining as analysis of held administrative data*	a. Yes* b. Partially, however, did not justify clearly enough why only two parameters from national guidance chosen c. Yes* d. Yes*	a. Yes* b. Yes* c. No, not discussed at all d. No, only 70%

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Appendix 6: Effective Practice and Organisation of Care taxonomy.

Based on the original tool published in 2002 (235)
Cochrane Effective Practice and Organisation of Care Review Group. Cochrane Effective Practice and Organisation of Care Review Group - Data collection checklist; 2002. [consulted 01/05/2018]. http://methods.cochrane.org/sites/methods.cochrane.org.bias/files/public/uploads/EPOC%20Data%20Collection%20Checklist.pdf
This review included interventions that fell under the following types as per the Effective Practice and Organisation of Care (EPOC) taxonomy (professional, financial, organisational, patient centred, regulatory).

Professional interventions
- **Distribution of educational materials (**Distribution of published or printed recommendations for clinical care, including clinical practice guidelines, audio-visual materials, and electronic publications. The materials may have been delivered personally or through mass mailings). - **Educational meetings** (Healthcare providers who have participated in conferences, lectures, workshops, or traineeships). - **Local consensus processes** (Inclusion of participating providers in discussion to ensure that they agreed that the chosen clinical problem was important and the approach to managing the problem was appropriate). - **Educational outreach visits** (Use of a trained person who met with providers in their practice settings to give information with the intent of changing the provider's practice. The information given may have included feedback on the performance of the provider(s). - **Local opinion leaders** (Use of providers nominated by their colleagues as 'educationally influential'. The investigators must have explicitly stated that their colleagues identified the opinion leaders). - **Patient mediated interventions** (New clinical information (not previously available) collected directly from patients and given to the provider e.g., depression scores from an instrument). - **Audit and feedback** (Any summary of clinical performance of healthcare over a specified period of time. The summary may also have included recommendations for clinical action. The information may have been obtained from medical records, computerized databases, or observations from patients). - **Reminders** (Patient or encounter specific information, provided verbally, on paper or on a computer screen, which is designed or intended to prompt a health professional to recall information. This would usually be encountered through their general education; in the medical records or through interactions with peers, and so remind them to perform or avoid some action to aid individual patient care. Computer aided decision support and drugs dosage are included). - **Marketing** (Use of personal interviewing, group discussion ('focus groups'), or a survey of targeted providers to identify barriers to change and subsequent design of an intervention that addresses identified barriers). - **Mass media** (1- varied use of communication that reached great numbers of people including television, radio, newspapers, posters, leaflets, and booklets, alone or in conjunction with other interventions; 2- targeted at the population level).
Financial interventions
(i) Provider: - **Fee-for-service** (provider has been paid for number and type of service delivered). - **Prepaid** (no other description). - **Capitation** (provider was paid a set amount per patient for providing specific care). - **Provider salaried service** (provider received basic salary for providing specific care). - **Prospective payment** (provider was paid a fixed amount for healthcare in advance). - **Provider incentives** (provider received direct or indirect financial reward or benefit for doing specific action).

- **Institution incentives** (institution or group of providers received direct or indirect financial rewards or benefits for doing specific action).
- **Provider grant/allowance** (provider received direct or indirect financial reward or benefit not tied to specific action).
- **Institution grant/allowance** (institution or group of providers received direct or indirect financial reward or benefit not tied to specific action).
- **Provider penalty** (provider received direct or indirect financial penalty for inappropriate behaviour).
- **Institution penalty** (institution or group of providers received direct or indirect financial penalty for inappropriate behaviour).
- **Formulary** (added or removed from reimbursable available products).

(ii) Patient:

- **Premium** (Patient payment for health insurance. It is important to determine if the patient paid the entire premium, or if the patient's employer paid some of it. This includes different types of insurance plans).
- **Co-payment** (Patient payment at the time of healthcare delivery in addition to health insurance e.g., in many insurance plans that cover prescription medications the patient may pay 5 dollars per prescription, with the rest covered by insurance).
- **User-fee** (Patient payment at the time of healthcare delivery).
- **Patient incentives** (Patient received direct or indirect financial reward or benefit for doing or encouraging them to do specific action).
- **Patient grant/allowance** (Patient received direct or indirect financial reward or benefit not tied to specific action).
- **Patient penalty** (Patient received direct or indirect financial penalty for specified behaviour e.g., reimbursement limits on prescriptions).
-

Organisational interventions Relates to the arrangement of healthcare provision. Interventions include provision of new service or change to healthcare professional roles e.g., enhancement of core day to day activities or providing care that may have otherwise been provided by other healthcare providers. This strategy would also include a pharmacist leading or becoming part of a multidisciplinary team where they were not before. They may liaise with other healthcare professionals to provide continuity of care between healthcare settings or to other healthcare professionals. The setting up of a pharmacist clinic or service that patient can attend would also be include here.

(i) Provider orientated interventions

- **Revision of professional roles** (Also known as 'professional substitution', 'boundary encroachment' and includes the shifting of roles among health professionals. For example, nurse midwives providing obstetrical care; pharmacists providing drug counselling that was formerly provided by nurses and physicians; nutritionists providing nursing care; physical therapists providing nursing care. (Also includes expansion of role to include new tasks).
- **Clinical multidisciplinary teams** (creation of a new team of health professionals of different disciplines or additions of new members to the team who work together to care for patients).
- **Formal integration of services** (bringing together of services across sectors or teams or the organisation of services to bring all services together at one time also sometimes called 'seamless care').
- **Skill mix changes** (changes in numbers, types, or qualifications of staff).
- **Continuity of care** (including one or many episodes of care for inpatients or outpatients):
    - Arrangements for follow up.
    - Case management (including co-ordination of assessment, treatment, and arrangement for referrals).
- **Satisfaction of providers** with the conditions of work and the material and psychic rewards (e.g., interventions to 'boost morale').
- **Communication and case discussion** between distant health professionals (e.g., telephone links; telemedicine; there is a television/video link between specialist and remote nurse practitioners).

(ii) Patient orientated interventions

- **Mail order pharmacies** (e.g., compared to traditional pharmacies).
- Presence and functioning of adequate **mechanisms for** dealing with patients' **suggestions and complaints.**
- **Consumer participation** in governance of healthcare organisation.
- Other (other categories to be agreed in consultation with the EPOC editorial team).

(iii) Structural interventions

- **Changes to the setting/site of service delivery** (e.g., moving a family planning service from a hospital to a school).
- **Changes in physical structure, facilities, and equipment** (e.g., change of location of nursing stations, inclusion of equipment where technology in question is used in a wide range of problems and is not disease specific, for example an MRI scanner).
- **Changes in medical records systems** (e.g., changing from paper to computerized records, patient tracking systems).
- **Changes in scope and nature of benefits and services.**
- **Presence and organisation of quality monitoring mechanisms.**
- **Ownership, accreditation, and affiliation status of hospitals and other facilities.**
- **Staff organisation.**

Patient-centred interventions This would include any intervention directed primarily at individuals such as direct provision of advice or information e.g., smoking cessation advice or strategies for weight management. (Screening for healthcare parameters e.g., taking blood test or checking BP is not included in this category).

- **Education/educational materials**
- **Peer support**
- **Support for self-management**. Including telephone and telemedicine interventions with predominant patients elements (with focus on self-management)
- **Behaviour change**
- **Reminders** e.g., reminder card
- **Motivational counselling**

Regulatory interventions Any intervention that aims to change health services delivery or costs by regulation or law. (These interventions may overlap with organisational and financial interventions.)

- **Changes in medical liability**
- **Management of patient complaints**
- **Peer review**
- **Licensure**

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Appendix 7: List of excluded studies and reasons for excluding studies after full text review

#	Study Name	Reason for Exclusion
1.	Alderman CP, Lucca JM. Psychiatry and clinical pharmacy: A logical partnership. Indian Journal of Psychiatry. 2017;59(2):138-140.	Editorial, not a study of an intervention.
2.	Attard A, McRobbie D, Taylor DM, West T. A career as ... a psychiatric liaison pharmacist. Hospital Pharmacist. 2008;15(3):99-100.	General overview of a career role – not a study of an intervention.
3.	Augsten A, Correa-Vento M, Cousins S, Bober D, Camejo M, Levy B, Tucker T. Long-acting therapy clinic: A pharmacy initiative for the treatment of serious mental illness. Journal of Pharmacy Practice. 2016;29(3):331.	No outcomes measured or reported.
4.	Ball MP, Hooper ET, Skipwith DF, Cates, ME. Clozapine-induced hyperlipidemia resolved after switch to aripiprazole therapy. Annals of Pharmacotherapy. 2005;39(9):1570-2.	No mention of pharmacist/pharmacy
5.	Baudry S. Four years evaluation on schizophrenic patients who followed a therapeutic education program called drug's workshops. European Archives of Psychiatry and Clinical Neuroscience. 2010;260.	No mention of cardiometabolic risk factors or metabolic syndrome or related diseases
6.	Bell JS; Whitehead P, Aslani P, McLachlan AJ, Chen TF. Drug-related problems in the community setting: Pharmacists' findings and recommendations for people with mental illnesses. Clinical Drug Investigation. 2006;26(7):415-25.	Nothing specific for cardiometabolic risk factors or metabolic syndrome or related diseases. Diagnoses of participants not reported.
7.	Binford SH, Johnson MD, Kennedy RS, Leffler JB. Clinician education improves lipid monitoring in patients taking second-generation antipsychotic agents, nationally and locally. Health Outcomes Research in Medicine. 2012;3(3).	Pharmacy/pharmacist not involved.
8.	Bradley BA. Psychiatric pharmacist in a federally qualified health center primary care clinic. Journal of Pharmacy Practice. 2013;26(3):341-2.	No explicit mention of cardiometabolic risk factors or metabolic syndrome or related diseases. Diagnoses of individuals on antipsychotics not stated.
9.	Brunette MF, Dzebisashvili N, Xie H, Akerman S, Ferron JC, Bartels S. Expanding cessation pharmacotherapy via videoconference educational outreach to prescribers. Nicotine and Tobacco Research. 2015;17(8):960-7.	Pharmacy/pharmacist not involved.
10.	Butler P, Simonson C, Goldie C, Kennedy A, Goldstone L. Baseline metabolic monitoring of atypical antipsychotics in an inpatient setting. Mental Health Clinician. 2013;3(3):122-8. And Butler P, Goldie C, Simonson C, Goldstone L, Kennedy A. Inpatient Pharmacist Intervention Helps Sustain Improved Rates of Baseline Metabolic Monitoring for Patients Initiated on Atypical Antipsychotics. http://www.pharmacy.arizona.edu/sites/default/files/Abstracts%20for%20Senior%20Projects%202014.pdf (second reference discussing outcomes of the first)	First paper describes the process the second paper describes the outcomes. Diagnoses of participants not stated.
11.	Buxton JA, Chandler-Altendorf A, Puente AE. A novel collaborative practice model for treatment of mental illness in indigent and uninsured patients. American Journal of Health-System Pharmacy. 2012;69(12);1054-62.	No mention of cardiometabolic risk factors or metabolic syndrome or related diseases
12.	Caballero J, Souffrant G, Heffernan E. Development and outcomes of a psychiatric pharmacy clinic for indigent patients. American Journal of Health-System Pharmacy. 2008;65(3):229-33.	Diagnoses of participants not stated.
13.	Canales PL, Dorson PG, Crismon ML. Outcomes assessment of clinical pharmacy services in a psychiatric inpatient setting. American Journal Health System Pharmacy. 2001;58(14):1309-16.	No mention of cardiometabolic risk factors or metabolic syndrome or related diseases. Diagnoses of participants not stated.
14.	Canning JE, Nelson LA, Elliott E, Hieber R, Liu Y. Assessment of adherence with metabolic monitoring before and after implementation of a pharmacy-driven computerized metabolic monitoring database. Journal of Pharmacy Practice. 2011;24(2);264-5.	Conference abstract. No outcomes reported. Diagnoses of participants not reported.
15.	Christopher M, Popish S, Yee M, Furman A, Kimura H. Academic detailing engages members of the healthcare team and veterans in improving care for mental health conditions. 2012;25(2):293.	Conference abstract. No mention of cardiometabolic risk factors or metabolic syndrome or related diseases
16.	Chung B, Dopheide J, Gregerson P. Psychiatric Pharmacist and Primary Care Collaboration at a Skid-Row Safety-Net Clinic. Journal of the National Medical Association. 2011;103(7):567-74.	Nothing specific relating to cardiometabolic risk factors or metabolic syndrome or related diseases
17.	Cobb CD. Optimizing medication use with a pharmacist-provided comprehensive medication management service for patients with psychiatric disorders. Pharmacotherapy. 2014;34(12):1336-40.	Outcomes related to cardiometabolic monitoring or metabolic syndrome or related diseases not reported.
18.	DeJongh B, Garcia G, Parra D, Fernandez-Milo A.. Design and implementation of a clinical pharmacist managed metabolic syndrome clinic in a mental health setting. Journal of Pharmacy Practice. 2011;24(2):268.	Work in progress – no outcomes reported. Diagnoses of participants not reported.
19.	Dhamane AD, Hudson TJ, Martin BC, Said Q, Brixner DI. Metabolic monitoring of patients prescribed second-generation antipsychotics. Journal of Psychiatric	No pharmacist involved. No intervention implemented. Diagnoses of participants not

	Practice. 2013;19(5):360-74.	reported.
20.	Dhamane AD, Martin B, Hudson TJ, Said Q, Brixner D. Assessment of metabolic monitoring of patients prescribed second generation antipsychotics (SGAs) using electronic medical record (EMR) data. Value in Health. 2010;13:A99.	Poster/conference abstract. No pharmacist involved. No intervention implemented. Diagnoses of participants not reported.
21.	Dopheide JA, Bostwick JR, Goldstone LW, Thomas K, Nemire R, Gable KN, Cates M, Caballero J, Smith T, Bainbridge J. Curriculum in psychiatry and neurology for pharmacy programs. American Journal of Pharmaceutical Education.2017;81(7).	Focused on educational programs of pharmacy professionals nothing specific to severe mental illness or metabolic or cardiometabolic risk factors or related diseases. Not a study of an intervention.
22.	Dorman C, Winkler H, Moore TA. Implementation and outcomes of mental health pharmacist-managed electronic consults at a VA health system. Journal of pharmacy practice. 2016;29(3):311.	Nothing specific relating to cardiometabolic risk factors or metabolic syndrome or related diseases.
23.	Edelsohn GA, Parthasarathy M, Terhorst L, Karpov IO, Schuster J. Measurement of metabolic monitoring in youth and adult medicaid recipients prescribed antipsychotics. Journal of Managed Care Pharmacy. 2015;21(9):769-77.	Not a study of an intervention.
24.	Erickson ZD, Kwan CL; Gelberg HA; Arnold IY; Chamberlin V; Rosen JA, Shah C, Nguyen CT, Hellemann G, Aragaki DR, Kunkel CF, Lewis MM, Sachinvala N, Sonza PA, Pierre JM, Ames D. A Randomized, Controlled Multisite Study of Behavioral Interventions for Veterans with Mental Illness and Antipsychotic Medication-Associated Obesity. Journal of General Internal Medicine. 2017;32:32-9.	Pharmacy/pharmacist not involved in the intervention.
25.	Gallimore CE, Sokhal D, Zeidler Schreiter E, Margolis AR. Pharmacist medication reviews to improve safety monitoring in primary care patients. Families, Systems and Health.2016;34(2):104-13.	Diagnoses of participants not reported. No mention of cardiometabolic risk factors or metabolic syndrome or related diseases.
26.	Ganzer N, Utter B, Dejongh B, Behrens M, Garcia G, Graham R. Re-implementation of a pharmacist-managed metabolic syndrome clinic in an outpatient mental health clinic setting. Mental health clinician. 2015;5(1):57-62.	Diagnoses of participants not reported.
27.	Gavin L, Frey T. Assessment of a pharmacist-run medication education group for inpatient psychiatric patients. Mental Health Clinician. 2012;2(4):94-9.	No mention of cardiometabolic risk factors or metabolic syndrome or related diseases. Diagnoses of participants not reported.
28.	Gisev N, Bell JS, O'Reilly C, Rosen A, Chen TF. An expert panel assessment of comprehensive medication reviews for clients of community mental health teams. Social Psychiatry and Psychiatric Epidemiology. 2010;45(11):1071-9.	Reported outcomes are not explicit enough to examine specific data for cardiometabolic risk factors or metabolic syndrome or related diseases
29.	Green S, Beveridge E, Evans L, Trite J, Jayacodi S, Evered R, Parker C, Polledri L, Tabb E, Green J, Manickam A, Williams J,Deere R, Tiplady B. Implementing guidelines on physical health in the acute mental health setting: a quality improvement approach. Interntional Journal Mental Health Systems. 2018;12:1.	Diagnoses of participants not reported.
30.	Greg Deardoff O, Nelson L, Elliott E, Liu Y, Schmidt S Stoner S, Nelson LA, Liu Y. Adherence and clinical outcome of metabolic monitoring in psychiatric patients transitioning from an inpatient to outpatient setting. Journal of Pharmacy Practice. 2011;24(2):263.	Work in progress. Conference poster abstract. No outcomes reported. No pharmacy/pharmacist intervention.
31.	Griebe KM, Caniff KE, Bostwick JR. Psychiatric Pharmacists: Key Allies to Improve Antipsychotic Metabolic Monitoring. Psychiatric Services. 2016;67(4):469-70.	General discussion of the topic not a study of an intervention
32.	Hammad EA, Yasein N, Tahaineh L, Albsoul-Younes AM. A randomized controlled trial to assess pharmacist- physician collaborative practice in the management of metabolic syndrome in a university medical clinic in Jordan. Journal of Managed Care Pharmacy. 2011;17(4):295-303.	Diagnoses of participants not stated.
33.	Hannou S, Pannatier A, Von Gunten A, Voirol P, Mall JF, De Giorgi I, De Boer E. CP-076 Effects of pharmacist interventions on inappropriate prescribing in a geriatric psychiatry unit. European Journal of Hospital Pharmacy: Science and Practice. 2014;21:A31.	Interventions carried out by pharmacist did not relate to cardiometabolic risk factors or metabolic syndrome or related diseases. Diagnoses of participants not reported.
34.	Hattingh HL, Scahill S, Fowler JL, Wheeler AJ. Exploring an increased role for Australian community pharmacy in mental health professional service delivery: evaluation of the literature. Journal of Mental Health. 2016;25(6): 550-9.	This is a narrative literature review of systematic reviews. Not a study of an intervention.
35.	Hor ES, Subramaniam S, Koay JM, Bharathy A, Vasudevan U, Panickulam JJ, Ng I, Arif NH, Russel V. Improving metabolic monitoring in patients maintained on antipsychotics in Penang, Malaysia. Australasian Psychiatry. 2016;24(1):67 – 71.	No pharmacy/pharmacist involved.
36.	Huynh P, Winkler H, Moore TD, Nelson J. Primary care mental health integration: Evaluating the impact of behavioral health clinical pharmacy specialists. Journal of Pharmacy Practice. 2015;28(3):354.	Work in progress. Conference abstract. Not severe mental illness (anxiety, depression and post-traumatic stress disorder). Not cardiometabolic risk factors or metabolic syndrome or related diseases.
37.	Ishkova-Volovets N. Improving adherence to metabolic monitoring guidelines for second-generation antipsychotics: The College of St. Scholastica; 2014.	Thesis for Doctor of Nursing practice. Pharmacy/pharmacist not included.
38.	Johnson K, Frede S, Fuller L, Weed E, Luder H. Identification and management of metabolic and movement abnormalities in patients taking antipsychotic medications in a community pharmacy. 2016; 56(3).	Conference abstract. No outcomes reported. Diagnoses of participants not reported.
39.	Kamath J, Singh R, Chen X, Wu H. Implementation of metabolic monitoring	No information about diagnoses of

	guidelines for patients receiving antipsychotic medications in a large outpatient psychiatry clinic: Interventions and outcomes. Neuropsychopharmacology. 2013;38:S517-8.	participants. Pharmacist/pharmacy not involved.
40.	Kim S. Clozapine support group therapy provided by the medication therapy management pharmacist from university outpatient psychosis treatment program. Journal of the American Pharmacists Association. 2013;53(2).	Conference abstract. Outcomes not reported clearly. Diagnoses of participants not reported.
41.	Kim S. Smoking cessation support group under pharmacist auspice at the university outpatient psychiatric clinic. Journal of Pharmacy Practice. 2016;29(3):333.	Conference abstract. Diagnoses of participants not reported.
42.	Klein M, Mahoney L, Kruse K, Pinter M. Impact on monitoring of fasting lipid panel and fasting plasma glucose in patients prescribed second generation antipsychotics with the implementation of an ambulatory pharmaceutical care service. 2010;23(2):169.	Conference abstract. Diagnoses of participants not reported.
43.	Kroening J. Community based psychiatric outpatient metabolic monitoring for atypical antipsychotics. The College of St. Scholastica; 2016.	Thesis for Doctor of Nursing practice. Pharmacy/pharmacist not included.
44.	Kurian J, Ramesh M, Rajesh, R, Kishore, M. Impact of collaborative coustomized patient education in psychiatric diseases. Value in health. 2017;20(5).	Conference abstract. Nothing related to metabolic syndrome or cardiometabolic risk factors or related diseases.
45.	Lai CL, Chan HY, Pan YJ, Chen CH. The effectiveness of a computer reminder system for laboratory monitoring of metabolic syndrome in schizophrenic outpatients using second-generation antipsychotics. Pharmacopsychiatry. 2015 ;48(1):25-9.	No pharmacy/pharmacist involvement.
46.	Li L.,Kirwin PD, Rosenheck R. Multimorbidities: Age-related relationships among medical disorders, psychiatric disorders, substance use disorders, and psychotropic prescriptions in the U.S. Veteran population. American Journal of Geriatric Psychiatry. 2016;24(3).	AGM conference abstract. No pharmacy/pharmacists involvement or intervention.
47.	Maslen CL, Rees L, Redfern PH. Role of the community pharmacist in the care of patients with chronic schizophrenia in the community. Journal of Pharmacy Practice. 1996;4(4):187-95.	Questionnaire study understanding the attitudes of community pharmacists to schizophrenia, but nothing related to metabolic syndrome/cardiometabolic risk factors or related diseases.
48.	Maulavizada H, Emmerton L, Laetitia HL. Can a pharmacy intervention improve the metabolic risks of mental health patients? Evaluation of a novel collaborative service. BMC Health Services Research. 2016;16(1):146	Diagnoses of participants not reported.
49.	McCleeary-Monthei E, Kutscher EC. Evaluation of lipid and glucose monitoring after implementation of a pharmacist initiated antipsychotic monitoring form. Journal of Pharmacy Practice. 2012;25(2);281.	Conference abstract. Work in progress. Diagnoses of participants not reported. No outcomes reported.
50.	McCue , Lacro JP. Effect of clinical pharmacist involvement with the mental health intensive case management (MHICM) team at VA San Diego healthcare system. Journal of Pharmacy Practice. 2011;24(2):247.	Conference abstract. Outcomes of monitoring not reported clearly.
51.	Moeller KE, Rigler SK, Mayora A, Nazir N, Shiremand TI. Quality of monitoring for metabolic effects associated with second generation antipsychotics in patients with schizophrenia on public insurance. Schizophrenia Research. 2011;126(1-3):117-23.	Pharmacy/pharmacist not involved.
52.	Montgomery J, Turner TJ, Quinn M, Harms J, Samol S, Fabian T. The role of a community pharmacy resident in expanding clinical pharmacy services within a traditional dispensing model. Pharmacotherapy. 2011;31(10).	Diagnoses of participant not reported. Outcomes not reported in detail.
53.	Morrato EH, Campagna EJ, Brewer SE. Programmatic efficiency of a pharmaceutical risk management program: Outcomes from diabetes screening of adults receiving antipsychotics. Pharmacoepidemiology and Drug Safety.2016;25:310-1.	Not a study of a pharmacy/pharmacist intervention. It is a calculation checking to assess screening yield and number needed to screen to detect new cases of diabetes of individuals on antipsychotics.
54.	Nelson LA, Graham MR, Lindsey CC, Rasu RS. Medication adherence, lipid and glycemic control in patients with psychotic disorders compared to patients without psychiatric illness receiving care in a veterans affairs medical system. Journal of Pharmacy Practice. 2011;24(2):248.	Not a study of an intervention.
55.	Onatade R, Oduniyi O. Improving the pharmaceutical care of patients on psychotropic medication admitted to an acute hospital – the impact of a proactive 'inreach' specialist psychiatric pharmacist service. Poster presented at United Kingdom Clinical Pharmacists Association conference 2016.	Unclear as to whether the diagnoses of the participants include severe mental illness or not.
56.	Owen RR, Drummond KL, Viverito KM, Marchant K, Pope SK, Smith JL, Landes RD. Monitoring and managing metabolic effects of antipsychotics: a cluster randomized trial of an intervention combining evidence-based quality improvement and external facilitation. Implementation science. 2013;8:120.	No pharmacy/pharmacist involvement. Diagnoses of target population for intervention not stated.
57.	Parker S, Henderson R, Dutton T, Pate JR, Bean JR. Metabolic monitoring for patients on second-generation antipsychotics using electronic notifications as a reminder system for providers: 266. Pharmacotherapy. 2016; 36(12):e272.	Diagnoses of participants not reported. Not clear if intervention implemented by pharmacy/pharmacist.
58.	Peh AL. Safety monitoring of patients on atypical antipsychotics. Source Quality & safety in health care. 2008;17(6):469-72.	Diagnoses of participants not reported.
59.	Pringsheim T, Kelly M, Urness D, Teehan M, Ismail Z, Gardner D. Physical Health and Drug Safety in Individuals with Schizophrenia. 2017;62(9);673-83.	Review of National Institute for Health and Care Excellence and Scottish Intercollegiate Guidelines Network guidelines. Not a study of

		an intervention.
60.	Raphael C, Fedoruk E. Practice spotlight: Pharmacists of the Centre for Addiction and Mental Health. Canadian Journal of Hospital Pharmacy. 2008;61(5:)346-7.	Discussion of service; not a study of an intervention, no outcomes reported.
61.	Riesselman A, Baker JM, Bodenberg M,Lucas P,Strobl B. Metabolic syndrome monitoring program: A clinical program to screen patients for metabolic syndrome in a state psychiatric hospital. Journal of Pharmacy Practice. 2011;24(2):275-6.	Work in progress. Conference poster abstract. No outcomes reported, Diagnoses of participants not reported.
62.	Roestenburg S, Brewster M, Stock CJ, LaFleur J. Clinical outcomes of veterans with serious mental illnesses enrolled in a pharmacist-managed metabolic monitoring clinic: A retrospective cohort study. Journal of Pharmacy Practice. 2015;28(3):338-9.	Conference abstract. Outcomes of intervention not reported.
63.	Sano T, Inoue M, Takizawa M, Shimamori Y, Kurosawa N. The Effect of Pharmacist-led Psychiatric Pharmacotherapy Conferences on the Appropriate Use of Antipsychotics. Journal of the Pharmaceutical Society of Japan. 2017;137(5):603-10.	Not available in English.
64.	Schellack N, Matlala M. Providing an overview of antipsychotic drugs: Is schizophrenia a psychiatric challenge? Pharmaceutical Journal. 2014;81(4):28-33.	Review article. Not a study of an intervention.
65.	Schmitz A, Rohrich M, Newman W, Wolf P. Cardiometabolic management in severe mental illness requiring an atypical antipsychotic. Mental Health Clinician. 2017;7(2):81-7.	Not a study of a pharmaceutical/pharmacy intervention.
66.	Seng KH. Reducing polypharmacy for elderly psychiatric patients for safe and high quality care. Quality and Safety in Health Care. 2009;18(4).	Conference abstract. No outcomes reported.
67.	Shishko I, Oliveira R, Moore TA, Smith AG. Pharmacist driven metabolic monitoring clinic of atypical anti psychotics. Journal of Pharmacy Practice; 2016;29(3):318-9.	Conference abstract. Work in progress. No outcomes reported. Diagnoses of participants reported.
68.	Stutzman D, Reta A, O'Callaghan R. Psychotropic prescribing practices and physician attitudes on integrating psychiatric pharmacist services in an ambulatory care setting. Journal of Pharmacy Practice. 2015;28(3):355.	Conference abstract. Work in progress. No outcomes reported. Diagnoses of participants not stated.
69.	Su HC, Chen CH, Chan AL. Cost of pharmaceutical care in patients with metabolic syndromes caused by atypical antipsychotics. Value in Health. 2010;13(3).	Diagnoses of participants not reported.
70.	Tai M, Lee B, Onukwugha E, Zito JM, Reeves GM, dosReis S. Impact of Coordinated Behavioral Health Management on Quality Measures of Antipsychotic Use. 2017.	Not a study of an intervention. Quasi-experimental design to evaluate the average treatment effect of the care coordination using a wraparound practice model on improving the quality of antipsychotic use.
71.	Tatreau JR, Harris S, Sheitman B, Steiner BD. Cardiometabolic Assessment, Diagnosis, and Treatment of Chronic Medical Illnesses During an Inpatient Psychiatric Hospitalization: Colocated Medical Care Versus Treatment as Usual. The primary care companion for CNS disorders. 2016;18(6).	Not a study of an intervention implemented by pharmacist; no pharmacy/pharmacist involvement.
72.	Traynor K. CMS paves way for pharmacists to help blunt metabolic effects of antipsychotics. 2017;74(14):1037-8.	Reporting on the work of another pharmacist, diagnoses of participants not reported.
73.	Wang I, Dopheide JA, Gregerson P. Role of a psychiatric pharmacist in a Los Angeles "Skid-Row" safety-net clinic. Journal of urban health: bulletin of the New York Academy of Medicine. 2011;88(4):718-23.	Interventions for metabolic syndrome or cardiometabolic risk factors or related diseases not explicitly stated. Unable to discern outcomes from the results reported.
74.	Ward K, Samara W, Popish S, Furman A, Meier J. Use of a clinical dashboard to improve cardiometabolic syndrome monitoring. Journal of Pharmacy Practice. 2012;25(2):297.	Diagnoses of participants not reported. Outcomes not reported.
75.	Wenger PJ, Mays KR. Effect of pharmacy team interventions on monitoring rates for second-generation antipsychotics in a correctional setting. Pharmacotherapy. 2012;32 (no. 10).	Diagnoses of participants not reported.
76.	Wiechers IR. Improving psychopharmacological care for older veterans: Implementation of phase 2 of the psychotropic drug safety initiative. Journal of Geriatric Psychiatry. 2016;24(3).	Conference abstract. No outcomes reported. Diagnoses of participants not reported.
77.	Williams T, Purvis TL. Development of an outpatient pharmacist-managed clozapine clinic. American journal of health-system pharmacy. 2012;69(14):1192-5.	Outcomes not explicitly reported.
78.	Wilson E, Randall C, Patterson S, Emmerson B, Moudgil V, Weaver T. Monitoring and management of metabolic abnormalities: mixed-method evaluation of a successful intervention. Australasian psychiatry. 2014;22(3):248-53.	Pharmacy/pharmacist not involved. Diagnoses of participants not reported.
79.	Xiangjun K. To ensure all ward 22a patients on atypical antipsychotics are monitored according to protocol. Annals of the Academy of Medicine Singapore. 2012;41(9).	Diagnoses of participants not reported.
80.	Zekovic A, Kristensen S, Pedersen LL. Implementation of clinical pharmacy in the acute psychiatric wards: Improving quality of medical treatment across health care sectors. International Journal of Clinical Pharmacy. 2017;39(1):228.	Oral symposium abstract. Diagnoses of participants not reported. No outcomes explicitly reported.

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Appendix 8: Results of systematic literature review

Table 1: Summary of characteristics of included studies

First Author (reference)	Year of publication	Country	Study purpose/objective/pharmacy professionals type	Method	Study type	Data analysis	Participant characteristics	Primary outcome measured and data analysis – relevant to cardiometabolic risk factor, metabolic syndrome or related disease	Setting
MacHaffie** (240)	2002	USA	From what sources do persons with SPMI obtain health promotion information? What is the reliability of health promotion information from different sources as perceived by persons with serious and persistent mental illness (SPMI). Pharmacist (not further specified)	Quant	Questionnaire and structured interview, descriptive	Statistical mean and ranking. Standard score equivalents (t-scores).	41 adult (age>18 years) patients with a 12 month prevalence of SPMI (12 with schizophrenia, 11 schizoaffective disorder, 9 bipolar I, 4 bipolar II, 1 psychotic disorder NOS, 3 major depressive disorder, 1 panic disorder) or a lifetime prevalence of these disorders accompanied by evidence that they would have been symptomatic in the last 12 months if it were not for treatment.	Response frequencies for amount of health promotion received from various sources and their perceived reliability. For each source of information numerical values assigned to the Likert scale responses. Scores summed by source and means obtained for each source. Sources then ranked for each statement according to their mean scores.	Mental health outpatient
Ohlsen (265)	2005	UK	To provide a care delivery system whereby physical problems could be identified and appropriate treatment and monitoring initiated by prompt referral to suitable specialist services or general practitioners, forging strong links between primary and secondary care and ensuring that mentally ill patients with physical health problems were receiving holistic care packages. Nurse led service but joint working agreement with other teams including pharmacy were put in place prior to starting the service. WSP = Well-being support programme Pharmacist (not further specified)	Mixed methods	Pre and post measurements of metabolic parameters and self- esteem. Qualitative description of management issues.	Descriptive statistics	134 adult (18-65 year old) patients with either schizophrenia or schizoaffective disorder.	Results from study relate to the intervention of the nurse advisor. Direct impact of pharmacist was not reported in the findings.	Community mental health team.
Runcie (241)	2007	UK	Evaluate the impact of a protocol for monitoring weight and blood glucose in psychiatric inpatients receiving antipsychotics. Hospital pharmacist.	Quant	Pre and post measurements: quasi	Descriptive statistics	Adults aged > 18 years .61 patients pre and 59 post intervention with schizophrenia, schizoaffective disorder, persistent delusional disorder, acute and transient psychotic disorder or induced delusional disorder.	No significant improvement in recording of admission weight or blood glucose was observed. Ongoing monitoring of weight after admission was significantly more common. For only 29% of patients studied in 2004 was there complete adherence to the protocol.	Psychiatric inpatients
Barnes (196)	2008	UK	To evaluate a quality improvement programme designed to increase screening for the metabolic syndrome in community psychiatric patients prescribed antipsychotics. Hospital chief pharmacist	Quant	Audit pre and post intervention: quasi	SPSS. Multilevel logistic regression. Binary logistic regression analysis.	Adults aged > 16 years. Pre intervention: 1616 (82.2% had psychotic spectrum disorder (ICD-10 F20-29), 260 (13.2) had bipolar disorder (ICD-10 F30-39), 90 (4.6%) other (not stated). Post intervention: 1277 (84.3%) psychotic spectrum disorder, 182(12.0) bipolar disorder, 54 (3.7%) other.	Measurement or test result was recorded in the clinical records in the previous year (2005): Baseline -BP in 26% of this sample, for BMI (or other obesity measure) in 17%, for plasma glucose (or HbA1c) in 28% and for plasma lipids in 22%. 1 year after intervention - BP in 43% of this sample, for BMI (or other obesity measure) in 34%, for plasma glucose (or HbA1c) in 38% and for plasma lipids in 35% Predictors of what clinical factors might be related to full metabolic screening : At baseline, age (odds ratio 1.02 (1.01–1.04) p=0.001) and a known diagnosis of dyslipidaemia (odds ratio 4.60 (2.85–7.42) p<0.001) were significant predictors	Community mental health team.

								At one year re-audit: A known diagnosis of diabetes (odds ratio 2.29 (1.46–3.58) p<0.001)and type of antipsychotic, relating specifically to clozapine treatment (odds ratio 3.51 (1.38–8.87) (p=0.008) , appeared as significant predictors	
Taveira (242)	2008	USA	To compare the efficacy of a pharmacist-led cardiovascular risk reduction clinic (CRRC) in the lowering of cardiovascular risk between those with and without mental health conditions. Clinical pharmacist.	Quant	Retrospective cross sectional cohort analysis.	Statistical mean and standard deviation. 2-sample t-test. Multivariable linear regression mode	Adults aged > 18 years; total of 297 of whom 176 had no mental health condition (MHC); 121 had an MHC of which 92 (76.0%) had a non-severe MHC diagnosis and 29 (24.0%) had a severe MHC (schizophrenia, schizoaffective disorder, bipolar disorder, psychosis not otherwise specified or posttraumatic stress disorder with psychosis).	The mean UKPDS score change from baseline is comparable for those without an MHC (0.10±0.14) vs those with a non-severe MHC (0.10±0.12, p=.78) and those with a severe MHC (0.10±0.15, p=.97).	Primary care clinic.
Schneiderhan (243)	2009	USA	To assess the usefulness of a metabolic risk screening program, including point-of-care glucose testing, to quantify baseline metabolic risk in outpatients receiving antipsychotics. Board certified psychiatric pharmacist.	Quant	Retrospective, cross-sectional, cohort study	SPSS. One-way analysis of variance. Pearson's $\chi 2$.	Adults aged > 18 years. Total participants (92) all of whom were on an antipsychotic. Diagnoses were recorded in 88, 53 (60%) schizophrenia or schizoaffective disorder, 18 (20%) bipolar disorder and 17 (19%) major depressive disorder.	63 (71%) met criteria for level 1 metabolic risk (abdominal obesity); of these 63 patients, 38 (60%) met criteria for level 2 risk (abdominal obesity plus hypertension). Patients with a random glucose level greater than 140 mg/dl had a higher likelihood for being at level 2 risk than level 1 risk ($\chi 2$=5.99, *df*=1, p=0.014). Women had a significantly higher likelihood for level 1 metabolic risk compared with men ($\chi 2$=5.99, *df*=1, p=0.019). African- Americans had a significantly higher likelihood of level 1 risk (p=0.026) and BMI greater than 30 kg/m2 (p=0.003) compared with Caucasians. Patients with a BMI greater than 30 kg/m2 had a significantly higher likelihood of diabetes (p=0.006), hypertension (p=0.03), and hyperlipidaemia (p=0.05).Overall, 5 (5%) of the 92 patients met criteria for prediabetes risk.	Psychiatric outpatient clinic outpatient.
Gable (143)	2010	USA	To demonstrate the role of a Board Certified Psychiatric Pharmacist (BCPP) on an Assertive Community Treatment (ACT) team by reviewing the recommendations and interventions a clinical pharmacist made over a 6 month period. Board certified psychiatric pharmacist	Quant	Retrospective chart review.	None	Total participants (34) – who had at least one active Axis I DSM-IV-TR SPMI such as schizophrenia, bipolar disorder, or major depressive disorder.	Physical health assessments, review of blood glucose logs, BP undertaken when appropriate (e.g., recent development of diabetes or hypertension). Labs recommended by pharmacist to monitor for adverse effects and disease states (15 times). Coordinate care with other healthcare providers, including those not part of the mental healthcare team - included recommendations made to primary healthcare providers on non-psychiatric issues including blood pressure, diabetes control (12 times). The interventions/recommendations were part of a study involving a comprehensive medicines management service provided by a pharmacist	Community mental health team
Lizer (244)	2011	USA	To determine if a pharmacist assisted psychiatric clinic would improve adherence to medications and quality of life over 6 months. Primary study endpoints were the change from baseline in Medication Adherence Rating Scale	Quant	Prospective single centre pilot study: quasi	PASW. Paired t-tests, Wilcoxon Sign Rank test, McNemar's test Pharmacist interventions were	27 individuals > 18 years with axis I diagnosis (11 (41%) bipolar disorder9 (33%) depression, 7 (26%) other (not stated) receiving at least one scheduled medication for mental illness.	**Quantitative** WHOQOL-BREF showed statistically significant changes in both the physical capacity (p=0.049) Secondary Study Endpoints	Psychiatric outpatient clinic

			(MARS), Brief Evaluation of Medication Influences and Beliefs (BEMIB), World Health Organization Quality of Life - BREF (WHOQOL-BREF) scales as well as hospitalizations and emergency room visits. Secondary endpoints included metabolic and physiologic parameters. Pharmacist (not further specified)			documented and analysed qualitatively – (number and type)		Overall, there were no significant changes in the metabolic parameters measured except for total cholesterol and LDL. Total cholesterol dropped from 185.7 (SD=42) mg/dL to 173.1 (SD=40.9) (p=0.04) and LDL dropped from 116.1 (SD=30.1) to 95.9 (SD=34.5) (p=0.04). When comparing subjects' mean (SD) weight, subjects who were on atypical antipsychotics gained an average of 2.9 pounds (6.8), while subjects not on atypical antipsychotics gained 1.8 (12.1) pounds (p=0.79). There was a non-significant increase in HDL (p=0.84). Other Results Other pharmacist recommendations included an increase in exercise, education for a decrease in tobacco use. **Qualitative analysis** of pharmacists' interventions included recommendations (number of times) to increase exercise to promote weight loss and reduce stress (12), calcium and vitamin D supplementation (12), smoking cessation education (9).Patient self-reported acceptance of these recommendations were: exercise (50%); smoking cessation (22%).	
Taylor* (261)	2011	UK	Identify and describe different models for the delivery of clozapine to people with TRS. Evaluate the association between different staff configurations and the experiences and health outcomes of service users. Explore the views of professionals about different team configurations. Examine the roles and responsibilities of pharmacists in each team and explore the factors that enable pharmacists to contribute most effectively to successful outcomes from care. Investigate the resource implications, costs, and value for money of the different service delivery approaches. Mental health pharmacists (including senior pharmacists)	Mixed method	Prospective.	SPSS (version 16) to generate descriptive, summary, and inferential statistics.	Treatment resistant schizophrenia (any age); 23 patient participant questionnaire 10 patients clinic visit observed; 9 interviewed. 23 healthcare professional survey,	Participants in the clinics with a pharmacist reported no difference in health, wellbeing, self-efficacy, and ability to manage their own health than clinics without pharmacist input. In terms of the most favourable behaviours (indicated by lower values), doctors scored favourably in 12 of the 19 areas, with nurses and pharmacists equal in 4 of 19 and phlebotomists 2 of the 19. Pharmacists demonstrated the least favourable consultation behaviours in 8 of the 19 areas, with nurses in 5 and doctors and phlebotomists in 4 of the 19. However, when the scores across all 19 domains were averaged the findings demonstrated with greater clarity the participants' perception of the HCP communication skills within a consultation Clinic staff from all clinics monitored the levels of cigarette smoking which is known to decrease blood levels of clozapine but were not monitoring intake of caffeine related products which increase plasma levels of clozapine. All the clinics were monitoring the physical elements of these risk factors such as weight, blood pressure and blood tests for glucose and lipids, which were completed on a regular basis. Although staff made every attempt to monitor the health of the patients during observations of the patients' journeys the researchers noted that essential equipment was not always available. In particular in one of the clinics where care was provided by a nurse	Community mental health team (clozapine clinic)

								there was no thermometer available to take measure body temperature. Ensuring that all necessary equipment is available must in part be the responsibility of the staff carrying out the clinical checks. However, in the interviews with staff they spoke of the lack of a specific budget for the clozapine clinics and that none of the staff knew who in the organisation was responsible for this. NB *please note only the results related to cardiometabolic/metabolic are documented here)*	
DelMonte (245)	2012	USA	To evaluate the effect of a computerized physician order entry (CPOE) pop-up alert designed to improve rates of laboratory metabolic monitoring of patients treated with second generation antipsychotics (SGAs). Clinical psychiatric pharmacist.	Quant	Single-centre, retrospective chart review: quasi	Chi-squared and Student's t-tests. Cochran–Armitage Trend test.	Before and after alert (respectively):62(36.3%) and 44(28%) schizophrenia, 43(25.1%)and 47 (29.9%)depressive disorders, 35(20.5%) and 39(24.8%) bipolar disorder, 9(5.3%) and 11(7.0%) mood disorder NOS, 6(3.5%) and 4(2.5%) personality disorders, 2(1.2%) and 2(1.3%) dementia, 2(1.3%) and 6(2.8%) anxiety disorders, 5(2.9%) and 0 substance related disorders, 4(2.3%) and 1(0.6%) adjustment disorder, 3(1.8%) and 2(1.3%) other. Age > 18 years.	Patients with glucose level available pre-alert 158 (92.4%) and post alert 157 (100) p=0.001. Blood glucose level ordered at the same time as the SGA ordered on the computer system 9 (5.7%) and 31 (19.7%) p<0.0001. Patients with fasting glucose level available (overall) 80 (46.8%) and 110 (70.0%) p<0.0001. Patients with lipid panel available 49 (28.7%) 117 (74.5%) p<0.001. Patients with both glucose level and lipid panel available 47 (27.5%) 117 (74.5%) p<0.0001. Patients with fasting a lipid panel available (overall) 32 (18.7%) 94 (59.9%) p<0.0001. Blood glucose level ordered at the same time as the SGA ordered on the computer system 4 (8.2%) 38 (32.5%) p=0.002.	Inpatient psychiatric unit
Koffarnus (246)	2012	USA	Evaluate adherence to American Diabetes Association (ADA) recommendations for diabetes monitoring following an educational Intervention for physicians in an inpatient psychiatric hospital. PharmD pharmacist.	Quant	Retrospective chart review: quasi	Descriptive statistics (means and frequencies). SAS	60 patients pre- intervention and 60 patients post intervention with a diagnosis of schizophrenia (3.3% pre and 13.3% post), schizoaffective disorder (33.3% pre and 30% post), bipolar disorder (40% pre and 23.3% post) and major depressive disorder (16.7% pre and 21.7% post).	A significant increase (from pre- to post-interventions) was observed in frequency of A1c documentation on admission [30.0% to 61.7%, respectively (X2 = 12.1175, p = 0.0005), For the secondary outcomes of the increase in frequency of admission documentation of fasting plasma glucose, serum creatinine, UMA, and fasting lipid profile within 72 hours of admission, FLP documentation was significantly increased [73.3% to 91.7%, respectively (X2 = 6.9841, p =0.0082)]. There were no significant differences in the documentation of fasting plasma glucose [88.3% to 93.3%, respectively (p = 0.3426)], serum creatinine [58.3% to 75.0%, respectively (p = 0.0528)], and UMA [0 to 3.3%, respectively (p = 0.4958)]. Additionally, there was a non-significant decrease from 4.0 ± 9.0 to 3.1 ± 7.0 days treated with sliding scale insulin (p = 0.5710).	Inpatient psychiatric unit

McCleeary-Monthei (247)	2012	USA	Determine if a metabolic monitoring form for antipsychotics initiated by pharmacists improves adherence to American Diabetic Association/ American Psychological Association guidelines. Determine what factors may affect adherence to the guidelines. Pharmacist (not further specified)	Quant	Retrospective quasi	SAS. Fisher's exact tests. Mann Whitney Wilcoxon tests.	Pre-intervention total of 33 patients of whom 7 (22%) schizophrenia, 9 (27%) bipolar, 13 (39%) psychoses. Post-intervention total of 30 patients of whom had 6 (20%) schizophrenia, 10 (33%) bipolar, 5 (17%) psychoses. Aged 18-65 years on inpatient ward ≥ 48 hours.	In the pre-intervention group. Patients with schizophrenia were significantly more likely to have baseline lipid monitoring (p=0.0418). In the post-intervention group in combined data, patients with a diagnosis of diabetes were more likely to have baseline lipid and glucose/A1c monitoring (p=0.0475, p=0.0496). All other results were not statistically significant.	Inpatient psychiatric unit
Ramanuj (248)	2012	UK	To assess whether the implementation of a high-visibility prompt and an educational programme would improve monitoring rates among patients prescribed regular antipsychotics. Head of pharmacy.	Quant	Quasi	Microsoft Windows Excel 2007 (version 12) and online statistical calculator (GraphPad QuickCalcs). Chi-squared test. Fisher's exact test.	Total of 36 patients in the first audit cycle of whom 14 (38.9%) schizophrenia/schizoaffective disorder, 5 (13.9%) bipolar disorder, 7(19.4%) unipolar depression and 7(19.4%) dementias. Second cycle (after the intervention) total of 38 of whom 12 (31.6%) schizophrenia/schizoaffective disorder, 9((23.7%) bipolar, 6(15.8%) unipolar depression, 2(5.3%) dementias	Glucose and cholesterol levels were monitored at baseline in only 44% and 16%, respectively, of patients in the first audit, although both showed significant improvement by the second audit. In the first audit only four patients (16.0%) had had both random plasma glucose and fasting cholesterol levels measured, but this figure had increased to 13 patients (52.0%) by the second audit. The proportion of patients in whom random plasma glucose and fasting cholesterol levels were measured 3 monthly after starting antipsychotic medication increased from 41.7% and 25%, respectively, in the first audit to 66.7% for both in the second audit. Baseline and annual monitoring rates for metabolic dysfunction and cardiovascular risk were not significantly affected by the risk profile of the antipsychotic prescribed either in 2008 or in 2010, except for the annual cholesterol monitoring rate, which was paradoxically lower for the high-risk antipsychotics than the all-antipsychotic rate in 2010.	Inpatient psychiatric unit
Watkins (266)	2012	USA	To improve medication management oversight for an SMI community-based population by developing a medication monitoring system based on current guidelines to optimize pharmacotherapy and minimize potential medication-related adverse effects. Improvement in coordination of care between healthcare providers. Clinical pharmacist	Mixed methods	Analysis of information from database for psychotropic monitoring	Descriptive statistics	68 adults (>18 years) with a primary diagnosis of schizophrenia or other psychotic disorders limited to schizoaffective disorder or bipolar disorder with psychotic features.	Orders for fasting blood glucose were discontinued (n=2, 100%) and changed to 'attempt fasting status' and 'obtain glycosylated hemoglobin (A1c)] and scheduled for every 6 months. Annual lipid panels were changed to every 6 months. Annual lipid panels were changed to every 6 months, if applicable No analysis of or results outcomes reported.	Community mental health team(university based service)
Kjeldsen (249)	2013	USA	To evaluate the effect of outreach visit by clinical pharmacists (providing education to mental health staff to support the implementation of screening of metabolic syndrome at a psychiatric ward. Clinical pharmacist.	Quant	Retrospective: quasi	SPSS. Student's t-test. Mann–Whitney test when non-normally distributed. Chi-squared test. Fisher's exact test. SPSS	A total of 205 adult (≥ 18 years) patients were included – 93 active implementation and 112 passive dissemination. Individuals with SMI (International Classification of Diseases-10 (ICD-10) criteria for schizophrenia (F20.0 – 20.99) or affective (bipolar) disorder (F30.0 – 31.99).	In total, 205 patients were included in the study (93 patients in the passive dissemination (PD) group, 112 patients in the active intervention (AI) group). A significant improvement of the use of the screening sheet from 36% in the PD group to 81% in the AI group was found ($p < 0.001$). Consequently, the quality of the screening	Inpatient psychiatric ward

								increased significantly resulting in 45% in the AI group being identified with metabolic syndrome compared with 10% in the PD group (p <0.001).	
Cohen (250)	2014	USA	To determine the effect of mental health conditions on the maintenance of glycaemic control and blood pressure control in patients with diabetes following successful completion of a CRRC program. (Follow-up study of Taveira). Clinical pharmacist.	Quant	Retrospective	Descriptive statistics Kaplan-Meier curves for time to failure Cox proportional hazards models - impact of co-variates on time to failure	Total of 231 adults, 108 of whom had mental health conditions – breakdown not given for diagnoses	For patients with and without mental health conditions, 50% of those who had been discharged from the CRRC with an SBP goal of <130 mmHg failed to maintain SBP by 1 quarter. The hazard ratio for failure to maintain SBP, with those without mental health conditions as the reference group, was 0.96 (95% CI 0.68 to 1.35). Overall, for patients with an A1C goal of <7%, the combined median time to failure was 3 quarters. Among patients without mental health conditions, 25% failed in 3 quarters, and of those with mental health conditions, 25% failed in 4 quarters. (HR 0.91; 95% CI 0.50 to 1.66).	Primary care
Lucca (251)	2014	India	To identify the adverse drug reactions (ADRs) to antipsychotics and its management in psychiatric patients. Clinical pharmacist.	Quant	Prospective interventional study: descriptive	Descriptive statistics (mean, range)	517 patients receiving antipsychotics, of which 89 (29.66%) psychosis, 88 (29.33% bipolar affective disorder, 59 (19.6%) depression, 42 (14%) schizophrenia (22 (7.33%) other diagnoses – not stated))	Approximately 90% of the patients with weight gain (n=30) were enrolled into weight management program (nonpharmacological intervention). If it exceeded 7% of the initial weight after 10 weeks, then switching to another antipsychotic was considered.	Tertiary care (inpatient) psychiatric hospital
Schneiderhan (252)	2014	USA	Determine the percentage of subjects taking antipsychotics who meet criteria for metabolic syndrome based on point-of-care testing analyses. Evaluate pharmacist comprehensive medication management services using point-of-care tests to reduce the mean difference in number of metabolic syndrome risk parameters at 6 and 12 months. PCS group – pharmacist clinic. NCS group – non-pharmacist clinic. Pharmacists qualified who were certified Minnesota medication therapy management services	Quant	Prospective, multisite, randomized, controlled study.	χ2 tests. 2-sample t tests. Multiple linear regression models. The mean of the summative scores compared across the PCS and NCS groups	Total 120 patients (60 PCS and 60 NCS). Anxiety disorders (76.7%, n = 89) (including posttraumatic stress disorder [n = 12] and obsessive-compulsive disorders [n = 3]), depressive disorders (65.8%, n = 79), bipolar disorders (47.5%, n = 57), schizophrenia (30.8%, n = 37), and schizoaffective disorder (22.5%, n = 27).	No statistical differences in metabolic syndrome based on point-of-care tests were observed between the 2 groups at baseline (PCS: 85.2%, n = 46 versus NCS: 71.2%, n = 42, *P* = .073) or at 12 months (PCS: 84.4%, n = 38 versus NCS: 70.2%, n = 33, *P* = .104). Subjects, overall, screened positive at baseline for dyslipidemia (85.8%, n = 106), hypertension (52.5%, n = 63), and diabetes (22.5%, n = 27) based on point-of-care testing for metabolic risk criteria. After 12 months, a nonsignificant (*P* = .099) higher adjusted mean number of metabolic syndrome parameters in PCS subjects compared to NCS subjects (mean difference [95% CI] = 0.41 [−0.08 to 0.90]) were found	Community – mental health team
Barnes (197)	2015	UK	To increase the frequency and quality of screening for the metabolic syndrome in people prescribed continuing antipsychotic medication. (Follow on study from Barnes 2008). Hospital chief pharmacist.	Quant	National quality improvement audit: quasi	Descriptive statistics	Adults > 16 years. Total of 1519 patients.72% schizophrenia, schizotypal and delusional disorders, 13% mood/affective disorders, 6% disorders of adult personality and behaviour 9% unknown or other diagnoses including mental retardation and organic disorders	Over the 6 years of the programme, there was a statistically significant increase in the proportion of patients for whom measures for all 4 aspects of the metabolic syndrome had been documented in the clinical records in the previous year, from just over 1 in 10 patients in 2006 to just over 1 in 3 by 2012. The proportion of patients with no evidence of any screening fell from almost ½ to 1 in 7 patients over the same period.	Community mental health team

Bozymski (253)	2015	USA	To demonstrate the need for pharmacy staff and to justify the benefits of implementing outpatient clinical pharmacy services through a collaborative drug therapy management protocol at a community mental health centre. To collect, analyse, and present data on current antipsychotic monitoring practices at an outpatient psychiatric clinic, specifically in relationship to evidence-based guidelines and to monitoring practices at two primary care clinics within the community. Board certified psychiatric pharmacist	Quant	Retrospective chart review: quantitative non-randomised with a control group.	ANOVA. Chi-square test and Fisher's exact test	Schizophrenia 49% (n=89) and schizoaffective disorder 23% (n=42). Age>18 years on an antipsychotic.88% (n=180) from GCSS and 12% (n=24) from PCS.	Monitoring of weight, blood pressure, fasting blood glucose, and fasting lipid panels was significantly better at the two primary care clinics than the outpatient psychiatric clinic. These respective measures were checked at 96%, 100%, 30%, and 25% of study visits at the primary care clinics, contrasting with respective frequencies of 14%, 6%, 0.2%, and 0.3% of study visits at GCSS ($p<0.05$). Family history monitoring took place at 57% of primary care clinic visits and 53.7% of GCSS visits, though this was not a statistically significant difference. With the limited amount of continuous data obtained, the only statistically significant differences between GCSS and the two primary care clinics were weight and blood pressure. The mean weights for these study groups were 94.4 kilograms and 168.1 kilograms, respectively ($p<0.05$). The mean systolic blood pressures were 130.5 mmHg and 121.6 mmHg ($p=0.00064$), and the mean diastolic blood pressures were 84 mmHg and 74 mmHg ($p<0.05$). While statistically insignificant, a large difference of means was found in measured triglycerides on fasting lipid panels, being 193.3 mg/dL for GCSS and 126.8 mg/dL for the primary care clinics ($p=0.11422$). Waist circumference was not measured or documented at any study visit.	Psychiatric outpatient clinic
Fischler (254)	2016	Canada	Facilitate implementation of clinical practice guidelines National Institute of Health and Care Excellence guideline for schizophrenia. Manager of pharmacy.	Quant	Retrospective: quasi	Descriptive statistics (mean and range). Modified Delphi Process	Adults with primary diagnosis of schizophrenia or schizoaffective disorder. Number of patients not stated	Adherence to guidance for metabolic monitoring (March 2014, 76.7 %; March 2015, 81.6 %), CBT-P referral (March 2014, 6.5 %; March 2015, 11. 4 %) and vocational rehabilitation referral (March 2014, 36.6 %; March 2015, 49.1 %) were increased after CPG implementation. There was an initial increase in adherence to antipsychotic monotherapy (March 2014, 53.4 %; November 2014, 62.7 %), which decreased back toward baseline (March 2015, 55.1 %).	Inpatient psychiatric
Lee (322)	2016	USA	To evaluate the sustained impact of a computerized physician order entry (CPOE) pop-up alert designed to improve rates of laboratory metabolic monitoring of patients treated with SGAs in an inpatient psychiatry unit. Interventions carried out by the psychiatry team to manage metabolic abnormalities found on screening were also identified. (Follow on study from DelMonte 2012). Board certified psychiatric pharmacist.	Mixed methods	Retrospective chart review	Chi-square, student's t-tests using SPSS. Interventions - no statistical tests but instead reviewed and described through a case series format.	This is a follow on study from DelMonte and reports a third set of results. In this group there were a total of 129 patients of whom 47(36.4%) schizophrenia, 34(26.4%) depressive disorders, 21 (16.3%) bipolar disorder, 10(7.8%)mood disorder NOS, 4(3.1%) personality disorders, 1(0.8%)dementia, 6(4.7%) anxiety disorders, 4(3.1%) substance related disorders, none with adjustment disorder, 2(1.6%) other. Age > 18 years.	**Quantitative** No significant decrease in monitoring of glucose levels and lipid panels (fasting or random). Nine patients with abnormally elevated laboratories were identified. Interventions by the psychiatry team included referrals to appropriate healthcare professionals and initiation of medication. Results – current population (n=129) and original post alert population (n=157) respectively: Patients with glucose level available 129 (100) and 157 (100) (no p value) Patients with fasting glucose level available (overall) 87 (67.4%) and 110 (70.0%) p=0.634	Inpatient psychiatric unit.

								Level ordered with SGA 3 (2.3%) and 31 (19.7) p <00001. Patients with lipid panel available 91 (70.5%) and 117 (74.5%) p=0.452 Patients with fasting lipid panel available (overall) 81 (62.8%) and 94 (59.9%) p=0.614 Panel ordered with SGA 3 (3.3%) and 38 (32.5%)p <0.0001 Patients with glucose level and lipid panel available 91 (70.5%) and 117 (74.5%) p=0.452 Fasting glucose level and lipid panel available 66 (51.2%) 75 (47.8%) p=0.568 **Qualitative** The interventions made by the psychiatry team to manage metabolic abnormalities were not analysed using statistical tests, but instead reviewed and described through a case series format.	
McMorris (262)	2016	USA	To develop and evaluate dietary teaching tools for a select population diagnosed with a severe mental illness and limited financial ability. A clinical pharmacist (certified in diabetes management) and a first-year pharmacy resident	Qual	Questioning & identification of themes. Focus groups	Focus group analysis methodology	1st phase: 5 Healthcare professionals (mix of psychiatrist, psychiatry resident, clinical social worker, professional counsellor, behavioural health case manager, recovery support specialist, nurse, administrative assistant, clinical pharmacist. 2nd patients who have a primary diagnosis of schizophrenia, schizoaffective disorder, or bipolar disorder (number of patients not stated).	Phase one: Ten cards were created and distributed to the HCPs. A focus group was conducted. HCPs reported the cards were useful in opening dietary choices dialogues and were able to give more specific information on alternative choices. Phase Two: From focus group feedback, specific cards for disease states, calorie guidelines, and budget limitations were developed. HCPs immediately utilized them.	Community mental health team – assertive community treatment team.
Porras-Segovia (255)	2016	UK	Case of an individual with refractory schizophrenia who developed rapid-onset insulin dependence at the commencement of his clozapine therapy. Clinical pharmacist.	Quant	Case report	None	One individual with treatment resistant schizophrenia	Case report of an individual with refractory schizophrenia who developed rapid-onset insulin dependence at the commencement of his clozapine therapy and in whom diabetes was treated successfully without discontinuing clozapine.	Inpatient psychiatric unit
Quirk** (263)	2016	UK	Describe the process and impact of implementation of the Lester tool (cardiometabolic health resource) in 4 mental health trusts running the program as a pilot. Assess the extent to which the Lester tool may be transferable to other groups of patients. Pharmacy team and pharmacist (not further specified).	Mixed methods	Questionnaire based survey. Focus group	Descriptive statistics Qualitative data - none	Adult patients with schizophrenia, bipolar disorder, or other psychotic disorders. Focus group with 5 service users Questionnaire based survey:195 individuals. Focus group: 5 individuals Implementation of electronic tool developed by pharmacy team: 52 patients baseline 29 at follow up	Qualitative data asked service users various questions about their physical/cardiometabolic health. Questionnaire-based survey of inpatients (1)Which healthcare professional(s) would you speak to if you thought your medication for your mental health was having a bad effect on your physical health? 533service users with SMI were asked this question and only 3 (0.6%) stated pharmacist. (2)Where do you get information about how to be physically fit and healthy? Of 564 none stated a pharmacist* (3)Respondents were asked to rate the frequency (on a scale from always to never) with which their mental health problems stopped them being physically fit and healthy. One respondent stated Gym or exercise time is limited to certain times in the day and I can't always attend. If the gym was open throughout	Psychiatric inpatients (mental health trust)

								the day, it would be easier. Being depressed and on medication makes the motivation suffer. One hospital NHS trust were involved in a pilot study to implement the cardiometabolic screening tool. (1)Pharmacy department within that hospital developed an electronic tool for collection of cardiometabolic health data. Data entry was completed by ward clerk Informants attributed the shift in the types of interventions offered (e.g., reduction in medication reviews, and increase in offers of advice regarding exercise and diet) to improved confidence among ward staff, meaning that they were more likely to offer to intervene themselves, rather than to refer service users to other professionals (doctors or pharmacists). One trust had a Physical Health Strategy Group is the governance group for physical healthcare which reports to the Executive Director of Nursing: the accountable officer. Membership of the group is multi-professional and includes pharmacists. Focus group activity with 5 service users (1)To what extent did you feel you were given information about potential adverse physical effects of medication and were empowered to make a decision weighing up the risks and benefits? The mental health trust has a good pharmacy website – but it is not clear how many people are aware of this, and access this. (2)What would make you want to look after yourself? What would make it easier for you to look after your physical health? Coming off medication (because it causes weight gain, demotivates). An understanding, knowledgeable carer to support you. Too often carers are not informed about diagnoses, medication, or side-effects.	
Shanker (264)	2016	UK	Pilot project to test new model of care – integrated CPA review involving both primary and secondary care team members. Clinical pharmacist.	Mixed methods	Prospective	None	Individuals on care program approach (CPA) who have severe mental illness (schizoaffective disorder, schizophrenia, bipolar disorder, drug-induced psychosis). Numbers not given.	No specific outcomes regarding monitoring. Patient feedback about the whole service was positive (waiting time, involvement in decision-making, management plan explained)	Primary care – GP surgery
Bozymski (256)	2017	USA	Primary objective - to evaluate the completion of cardiometabolic interventions at a coordinated specialty care clinic through a retrospective chart review of enrolled clients. Psychiatric pharmacist.	Quant	Retrospective: descriptive	Descriptive statistics SPSS	163 in total - 90 subjects schizophrenia (55.2%), 45 with psychosis not otherwise specified (27.6%), 19 with schizophreniform disorder, (11.7%), and 9 with schizoaffective disorder (5.5%).	Approximately one-third of subjects reported tobacco use, and 47 subjects admitted to illicit drug use (primarily marijuana). Nearly one-fourth of subjects also met diagnostic criteria for dyslipidaemia or obesity at some point in the study, with lesser degrees of hypertension and diabetes mellitus; no subjects met criteria for a cardiometabolic abnormality according to baseline data.	Community clinic

								As a result of the use of the tool the following interventions were made – referral to dietician or health program n=29 (17.8%), start diabetes medication n=13 (8.0%), adjust diabetes medication 2 (1.2%), start dyslipidaemia 1 (0.6%). Dyslipidaemia and obesity were (later) found after use of clinical decision support tool found in 37 (22.7%) and 35 (21.5%) clients, respectively.	
Sud (257)	2017	UK	Evaluate the impact of a pharmacist-led metabolic monitoring service for individuals with severe mental illness. Senior Hospital Mental Health Clinical Pharmacist	Quant	Retrospective: quasi	Descriptive statistics	Individuals with severe mental illness schizophrenia, bipolar disorder, schizoaffective disorder, drug induced psychosis and any other diagnosis. Data for inpatient audits 252 patients per year for three years 2014-2017, early intervention audit 150 patients per year for two years 2016-1017, 900 community mental health patient.	Improvement in rate of screening and monitoring Rate of screening alone in 2013 was 24% (average) Rate of screening and related interventions (total) was 87% as measured 2015 inpatient only. In 2016 99% for inpatients and 95% for early intervention team In 2017 100% for inpatient, 97% for early intervention and 87% for community mental health team patients on CPA	Psychiatric inpatients. Community mental health team. Early intervention
Sasson (258)	2017	USA	Evaluate whether implementing psychopharmacology rounds in a nursing home will decrease overall rates antipsychotic use. This study also measured HbA1c done in past year and lipid panel within 2 years as a secondary outcome. Clinical pharmacist	Quant	Prospective single centre: quasi	Fischer's exact test	81 patients in total who were residents at the nursing home, of these 14 had a concomitant diagnosis of dementia and at least one of the following diagnoses: schizophrenia, bipolar, or depression; 31 had dementia and 36 had other diagnoses (not stated).	Metabolic laboratory monitoring improved from 58% (33/57) to 83% (45/54) (p = 0.003) however, not broken down for each diagnosis.	Nursing home
Sharma – two publications from one research study (paper and poster) (238,239)	2017, 2018	Australia	Assess the practices and attitudes of Australian mental health practitioners towards assisting their clients to stop smoking and their beliefs about potential (Tobacco Harm Reduction) THR strategies for patients with SMI. Pharmacist (not further specified)	Quant	Online, cross-sectional, national survey	SPSS Descriptive statistics Binomial multivariable logistic regression models	267 mental health professionals: Medical practitioners 37 (13.85), Nurses 61 (22.84), Allied health practitioners (occupational therapist, psychologists, pharmacists, and social workers) 66 (24.7), Community mental health practitioners 74 (22.84), Others (not defined) 29 (3.4).	Most practitioners (77.5%) asked their clients about smoking and provided health education (66.7%) but fewer provided direct assistance (31.1–39.7%). Most believed that tobacco harm reduction strategies are effective for reducing smoking related risks (88.4%) and that abstinence from all nicotine should not be the only goal discussed with smokers with SMI (77.9%). Many respondents were unsure about the safety (56.9%) and efficacy (39.3%) of e-cigarettes. Practitioners trained in smoking cessation were more likely (OR: 2.9, CI: 1.5–5.9) to help their clients to stop smoking. Community mental health practitioners (OR: 0.3, CI: 0.1–0.9) and practitioners who were current smokers (OR: 0.3, CI: 0.1–0.9) were less likely to adhere to the 5As of smoking cessation intervention. The results of this study emphasize the importance and need for providing smoking cessation training to mental health practitioners especially community mental health practitioners. 5As = ask, assess, advise, assist, arrange	Public & private covering urban and non-urban settings.

Pena (259)	2018	USA	The purpose of this project was to increase baseline metabolic syndrome monitoring rates in patients taking SGAs by implementing interventions to overcome barriers to monitoring and to accessing the MSMC. Clinical pharmacist	Quant	Pre and post study of metabolic parameter measurements: quasi Survey of Mental health professionals	Chi-square tests to calculate the change in monitoring. Descriptive statistics were used to evaluate referral rates and patient appointment attendance	Referral rate to pharmacist clinic was 24 patients prior to intervention, and 33 patients post intervention. However, outcome data only reported for 17 (51.5%) of the 33 referred post intervention. No breakdown given as to how many have SMI – but authors report that at the facility 85.9% of patients with a diagnosis of schizophrenia had an active prescription for an antipsychotic. 9 mental health professionals completed the survey.	There was a 37.5% increase in overall referral rates to the MSMC after intervention, but only 51.5% of patients attended appointments as scheduled. Monitoring of vital signs increased but monitoring of laboratory parameters decreased. A total of 60% (9 of 15) of providers completed a survey, of which one third indicated they still forget to refer patients to the MSMC.	Mental health outpatient.
Health foundation (268)	2018	UK	A collaborative project between primary care, community pharmacy and secondary care aimed at improving the rate of physical health checks for those with psychotic illness and provide health coaching for these patients. Community pharmacist (and mention of community pharmacy but not clear if members of staff other than the community pharmacist were involved or not)	Mixed methods	Results of health screening before and after intervention; patient activation measure and health coaching compared to treatment as usual (TAU). Information regarding satisfaction with service collected from patients and CPA coordinator. Community pharmacists feedback on service provision and benefit to patients	Descriptive statistics. Patient activation measure score Qualitative statements reported as raw data – no synthesis	180 patients with psychotic illness were referred to undertake the research pathway/protocol. 10 community pharmacies Number of care coordinators/CPNs not stated	In the locality there were 350 potentially eligible patients, of these 180 patients with psychotic illness were referred of which 140 (70%) attended the community pharmacy. 71% of those that attended had all four screening parameters measured (BP, BMI, glucose, lipids) compared to 36% before the intervention was implemented. 100% of patients received health coaching for smoking, exercise, and diet (22 - stop smoking; **56 – exercise;** 78 – weight loss or healthy eating). PAM questionnaire: 1st appointment 120 patients completed with average score of 52.72; 2nd appointment 41 patients completed with an average score 57.26 and at the 3rd appointment 15 patients completed with an average score of 58.46. 100% of CPA coordinators/CPN – data on satisfaction was unclear; 100% of patients agreed/strongly agreed with the time taken to get an appointment and support received. Qualitative information from 4 community pharmacists was not synthesized at all and a sample of community pharmacist opinions on their role/what they felt as well as what they felt the impact for patients – the comments they made were reported. However, unclear whether the 4 pharmacists represented those that responded or if it was a sample of the information they provided	Community pharmacy
Raynsford (260)	2018	UK	The aim of this study was to explore the impact of a specialist mental health pharmacist and pharmacy technician on individuals with SMI in primary care (GP practices). Specialist mental health pharmacist and mental health pharmacy technician.	Quant	Prospective	Descriptive statistics	Primary care (GP) SMI registers of 5 GP surgeries were reviewed by pharmacy technicians (total 472 patients). 316 (67%) of these patients were prescribed mood stabiliser or antipsychotics. Pharmacists received referral for 197 patients and undertook interventions for physical health issue (blood tests or ECG) in 22 of these.	Blood tests were overdue in 16 (73%) cases and out of range in 6 (27%). Reasons identified for bloods being overdue include failure to attend despite requests, patient being out of the country for a long period of time or query regarding whether tests were to be done in secondary or primary care. Overdue blood tests were followed up with the appropriate team. Repeat blood tests were done where bloods were out of range and followed up with the appropriate team.	GP surgery in primary care

*Taylor (261), Quirk (263), Shanker (264) & Raynsford (260) included some work and results that were completely irrelevant to the objectives of this literature review: we will only consider those aspects pertinent to our review question

** asked the opinion/views of an individual with SMI

NB none of the studies included informal carers of those with SMI

Variability existed within the dataset for many characteristics including participant characteristics such as definition of SMI and age, study setting, outcomes measured, and data collected and did not allow for quantitative data to be pooled or examined by meta-analysis. The authors (DS, EL, RM) used the following methods to analyse the data: (i) a mapping review and (ii) implementation strategies used to implement the study intervention were classified using the EPOC taxonomy.

Table 2: Summary of setting type of included studies

Setting	Number of studies
Mental health outpatient/Community mental health team	15
Inpatient	12
Primary care (primary care clinic)	2
General Practitioner (GP) surgery	1
Community pharmacy	1
Early intervention/first episode psychosis services	1
Other (mix of urban, non-urban and metropolitan centres)	2*
Total	34

*Two papers from the same study

Table 3: Summary of pharmacy staff/professional type of included studies

Pharmacy staff/professional type	Number of studies*
Head of pharmacy/pharmacy manager	4
Specialist mental health pharmacist/clinical psychiatric pharm/psychiatric pharmacist	9
Clinical pharmacist	9
Pharmacist	6
Clinical pharmacist with extra qualification	2
Specialist mental health psychiatric technician	1
Community pharmacy	1
Community pharmacy team	1
Pharmacy team	1
1st year pharmacy resident	1
Hospital pharmacist	1

*Total not provided as some studies used more than one staff type in the implementation of study intervention

Table 4: Summary of implementation strategies according to EPOC taxonomy

NB none of the studies included a regulatory strategy

	Screening for CMR, MetS and related diseases				Screening, identification of risk /abnormal result/diagnosis and implementation of clinical interventions for CMR, MetS and related diseases				Implementation of clinical interventions for CMR, MetS and related diseases				Impact assessment possible? ◊
Study, Ref	Patient	Profess	Financial	Organisation	Patient	Profess	Financial	Organisation	Patient	Profess	Financial	Organisation	
MacHaffie (240)	**Not an intervention study, questionnaire.**												
Ohlsen (265)	**Results of pharmacist input not reported**												**X**
Runcie (241)						✓							✓
Barnes (196)	✓	✓											✓
Taveira (242)					✓	✓		✓					✓
Schneiderhan (243)				✓									**X**
Gable (143)					✓	✓		✓					**X**
Lizer (244)					✓	✓		✓					✓
Taylor (261)					✓			✓					**X**
DelMonte (245)		✓											✓
McCleeary-Monthei (247)		✓											✓
Ramanuj (248)		✓											✓
Watkins (266)	✓	✓		✓									✓
Kjeldsen (249)		✓											✓
Cohen (250)*													✓
Lucca (251)												✓	**X**
Schneiderhan (252)					✓			✓					✓
Bozymski (253)								✓					✓
Barnes (197)	✓	✓											✓
Fischler (254)		✓											✓
Lee (267)						✓							✓
McMorris (262)										✓			**X**
Porras-Segovia (255)										✓			**X**
Quirk (263)	**Pharmacy designed tool for recording data by other staff, however, exact details unclear.**												
Shanker (264)								✓					**X**
Koffarnus (246)		✓		✓									✓
Bozymski (256)						✓							**X**
Sud (257)						✓	✓	✓					✓
Sasson (258)				✓									✓
Sharma (238,239)	**Not an intervention study, survey.**												
Pena (259)	✓	✓	✓	✓									✓
Health foundation (268)					✓	✓		✓					✓ **(For 2 of 4 outcomes measured)**
Raynsford (260)				✓									**X**

*Although this study did not involve implementation of an intervention it was included as it provided follow-up data for a study that did.

◊ if data were provided to assess impact of the intervention before and after or to a comparator group or described impact over a period of time.

Appendix 9: Study protocol and associated documents

Study Protocol

CARDIOPHITNESS:

Cardiometabolic health and **Ph**armac**i**s**t**s in Severe Mental Ill**ness.**

VERSION CONTROL

Version number and date		Author	Next steps
v 1.0	04/04/2018	DS	Sent to Dr Ian Maidment, PhD Supervisor
v 1.1	11/05//2018	DS	Incorporated revisions: as suggested by supervisor, NIHR CRN East Midlands
v 1.2	22/06/2017	DS	Incorporated revisions; as suggested by project manager (research and knowledge exchange, Aston University)
v 1.3	04/07/2018	DS	Incorporated further revisions; as suggested by project manager (research and knowledge exchange, Aston University)
v 1.4	09/11/2018	DS	<u>Amendments as per Ethics review (24/10/2018 – 09/11/2018):</u> Amendments to circumstances under which care professionals will be offered £10 gift voucher <u>Amendments as per HRA review (04/10/2018)</u> Statement added to section 13.0 regarding arrangements for identifiable data (consent forms) to be transferred back to the NHS site.
v 1.5	30/12/2018 30.01.2019	DS DS	<u>Amendments as per 1st year review at Aston University:</u> Inclusion criteria for participants to include patients with SMI who have cardiometabolic risk and/or metabolic syndrome and have had contact with pharmacy; carers who look after these patients. Include pharmacists as a separate group of participants. Methods and route of patient and care professional participants to include other activities: distribution of study material by R&D Lead for Leicestershire CCGs, People in Research platform, social media, and newsletters.
V 1.6	26.06.2019	DS	<u>Amendment to inclusion criteria for carers</u> Inclusion criteria for carers to be amended to carers who aren't dyads of patients recruited to the research study. We will therefore be able to recruit any carer and carers who are dyads to the study.

Contents

1.0 Introduction

The **CARDIOPHITNESS** (**Cardio**metabolic health and **Ph**armac**ist**s in Severe Mental Ill**ness**) study is the second phase of a PhD exploring the role of pharmacy and pharmacists in the physical health of those with severe mental illness and is informed by an earlier literature review.

Mental illness accounts for around 23% of the total disease burden and leading cause of disability in the United Kingdom (1,2), and for significant health and social care costs (1,2). A considerable fraction of these costs can be attributed to physical illnesses in people with severe mental illnesses (3). The definition of severe mental illness (SMI) encompasses schizophrenia, bipolar affective disorder, schizophrenia-like psychosis (e.g., schizoaffective disorders) and other psychoses. Those with SMI have significantly higher rates of mortality and comorbid physical ill health when compared to the rest of the population (4.5.6.7.8.9). Individuals with SMI die on average 20 years earlier than people without SMI (10). The underlying causes for this are both complex and multifactorial (11).

The vast majority of these deaths are due to long-term physical illness such as cardiovascular disease, cancer, respiratory disease, and diabetes (6, 12, 13,14). There is a three-fold increase in the risk of death from coronary heart disease (8, 11), two-fold increased risk of diabetes (14, 15) and overall a ten-fold risk in death when compared to the general population (14,15).
Physical ill health in patients with SMI may be due to a genetic predisposition, however, environmental factors and lifestyle factors such as poor diet, smoking, lack of physical activity and obesity/overweight play a prominent part (18). In addition, for those with SMI there is inequity in access to medical care and quality of care. Additionally, health checks targeted at prevention are carried out less frequently in both primary and secondary care for those with SMI when compared with the general population (19-21). Studies have shown that those with SMI are just as motivated to make lifestyle change, in the case of smoking, can achieve cessation (22,23) In those with SMI the prevalence of obesity/overweight, smoking, poor diet, and lack physical activity is much higher; in England 40.5% of adults who have SMI are smokers (24) more than double that of the general population (15.5%) (25). Not only is diet poor (26,27) but levels of obesity (which range from 40-60%) are up to four times higher than the general population (28-30). Those with SMI are less physically active (31-33).
Unhealthy lifestyles and inadequate physical healthcare are also risk factors for dementia and Alzheimer's disease (34,35,36). Evidence suggests that vascular risk factor control can reduce a proportion of new cases of dementia, diabetes and CVD are risk factors can lead to the development of mild cognitive impairment, as well as dementia and Alzheimer's disease (36,37,38,39) . The rates of physical ill-health (mainly diabetes and hypertension) are also higher in older patients with dementia (39).
Adverse side-effects of psychotropic medication include weight gain and obesity which subsequently increase the risk of diabetes and cardiovascular disease (CVD) (12, 40). Weight gain during acute and long-term continuous treatment with antipsychotics is well-established adverse side-effect (41, 42, 43) affecting 15-75% of patients (44). Antidepressants e.g., paroxetine and mood stabilisers e.g., valproate have also been associated with increased weight (42, 43). Antipsychotics can increase diabetes mellitus risk with the newer (so called atypical/second generation antipsychotics) having a stronger diabetogenic risk than the older (typical) antipsychotics (41, 42, 43). There also appears to be an independent effect of antipsychotics contributing to CVD risk; individuals with SMI are three times more likely to experience sudden cardiac death compared to the general population (45,46).

'Medicines optimisation is defined as a person-centred approach to safe and effective medicines use to ensure that people obtain the best possible outcomes from their medicines' (47). Medicines optimisation is an important consideration in those with SMI. Intolerable side-effects are a significant contributor to non-adherence with psychiatric medications (48).

Metabolic side-effects such as central obesity/weight gain, further contribute to lack of adherence (48, 49, 50). Research studies which investigate the role of support services for those with schizophrenia to improved medication adherence has yielded varying results (50). Pharmacists are experts in medication management and have knowledge, for example, about side-effects, adverse drug reactions, screening and interpretation of blood tests, choice of medication and strategies to improve adherence as well as being an important part of the multidisciplinary team (51). In addition, they can provide information, tools, and signposting to facilitate positive lifestyle changes such as smoking cessation (52).

The views and perspectives of patients with SMI, their carers and care professionals are crucial in understanding the current and potential roles that pharmacy could play in the management of cardiometabolic risk factors, metabolic syndrome, diabetes, heart disease and related disorders. The research literature that does contains very limited amounts of qualitative information about the views and perspectives of key stakeholders on the role of pharmacy (53-63). This research study has been informed by a previous literature review on this topic; to our knowledge there is no published literature that investigates or explores patients', caregiving dyads, carers, or care professionals' perspectives of how they view and utilise pharmacy for support. In addition, nothing exists which attempts to triangulate the views of these key stakeholders on these issues. This study was therefore undertaken to address this gap.

Ultimately the aim is to reduce the inequalities in health that exist for individuals with SMI by improving the physical health of those with SMI. In this application I propose to examine in detail the role of pharmacy, pharmacists and to improve physical health in people with SMI.

2.0 Aims and objectives

The overall aim of this research programme of work is to explore the place and contributions of pharmacy in providing support and care (including lifestyle and medicines optimisation) for cardiometabolic risk factors and metabolic syndrome for individuals with SMI. This study had four main objectives:

- To examine and understand the experiences and views of patients with SMI and their informal carers about care received for cardiometabolic risk factors, metabolic syndrome, diabetes, heart disease and related diseases.
- To examine and understand how patients with SMI and their informal carers engage with activities in looking after and seek advice and support when needed for cardiometabolic risk factors, metabolic syndrome, diabetes, heart disease and related diseases.
- To explore the views of patients with SMI and their informal carers on whether and how they utilise pharmacy for care and support for cardiometabolic risk factors, metabolic syndrome, diabetes, heart disease and related disease.
- To explore the views and experiences of care professionals on providing care for cardiometabolic risk factors, metabolic syndrome, diabetes, heart disease and related diseases; as well their views on pharmacy and pharmacists providing this care.

3.0 Study design

An exploratory qualitative study design that will follow Consolidated Criteria for Reporting Qualitative studies (COREQ) guideline will be employed (64). This will be undertaken using semi-structured interviews where participants provide a detailed account of their views guided by an interview schedule. The setting will be in both primary care and secondary care in the UK. The target population are individuals aged 18 and over with SMI, informal carers of those with SMI and care professionals directly involved in their care.

4.0 Overview of recruitment strategy

Patients with SMI	**Informal carers of individuals with SMI.**	**Care professionals and pharmacy professionals who are directly involved in the care of those with SMI.**
Indirect	**Indirect**	**Indirect**
Poster (Appendix 9) displayed in site reception areas sent to SMI patient support groups sent to research manager at LPT NHS Trust who will contact SMI patients via the Embedding Patient and Public Involvement Collaboration project (a service development initiative for research and development in LPT NHS Trust) Display the opportunity on People in Research platform https://www.peopleinresearch.org/ Other patient and public involvement activities including social media and newsletters	Poster (Appendix 9) •displayed in site reception areas •sent to SMI carer support groups •sent to research manager at LPT NHS Trust who will contact carers via the Embedding Patient and Public Involvement Collaboration project •Display the opportunity on People in Research platform https://www.peopleinresearch.org/ •Other patient and public involvement activities including social media and newsletters	Poster (Appendix 9) Sent to NIHR CRN East Midlands for distribution to primary care professionals and pharmacy professionals. Sent to R&D department of Leicestershire Partnership NHS Trust for distribution to mental health professionals in secondary care, via global email, weekly e-newsletter and as an attachment to their postgraduate education session timetable Send to R&D Lead for Leicestershire CCGs for distribution to GP practices, other care professionals and pharmacy professionals within the CCGs
&	&	&
Direct	**Direct – to recruit caregiving dyads only** •When face-to-face interviews take place with individuals with SMI they will be given an information pack about the study to hand to their nominated informal carer. The information pack will contain a letter of invitation and carer PIS (Appendix 10) •The nominated informal carer should be someone who the individual with SMI identifies as the person they get most support from.	**Direct**
LPT NHS Trust (Mental health trust) to identify patients who meet eligibility criteria through reporting systems and team leader/care coordinators/consultants provide those patients with a letter of invitation and patient PIS (Appendix 10) NIHR CRN East Midlands and the R&D Lead for Leicestershire CCGs who will contact GP surgeries and send them an introductory letter. Interested practices will identify patients who meet the eligibility criteria through reporting systems and post out letter of invitation and patient PIS (Appendix 10) to these patients. In addition, opportunistic recruitment will be undertaken by the GP surgeries (poster will be given to eligible patients).		Lead researcher to ask LPT NHS Trust Senior Pharmacist/Pharmacy manager to send out email and poster (Appendix 9) to: Team leaders/consultants within LPT NHS Trust LPC and ask them to forward to their community pharmacist members Medicines optimisation pharmacist lead for each CCG for distribution to their pharmacists The lead for the College of Mental Health Pharmacists so they can contact their members via appropriate channels Pharmacy team at the NHS trust (by pharmacy manager) Also, other professional contacts as appropriate
↓		↓
Reminder: 2-4 weeks later		Reminder:2-4 weeks later
↓	↓	↓
For those individuals who contact the lead researcher	**For those individuals who contact the lead researcher**	**For those individuals who contact the lead researcher**
Eligibility screening: screen for eligibility and assess capacity for participation. Answer any questions or queries. Send out letter of invitation and patient PIS (Appendix 10) where appropriate.	**Eligibility screening**: screen for eligibility and assess capacity for participation. Answer any questions or queries. Send out letter of invitation and carer PIS (Appendix 10) where appropriate.	**Eligibility screening**: screen for eligibility Answer any questions or queries. Send out and letter of invitation and care professional/pharmacy professional PIS (Appendix 10) where appropriate.
↓	↓	↓
Follow up – arrange interview	**Follow up – arrange interview**	**Follow up – arrange interview**
↓	↓	↓
Written informed consent. Formal consent processes undertaken including signing consents for participation	**Written informed consent.** Formal consent processes undertaken including signing consents for participation	**Written informed consent.** Formal consent processes undertaken including signing consents for participation
↓	↓	↓
Enrolment and data collection. Time location for interview arranged. Conduct interview as soon as possible after enrolment	**Enrolment and data collection.** Time location for interview arranged. Conduct interview as soon as possible after enrolment	**Enrolment and data collection.** Time location for interview arranged. Conduct interview as soon as possible after enrolment

Decline at any point. Patient to withdraw no further action	**Decline at any point.** Informal carer to withdraw no further action	**Decline at any point.** Care professional or pharmacy professional to withdraw no further action

5.0 Individuals with SMI

5.1 Inclusion criteria

Aged 18 years or over. No upper age limit.

A diagnosis of schizophrenia, bipolar disorder, schizoaffective disorder, or other non-organic psychosis (ICD-10 codes F10.5, F11.5, F12.5, F13.5, F14.5, F15.5, F16.5, F19.5, F20-29, F30.2, F31.2, F31.5, F32.3 and F33.3) which has been given to them by mental health/psychiatric services **or** SMI patient support group member.

Have a cardiometabolic risk factor and/or metabolic syndrome.

Have had support from pharmacy.

With capacity to provide informed consent to participate in the study.

5.2 Exclusion criteria

Individuals with SMI under the age of 18.

Non-English speaking.

Lack of capacity to consent.

5.3 Recruitment

Individuals with SMI will be recruited using several methods to maximise participation. Methods will be employed to avoid inadvertent targeting of individuals who do not meet the inclusion criteria. These methods will include displaying the poster (Appendix 9) at site reception areas (e.g., reception area of mental health community outpatient department); the poster (Appendix 9) will also be sent to SMI patient support groups and to the research manager at LPT NHS Trust who will contact patients via the Embedding Patient and Public Involvement Collaboration project (a service development initiative for research and development in LPT NHS Trust).

The lead researcher will arrange a meeting with R&D team at LPT NHS Trust.

- The research study will be discussed at this meeting.
- The lead researcher will request a targeted approach to recruiting at this meeting: they will request that the R&D team contact the Business Information Manager in the Performance and Information department of LPT NHS Trust.
- The Business Information Manager will generate a list of patients who meet the eligibility criteria (from electronic record systems) and then send this list to the R&D team.

- The R&D team will then send this list of patients to team leaders/care coordinators/consultants who will then provide each of their patients on this list with a patient participant information sheet (PIS) and letter of invitation (Appendix 10)

The lead researcher will arrange a meeting with the NIHR CRN East Midlands and the R&D Lead for Leicestershire CCGs. The research study will be discussed at this meeting. The CRN and the R&D Lead for Leicestershire CCGs will contact GP surgeries with an introductory letter asking if they are interested in takin part and identify patients who meet the eligibility criteria. The surgery will be contacted 2-4 weeks later to follow up and if they are willing to take part, they will be sent prepaid envelopes containing copies of a patient PIS and letter of invitation (Appendix 10); these will be sent out in the post to the patients identified by the GP surgery. In addition, opportunistic recruitment will be undertaken by the GP surgeries (poster will be given to eligible patients when they are seen by care professionals e.g., GP consultation). We may also recruit individuals with SMI who became aware of the study via our PPI (patient and public involvement) engagement activities e.g., via mental health charities such as Bipolar UK blogs, patient group meetings etc. and voluntarily offer to participate in the study. This will include displaying the opportunity on People in Research platform https://www.peopleinresearch.org/. Other patient and public involvement activities including social media and newsletters.

5.4 Eligibility screening and consent

Only potential participants who have contacted the lead researcher using the contact details provided on the poster, invitation letter or PIS will be contacted.

The lead researcher will contact the potential participant to discuss the study and answer any questions they may have before checking their eligibility. This will include asking them if they have (a) a diagnosis (from mental health/psychiatric services) of schizophrenia, bipolar disorder, schizoaffective disorder or other non-psychotic disorder and (b) any of the following: cardiometabolic risk factors and/or metabolic syndrome including smoking, overweight/obese, weight gain, high blood pressure, hypertension, medication for high blood pressure, raised blood glucose, diabetes, heart disease or abnormal blood lipids and (c) have had support from pharmacy.

For those confirming they meet the criteria outlined in (2) above who are still interested in participating the following documentation then an information pack will be sent out (letter of invitation and patient PIS (Appendix 10) if they haven't received these already. If there has been no response after two weeks from those individuals sent the information at this point the lead researcher will make follow up contact with the potential participant.

Individuals who self-report a diagnosis of SMI but have not had contact with mental health or psychiatric services (this may occur if recruited via the poster) will be provided with information about such services and directed to contact them as appropriate. These individuals will be thanked for expressing an interest in the study but informed that they are not eligible to take part.

A face-to-face appointment will be arranged to carry out the interview at a mutually convenient time and venue.

When the lead researcher meets the potential participant face-to-face, capacity to consent will be undertaken and they will be given the opportunity to ask additional questions about the study.

They will be reminded that although the interview will be digitally recorded (using an encrypted digital recorder) all information they disclose is confidential and their name will not be used in any quotations in written reports, publications, or presentations.

The lead researcher will then reimburse the participant for any reasonable out of pocket and travel expenses and also offer a £10 gift voucher as a sign of appreciation for participation in the interview. The researcher will advise the potential participant that taking part is entirely voluntary and that it will not affect the care they receive from the NHS and that they are free to withdraw at any time without providing a reason. They will be informed that they have until the point at which their data is anonymised to withdraw all or any of the information provided or discussed in the interview.

Once written informed consent has been obtained (consent form) a short background information questionnaire (for demographic data and clinical data) (e.g., diagnosis) will be completed with the participant before commencing the interview.

5.5 Interviews

Interview topic guide (Appendix 11) have been prepared prior to the semi-structured interviews to guide data collection and to guide and focus discussion, however the interviews were flexible and participants were able to discuss any relevant issues and to reflect. All interviews will be audio-recorded and transcribed verbatim and undertaken by the lead researcher (Dolly Sud). In addition, handwritten notes will be taken during each interview to record any important observations and after the interviews to record any additional statements as well as the researcher's reflection of the interview. Each interview participant will be allocated an identification code, which will be used on all documentation (including background questionnaire) and transcripts relating to an individual participant. We will keep anonymised transcripts/handwritten notes taken during interviews. Original audio recordings will be destroyed.

6.0 Informal carers of individuals with SMI

6.1 Inclusion criteria

This person will be identified by a participant with SMI as the person (who is not a care professional) they get most support from, not necessarily a family member.

Adults aged 18 years and over. No upper age limit.

(1) An informal carer for a patient recruited to the study. This person will be identified by the patient as the person (who is not a care professional) they get most support from, not necessarily a family member)

OR

(2) carer who provides care for someone who has SMI (the person with SMI must have a cardiometabolic risk factor and/or metabolic syndrome and they must have had support from pharmacy)

With capacity to provide informed consent to participate in the study

6.2 Exclusion criteria

< 18 years old

Non-English speaking

Lack of capacity to consent

6.3 Recruitment

Methods will be employed to avoid inadvertent targeting of individuals who do not meet the inclusion criteria. The aim of the recruitment strategy is to recruit carers and caregiving dyads. Caregiving dyads will be recruited in the following way: when face-to -ace interviews take place with individuals with SMI they will be given an information pack about the study to hand to their nominated informal carer. The information pack will contain a letter of invitation and carer PIS (Appendix 10). Carers (who are not dyads) will also be recruited. We may also recruit carers (who are not dyads) who became aware of the study via our PPI (patient and public involvement) engagement activities e.g., via mental health charities such as Bipolar UK blogs, carer group meetings etc. and voluntarily offer to participate in the study. This will include displaying the opportunity on People in Research platform https://www.peopleinresearch.org/. Other patient and public involvement activities including social media and newsletters.

6.4 Eligibility screening and consent

Only informal carers who have contacted the lead researcher using the contact details on the poster, letter of invitation or carer PIS will be contacted.

The lead researcher will contact the potential participant to discuss the study and answer any questions they may have before checking their eligibility. This will consist of asking them if they are an informal carer providing the care for someone with a diagnosis of schizophrenia, bipolar disorder, schizoaffective disorder, or other non-psychotic disorder. If necessary, letter of invitation and carer PIS will be sent out.

If they are a caregiving dyad of patient recruited to the study, they will be asked to identify the patient recruited to the study from whom they received the information pack from. The unique participant identification number of that patient recruited will be retrieved and this number will be noted alongside the informal carers unique participant identification number to allow for the lead researcher to link the data during the data analysis process.

For those individuals who meet the inclusion criteria and are still interested in participating, a face-to-face appointment will be arranged to carry out the interview at a mutually convenient time and venue.

When the lead researcher meets the potential participant face-to-face, capacity to consent will be undertaken and they will be given the opportunity to ask additional questions about the study.

They will be reminded that although the interview will be digitally recorded (using an encrypted digital recorder) all information they disclose is confidential and their name will not be used in any quotations in written reports, publications, or presentations.

The lead researcher will then reimburse the participant for any reasonable out of pocket and travel expenses and also offer a £10 gift voucher as a sign of appreciation for participation in the interview. Finally, before written consent is provided the researcher will advise the potential participant that taking part is entirely voluntary and that it will not affect the care that the person they care for receives from the NHS (if relevant) and that they are free to withdraw at any time without providing a reason. They will be informed that they have until the point at which their data is anonymised two weeks after the interview to withdraw all or any of the information provided or discussed in the interview.

Finally written informed consent will be obtained. Once written consent has been obtained the participant a short background information questionnaire (for demographic data) will be completed with the participant before commencing the interview.

6.5 Interviews

Interview topic guide (Appendix 11) have been prepared prior to the semi-structured interviews to guide data collection and to guide and focus discussion, however the interviews were flexible and participants were able to discuss any relevant issues and to reflect. All interviews will be audio-recorded and transcribed verbatim. In addition, hand-written notes will be taken during each interview to record any important observations and after the interviews to record any additional statements as well as the researcher's reflection of the interview. Each interview participant will be allocated an identification code, which will be used on all documentation (including background questionnaire)) and transcripts relating to an individual participant. We will keep anonymised transcripts/handwritten notes taken during interviews. Original audio recordings will be destroyed.

7.0 Care professionals and pharmacy professionals

7.1 Inclusion criteria

Care professionals and pharmacy professionals who are directly involved in the care of individuals with SMI who have a cardiometabolic risk factor and/or metabolic syndrome and who have had support from pharmacy.

7.2 Exclusion criteria

Care professionals and pharmacy professionals who are not directly involved in the care of individuals with SMI.

7.3 Recruitment

Poster (Appendix 10) will be sent to NIHR CRN East Midlands and R&D Lead for Leicestershire CCGs and for distribution to GP practices.

Poster (Appendix 10) will be sent to the R&D department of Leicestershire Partnership NHS Trust for distribution to mental health professionals via mechanisms including global email, NHS Trust e-newsletter and as an attachment to their postgraduate education session timetable.

Lead researcher to ask LPT NHS Trust Senior Pharmacist/Pharmacy Manager to send out email and poster (Appendix 10) to:

- team leaders/consultants within LPT NHS trust.
- LPC and ask them to forward to their community pharmacist members.
- Medicines optimisation pharmacist lead for each CCG for distribution to their pharmacists.
- The lead for the College of Mental Health Pharmacists so they can contact their members via appropriate channels.
- Pharmacy team at the trust (by a pharmacy manager).

We will also recruit via other professional contacts as appropriate.

7.4 Eligibility screening and consent

Only care professionals and pharmacy professionals who contacted the lead researcher using the contact details on the poster will be contacted.

At this point the lead researcher will contact the potential participant to discuss the study and answer any questions they may have before checking their eligibility. This will consist of asking them if they are a care professional or pharmacy professionals directly involved in the care of an individual who has a diagnosis of schizophrenia, bipolar disorder, schizoaffective disorder, or other non-organic psychosis and that the person they care for has a cardiometabolic risk factor and/or metabolic syndrome and has had support from pharmacy.

For those confirming they meet the criteria outlined in (2) and who are still interested in participating the following documentation: then be sent out: letter of invitation and care professional/pharmacy professional PIS (Appendix 10). Any potential participants who reveal they do not meet the inclusion criteria will be thanked for expressing an interest in the study but informed that they are not eligible to take part.

If there has been no response after two weeks the lead researcher will make follow up contact with the potential participant

A face-to-face appointment will be arranged to carry out the interview at a mutually convenient time and venue.

They will be reminded that although the interview will be digitally recorded (using an encrypted digital recorder) all information they disclose is confidential and their name will not be used in any quotations in written reports, publications, or presentations.

The lead researcher will offer a £10 gift voucher as a sign of appreciation for participation in the interview if they take part in their own time. The care professional or pharmacy professional will not be offered a £10 gift voucher if they part in the study during their work time. Finally, before written consent is provided the researcher will advise the potential participant that taking part is entirely voluntary and that they are free to withdraw at any time without providing a reason. They will be informed that they have until the point at which their data is anonymised to withdraw all or any of the information provided or discussed in the interview.

Finally written informed consent will be obtained. Once written consent has been obtained the participant a short background information questionnaire (for demographic data) will be completed with the participant before commencing the interview.

7.5 Interviews

Interview topic guide (Appendix 11) have been prepared prior to the semi-structured interviews to guide data collection and to guide and focus discussion, however the interviews are flexible and participants will be able to discuss any relevant issues and to reflect. All interviews will be audio-recorded and transcribed verbatim. In addition, hand-written notes will be taken during each interview to record any important observations and after the interviews to record any additional statements as well as the researcher's reflection of the interview. Each interview participant will be allocated an identification code, which will be used on all documentation (including background questionnaire) and transcripts relating to an individual participant. We will keep anonymised transcripts/handwritten notes taken during interviews. Original audio recordings will be destroyed.

8.0 Sample size

The sample size will not be informed by a formal statistical power calculation. Purposive sampling will be used to seek information-rich cases which capture core themes and are representative of the general population. The sample size will be up to 15 people with SMI, up to 15 informal carers, up to 15 care professionals and up to 15 pharmacy professionals. A provisional anticipated upper sample size that might potentially generate adequate data that would provide rich, complex, and multifaceted data about patternings related to the phenomena of interest was estimated. The exact number will be determined by the point of data saturation when it appears that no new substantive themes are identified in the data. The sample size will not be informed by a formal statistical power calculation.

9.0 Data analysis

A table summarising the demographic (and in the case of patients, clinical) data (using unique patient identification numbers) will be produced to provide an overview of the population of each group studied. A qualitative framework analysis will be undertaken to explore the experiences and perspectives of the participants using an open-coding method (65, 66, 67). Framework analysis is a tool that has no allegiance to either inductive or deductive thematic analysis; this research will be both deductive and inductive (68). Each transcript will be read and coded separately using NVivo® software if considered appropriate. Common themes will be merged to create categories, enabling analysis of data

to reflect recurring and representative themes (38). Validity will be increased by actively seeking deviant cases and outliers (65). The analysis of the different strands of qualitative data will be informed by an ongoing review of the literature (69). However, where appropriate the data analysis and interpretation will be informed by wider relevant literatures, for example theories relevant to preventative healthcare use. Data analysis will therefore be exploratory and will include substantial Third sector and PPI consultation to enrich the discussion with my supervisory team.

10.0 Research Governance

The study will be conducted to protect the human rights and dignity of the participant as reflected in the 1996 version of the Helsinki Declaration.

Reasonable out of pocket and travel expenses associated with participating in the research (e.g., attending an interview) will be reimbursed for patients and carers and participants will also be offered a £10 gift voucher as a sign of appreciation for participation in the interview (this will be offered in all cases for patients and carers but only for care professionals or pharmacy professionals if they participate in their own time not in their work time). This is line with INVOLVE guidance.

11.0 Study sponsorship

Aston University will act as sponsor for the CARDIOPHITNESS Study.

12.0 Ethical issues and approval

Ethical approval will be obtained from the HRA.

13.0 Data storage and confidentiality

Interviews will be recorded using an encrypted digital recorder. All data will be stored in accordance with data protection requirements. Printed copies and consent-related documents will be stored in a site file, which will be kept in a locked filing cabinet within the LPT NHS Trust. All electronic data will be stored on password protected NHS computers and laptop and backed up on a secure NHS server. Only the lead researcher will have access to the data. (A study master file will be kept at Aston University - however, this will not contain any patient identifiable information).

Consent will be undertaken immediately prior to the interviews being conducted. As such in all cases this will be done by the lead researcher who will be carrying out the interviews. Once the interview has been completed the consent forms will be taken to the pharmacy department within LPT NHS Trust and stored in locked filing cabinets.

A summary of the findings of the research will be available on completion of the study on the following webpage. This will not contain any identifiable information.

http://www.leicspart.nhs.uk/_InvolvingYou-CardioPhitnessResearchStudy.aspx

14.0 Informing participants of anticipated risks and benefits.

All participants will be sent a participant information sheet, which will inform them about the potential benefits and risks of taking part.

Chief Investigator signature:  .

Date: 26.06.2019

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CARDIOPHITNESS study poster v 1.4
26.06.2019. IRAS project ID 233121

Aston University
Birmingham

NHS
Leicestershire Partnership
NHS Trust

Research participants needed

Are you interested in physical health in mental health?

- ✓ **Do you have a severe mental illness (schizophrenia, schizoaffective disorder, bipolar affective disorder, or any other form of non-organic psychosis) or are you a carer or care professional or pharmacy professional providing care for someone with a severe mental illness?**
- ✓ **Would you like to share your views and opinions on physical activity, smoking, nutrition, heart disease, diabetes, obesity/overweight and what pharmacy/pharmacists can do to help?**

Then we would really like to hear from you.

For more information please contact Dolly Sud.

sudd@aston.ac.uk

CARDIOPHITNESS: **Cardio**metabolic health and **Ph**armac**i**s**t**s in Severe Mental Ill**ness** study

CARDIOPHITNESS STUDY sudd@aston.ac.uk or call 0116 295 8989 option 2 then option 3 quoting CARDIOPHITNESS study.

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Introductory email to care professionals and pharmacy professionals.

IRAS project ID 23312 v1.3 09/11/2018

Subject: CARDIOPHITNESS study

Dear colleague,

CARDIOPHITNESS: Cardiometabolic health and Pharmacists in Severe Mental Illness.

I am emailing on behalf of PhD student in the School of Life & Health Sciences at Aston University, Dolly Sud. Dolly's supervisors are Dr Ian Maidment, Senior Lecturer in Clinical Pharmacy, Aston University and Professor Eleanor Bradley, Professor of Health Psychology, University of Worcester.

Dolly is conducting a research study exploring the role of pharmacy and pharmacists in supporting cardiometabolic risk factor reduction and management/prevention of metabolic syndrome, diabetes, heart disease and related disease in individuals with severe mental illness (SMI) (schizophrenia, bipolar affective disorder, schizoaffective disorder, and other non-organic psychoses). As part of the study, Dolly is undertaking semi-structured interviews with care professionals and pharmacy professionals involved in the care of those with SMI. Dolly has obtained NHS ethics, REC, HRA and Aston University (sponsor) approvals to do this.

Dolly looking to recruit care professionals and pharmacy professionals with any level of experience, looking after individuals with SMI who have had any support from pharmacy. Do you meet this criteria? Please see the attached poster which provides further information about the study as well as contact details.

Dolly looks forward to hearing from you. If you have other colleagues that may be interested, please also let them know.

Thank you.

Kind regards

Pharmacy Manager
(Leicestershire Partnership NHS Trust)

Contact details of the lead researcher/PhD student:
Dolly Sud.
Researcher
sudd@aston.ac.uk

Appendix 10: Letters of invitation and Participant Information Sheets

CARDIOPHITNESS Letter of invitation to patient – IRAS project ID 233121

Letter of invitation to patient_v 1.3 _09/11/2018

Dolly Sud.
Lead Researcher CARDIOPHITNESS study,
c/o Pharmacy Department Leicestershire Partnership NHS Trust,
Bradgate Mental Health Site,
Glenfield Hospital,
Groby Road,
Leicester,
Leicestershire. LE3 9EJ.

Telephone: 0116 295 8989 option 2 option 3 (please quote CARDIOPHITNESS study)
Email: sudd@aston.ac.uk

Dear patient,

Invitation to take part in a research study.

CARDIOPHITNESS: **Cardio**metabolic health and **Ph**armac**ist**s in Severe Mental Ill**ness.**

I am PhD student at Aston University, I am writing to invite you to take part in a research project that is aimed at exploring the role of pharmacy in physical healthcare in individuals with severe mental illness. People with severe mental illness (including schizophrenia, bipolar affective disorder, and schizoaffective disorder) have a higher risk of physical health problems, such as heart disease and stroke (cardiovascular disease) and diabetes.

Treatment and prevention of these would include, for example, managing diabetes effectively, cutting down or stopping smoking, increasing physical activity, and improving diet and nutrition. Pharmacy and pharmacists already provide support for this by supplying medication and helping you get the best out of those medications.

I have included an information sheet which will provide you with further details of the study, and what will be required of you if you decide to take part.

Please note that this letter and information sheet have been sent to you by a member of your healthcare team on behalf of the research team. The research team do not have access to any of your health records or contact details.

If you have any questions, or need more information about the study, please do not hesitate to contact me. Thank you.

Yours sincerely

Dolly Sud.
Researcher.

Aston University Birmingham

NHS Leicestershire Partnership NHS Trust

Participant Information Sheet – Patients

Study Title:

CARDIOPHITNESS: **Cardio**metabolic health and **Ph**armac**ist**s in Severe Mental Ill**ness**

This information sheet will help you to understand why this research is being done and what is involved. Please take time to read it carefully and discuss with others if you wish. We will be happy to go through this information with you and answer any questions.

Why is this research study important?

People with severe mental illness have a higher risk of physical health problems, such as heart disease and stroke (cardiovascular disease) and diabetes when compared to the general population. These physical health problems often go undetected and untreated. The views and experiences of patients on the care received for these physical health problems has not been well understood, this research aims to remedy this.

What is the purpose of this study?

This research study is part of a postgraduate research project (PhD). The purposes of this study are to explore and understand the views and experiences of patients, their informal carers and care professionals and pharmacy professionals on:

- Physical health in severe mental illness in particular heart disease, diabetes, and related diseases
- How pharmacy and pharmacists might support care for these diseases
- What patients do to help themselves for these diseases

Why have I been invited?

We have invited you to take part in this study because you are an adult over the age of 18 and have a severe mental illness such as schizophrenia, bipolar affective disorder, schizoaffective disorder, or other type of psychosis

- and you have a cardiometabolic risk factor and/or metabolic syndrome (such as smoking, diabetes, heart disease, being overweight)
- and you have had support from pharmacy.

Do I have to take part?

No. It is up to you to decide whether you wish to take part. You are under no obligation to participate in any research. If you decide not to take part, it will not affect the rest of your care.

If you do decide to participate, you will be asked to sign and date a consent form. You would still be free to withdraw from the study at any time without giving a reason.

What will happen if I decide to take part?

You will be invited to discuss your physical health and your views on pharmacy. Before the interview begins you will be asked to provide some background information about yourself e.g., gender, medication. The interview will be held at a convenient location and time agreed with you and should not last for more than an hour. The interview will be audio recorded. All information and data collected from you will be held in such a way that you cannot be identified (i.e., it will be anonymous).

What are the possible benefits of taking part?

The results will be used by the research team to improve health services for people with severe mental illness.

What are the possible risks of taking part?

You may feel that some of the questions we ask about your personal health or medication are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately. If necessary, you can get help and support from your care coordinator or lead clinician.

Are there any expenses or payments involved?

You will not receive a payment for taking part in the study. We will reimburse any reasonable out of pocket expenses associated with taking part in this study. As a thank you for taking part, we will also offer you a £10 gift voucher.

What if I change my mind during the study?

If you do take part and then decide to stop, you are free to withdraw from the study at any time without giving a reason by contacting the lead researcher Dolly Sud. You do not have to give a reason if you change your mind about taking part. You will be withdrawn from the study and this will not affect your usual treatment or care in anyway. It is not necessary but may be helpful for future study design if you could give the reason for withdrawal.

You can also withdraw any part or all your data at any point, up to 2 weeks after completion of your interview by contacting the lead researcher Dolly Sud.

Will my taking part in the study be kept confidential?

Yes. A code will be attached to all the data you provide to maintain confidentiality.

Your personal data (name and contact details) will only be used if the researchers need to contact you to arrange study visits or collect data by phone. Analysis of your data will be undertaken using coded data.

The data we collect will be stored in a secure document store (paper records) or electronically on a secure encrypted mobile device, password protected computer server or secure cloud storage device.

To ensure the quality of the research the study Sponsor and the NHS Organisation supporting the study may need to access your data to check that the data has been recorded accurately. If this is required your personal data will be treated as confidential by the individuals accessing your data.

If during the study you tell the research team something that causes them to have concerns in relation to your health and/or welfare then may need to breach your confidentiality. The researcher has a duty of care to report to the relevant authorities possible harm/danger to yourself or others.

What will you do with my information from the study?

We will use the information you provide to understand more about the experience of physical health (specifically heart disease, obesity/overweight, diabetes, smoking and related diseases – collectively these are known as cardiometabolic risk factors and metabolic syndrome) in severe mental illness, as well as the care and support that pharmacy/pharmacists can provide for these individuals. We will keep identifiable information about you for two weeks after the interview. You will have until the point at which your data is anonymised two weeks after the interview to withdraw all or any of the information provided or discussed in the interview. Two weeks after the interview all your information will be anonymised so you cannot be identified. Your name will not appear on materials resulting from the study.

The findings from this research study will be used as part of the write up for the PhD and presented at appropriate conferences. We will write about the study in publications read by researchers and care providers as well as patients and their informal carers. We will also produce a summary of the findings to share with others, including our participants. The findings may also be used to help inform policy and/or further research.

A summary of the findings of the research will be available on completion of the study on the following webpage. This will not contain any identifiable information.

http://www.leicspart.nhs.uk/_InvolvingYou-CardioPhitnessResearchStudy.aspx

Who is organising this study and acting as data controller for this study?

Aston University is the sponsor for this study based in the United Kingdom. We will be using information from you (provided during the interview) to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at www.aston.ac.uk/dataprotection or by contacting our Data Protection Officer at dp_officer@aston.ac.uk

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

Our Data Protection Officer is Victoria Mee and you can contact her at: dp_officer@aston.ac.uk
Leicestershire Partnership NHS Trust will collect information from you for this research study in accordance with our instructions.

Leicestershire Partnership NHS Trust will keep your name and contact details confidential and will not pass this information to Aston University. Leicestershire Partnership NHS Trust will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study.

Certain individuals from Aston University and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Aston University will only receive information that has been anonymised. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

Leicestershire Partnership NHS Trust will only keep anonymised information about this study for 6 years after the study has finished.

Who has reviewed the study?

All research involving NHS patients is reviewed by an independent group of people, called a Research Ethics Committee. This study was given a favourable ethical opinion by the West Midlands – Coventry & Warwickshire Research Ethics Committee.

What if I have a concern about the study?

If you have any concerns about anything to do with this study, please speak to the research team and we will do our best to answer your questions. Contact details can be found at the end of this information sheet.

If the research team are unable to address your concerns or you wish to make a complaint about how it is being conducted then you should contact the Aston University Director of Governance, Mr John Walter, at j.g.walter@aston.ac.uk or telephone 0121 204 4869.

You may also wish to speak to someone independent to the research by contacting the LPT Complaints Team; Tel: 0116 295 0831 email: complaints@leicspart.nhs.uk

If I want to take part or would like any further information, what do I do next?

Should you have any further questions about this study or wish to take part then please contact the lead researcher, Dolly Sud. Email: sudd@aston.ac.uk or call 0116 295 8989 then select option 2 then option 3 quoting CARDIOPHITNESS study.

The supervisor for the PhD is Dr Ian Maidment. Email: i.maidment@aston.ac.uk or on 0121 204 3002

Thank you for taking time to read this information sheet. If you have any questions regarding the study, please do not hesitate to ask one of the research team.

Dolly Sud
Researcher

CARDIOPHITNESS Letter of invitation to informal carer. IRAS project ID 233121

Letter of invitation to informal carer_v 1.3 09/11/2018

Dolly Sud.
Lead Researcher CARDIOPHITNESS study,
c/o Pharmacy Department Leicestershire Partnership NHS Trust,
Bradgate Mental Health Site,
Glenfield Hospital,
Groby Road,
Leicester,
Leicestershire. LE3 9EJ.

Telephone: 0116 295 8989 option 2 option 3 (please quote CARDIOPHITNESS study)
Email: sudd@aston.ac.uk

Dear carer,

Invitation to take part in a research study.

CARDIOPHITNESS: **Cardio**metabolic health and **Ph**armac**ist**s in Severe Mental Ill**ness.**

I am PhD student at Aston University, I am writing to invite you to take part in a research project that is aimed at exploring the role of pharmacy in physical healthcare in individuals with severe mental illness. We are inviting you as you are someone who takes care of someone who has severe mental illness (this includes schizophrenia, schizoaffective disorder, bipolar affective disorder, or other type of psychosis). People with severe mental illness have a higher risk of physical health problems, such as heart disease and stroke (cardiovascular disease) and diabetes.

Treatment and prevention of these would include, for example, managing diabetes effectively, cutting down or stopping smoking, increasing physical activity, and optimising diet and nutrition. Pharmacy and pharmacists already provide support for this by supplying medication and helping you get the best out of those medications.

I have included an information sheet which will provide you with further details of the study, and what will be required of you if you decide to take part.

Please note that the research team do not have access to any of your health records or contact details. The person you care for has agreed to provide this letter and information sheet to you on behalf of the research team.

If you have any questions, or need more information about the study, please do not hesitate to contact me. Thank you.

Yours sincerely

Dolly Sud
Researcher

Participant Information Sheet – informal carers

Study Title:

CARDIOPHITNESS: **Cardio**metabolic health and **Ph**armac**ist**s in Severe Mental Ill**ness**

This information sheet will help you to understand why this research is being done and what is involved. Please take time to read it carefully and discuss with others if you wish. We will be happy to go through this information with you and answer any questions.

Why is the research study important?

People with severe mental illness have a higher risk of physical health problems, such as heart disease and stroke (cardiovascular disease) and diabetes when compared to the general population. These physical health problems often go undetected and untreated. The views and experiences of patients on the care received for these physical health problems has not been well understood, this research aims to remedy this.

What is the purpose of this study?

This research study is part of a postgraduate research project (PhD). The purposes of this study are to explore and understand the views and experiences of patients, their informal carers and care professionals and pharmacy professionals on:

- Their physical health in particular heart disease, diabetes, and related diseases
- How pharmacy and pharmacists might support care for these diseases
- What patients do to help themselves for these diseases

Why have I been invited?

We have invited you to take part in this study because you care for someone who has severe mental illness such as schizophrenia, bipolar affective disorder, schizoaffective disorder, or other type of psychosis

- and they have a cardiometabolic risk factor and/or metabolic syndrome (such as smoking, diabetes, heart disease, being overweight)
- and they have had support from pharmacy

.

Do I have to take part?

No. It is up to you to decide whether you wish to take part.

If you do decide to participate, you will be asked to sign and date a consent form. You would still be free to withdraw from the study at any time without giving a reason.

What will happen if I decide to take part?

You will be invited to discuss your physical health and your views on pharmacy interview will be held at a convenient location and time agreed with you and should not last for more than an hour. Before the interview begins you will be asked to provide some background information about yourself e.g., gender. All information and data collected from you will be held in such a way that you cannot be identified (i.e., it will be anonymous).

What are the possible benefits of taking part?

The results will be used by the research team to improve health services for people with severe mental illness.

What are the possible risks of taking part?

You may feel that some of the questions we ask about the personal health or medication for the person you care for are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately.

Are there any expenses or payments involved?

You will not receive a payment for taking part in the study. We will reimburse any reasonable out of pocket expenses associated with taking part in this study. As a thank you for taking part, we will also offer you a £10 gift voucher.

What if I change my mind during the study?

If you do take part and then decide to stop, you are free to withdraw from the study at any time without giving a reason by contacting the lead researcher Dolly Sud. You do not have to give a reason if you change your mind about taking part. You will be withdrawn from the study and this will not affect your usual treatment or care in anyway. It is not necessary but may be helpful for future study design if you could give the reason for withdrawal.

You can also withdraw any part or all your data at any point, up to 2 weeks after completion of your interview by contacting the lead researcher Dolly Sud.

Will my taking part in the study be kept confidential?

Yes. A code will be attached to all the data you provide to maintain confidentiality.

Your personal data (name and contact details) will only be used if the researchers need to contact you to arrange study visits or collect data by phone. Analysis of your data will be undertaken using coded data.

The data we collect will be stored in a secure document store (paper records) or electronically on a secure encrypted mobile device, password protected computer server or secure cloud storage device.

To ensure the quality of the research the study Sponsor and the NHS Organisation supporting the study may need to access your data to check that the data has been recorded accurately. If this is required your personal data will be treated as confidential by the individuals accessing your data.

If during the study you tell the research team something that causes them to have concerns in relation to your health and/or welfare then may need to breach your confidentiality. The researcher has a duty of care to report to the relevant authorities possible harm/danger to yourself or others.

What will you do with my information from the study?

We will use the information you provide to understand more about the experience of physical health (specifically heart disease, obesity/overweight, diabetes, smoking and related diseases – collectively these are known as cardiometabolic risk factors and metabolic syndrome) in severe mental illness, as well as the care and support that pharmacy/pharmacists can provide for these individuals. We will keep identifiable information about you for two weeks after the interview. You will have until the point at which your data is anonymised two weeks after the interview to withdraw all or any of the information provided or discussed in the interview. Two weeks after the interview all your information will be anonymised so you cannot be identified. Your name will not appear on materials resulting from the study.

The findings from this research study will be used as part of the write up for the PhD and presented at appropriate conferences. We will write about the study in publications read by researchers and care providers as well as patients and informal carers. We will also produce a summary of the findings to share with others, including our participants. The findings may also be used to help inform policy and/or further research.

A summary of the findings of the research will be available on completion of the study on the following webpage. This will not contain any identifiable information.

http://www.leicspart.nhs.uk/_InvolvingYou-CardioPhitnessResearchStudy.aspx

Who is organising this study and acting as data controller for this study?

Aston University is the sponsor for this study based in the United Kingdom. We will be using information from you (provided during the interview) to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at www.aston.ac.uk/dataprotection or by contacting our Data Protection Officer at dp_officer@aston.ac.uk.

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

Our Data Protection Officer is Victoria Mee and you can contact her at: dp_officer@aston.ac.uk. .

Leicestershire Partnership NHS Trust will collect information from you for this research study in accordance with our instructions.

Leicestershire Partnership NHS Trust will keep your name and contact details confidential and will not pass this information to Aston University. Leicestershire Partnership NHS Trust will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from Aston University and regulatory organisations may look at your research records to check the accuracy of the research study. Aston University will only receive information that has been anonymised. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

Leicestershire Partnership NHS Trust will only keep anonymised information about this study for 6 years after the study has finished.

Who has reviewed the study?

All research involving NHS patients is reviewed by an independent group of people, called a Research Ethics Committee. This study was given a favourable ethical opinion by the West Midlands – Coventry & Warwickshire Research Ethics Committee.

What if I have a concern about the study?

If you have any concerns about anything to do with this study, please speak to the research team and we will do our best to answer your questions. Contact details can be found at the end of this information sheet.

If the research team are unable to address your concerns or you wish to make a complaint about how it is being conducted then you should contact the Aston University Director of Governance, Mr John Walter, at j.g.walter@aston.ac.uk or telephone 0121 204 4869.

You may also wish to speak to someone independent to the research by contacting the LPT Complaints Team; Tel: 0116 295 0831 email: complaints@leicspart.nhs.uk

If I want to take part or would like any further information, what do I do next?

Should you have any further questions about this study or wish to take part then please contact the researcher, Dolly Sud; sudd@aston.ac.uk

The supervisor for the PhD is Dr Ian Maidment. Email: i.maidment@aston.ac.uk, or on 0121 204 3002

Thank you for taking time to read this information sheet. If you have any questions regarding the study, please do not hesitate to ask one of the research team.

Dolly Sud
Researcher

CARDIOPHITNESS Letter of invitation to care professionals and pharmacy professionals.
IRAS project ID 233121

Letter of invitation to care professional_v1.2 14/07/2018.

Dolly Sud.
Lead Researcher CARDIOPHITNESS study,
c/o Pharmacy Department Leicestershire Partnership NHS Trust,
Bradgate Mental Health Site,
Glenfield Hospital,
Groby Road,
Leicester,
Leicestershire. LE3 9EJ.

Telephone: 0116 295 8989 option 2 option 3 (please quote CARDIOPHITNESS study)
Email: sudd@aston.ac.uk

Dear colleague,

Invitation to take part in a research study.

CARDIOPHITNESS: **Cardio**metabolic health and **Ph**armac**ist**s in Severe Mental Ill**ness.**

I am PhD student at Aston University, I am writing to invite you to take part in a research study that is aimed at exploring the role of pharmacy in the treatment and prevention of cardiometabolic disease, metabolic syndrome, and related diseases such as diabetes, heart disease and obesity/overweight in individuals with severe mental illness (i.e., schizophrenia, schizoaffective disorder, bipolar affective disorder, and other non-organic psychotic disorders).

You have been invited because you are a care professional or pharmacy professional involved in managing and supporting people with severe mental illness. Your views and opinions will be helpful in understanding how and what pharmacy can do in cardiometabolic risk and metabolic syndrome.

I have included an information sheet which will provide you with further details of the study, and what will be required of you if you decide to take part.

In the meantime, if you have any further enquiries, please do not hesitate to contact me. Thank you.

Yours sincerely

Dolly Sud.
Researcher.

Participant Information Sheet – Care Professionals and Pharmacy Professionals

Study Title:

CARDIOPHITNESS: **Cardio**metabolic health and **Ph**armac**ist**s in Severe Mental Ill**ness**

We would like you to invite you to take part in our research study. Before you decide, we would like you to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and discuss with others if you wish. We will be happy to go through the information sheet with you and answer any questions you have.

Why is the research study important?

The physical health of individuals with mental illness is important. In particular, the risk of heart disease, diabetes, and other heart related conditions in those with severe mental illness. The National Health Service (NHS) recognises that if healthcare professionals provide support for physical health for those with mental health conditions, then they will experience a better quality of life and better outcomes. Pharmacists and pharmacies provide valuable healthcare and play an important role for people with severe mental illness, such as supplying medication and undertaking medication reviews. However, the views of healthcare professionals on pharmacists and pharmacies providing this care have not been well understood, hence the necessity of this study.

What is the purpose of this study?

This research study is part of a postgraduate research project (PhD). The main purpose is to explore how pharmacy and pharmacists can help support people with severe mental illness take care of their physical health, in particular treatment, prevention, and management of metabolic syndrome and cardiometabolic risk factors. We will be undertaking semi structured interviews with patients, their informal carers and care professionals and pharmacy professionals about:

- Physical health in severe mental illness in particular heart disease, diabetes, and related diseases
- How pharmacy and pharmacists might support care for these diseases
- What patients do to help themselves for these diseases

Why have I been invited?

We have invited you to take part in this study because you are involved in managing and/or supporting people with severe mental illness who have a cardiometabolic risk factor and/or metabolic syndrome (such as smoking, diabetes, heart disease, being overweight) and have had support from pharmacy.

Do I have to take part?

No. It is up to you to decide whether you wish to take part.

If you do decide to participate, you will be asked to sign and date a consent form. You would still be free to withdraw from the study at any time without giving a reason.

What will happen if I decide to take part?

You will be invited to discuss how you support people with severe mental illness with regards cardiometabolic risk factors and metabolic syndrome as well as your view about support from pharmacy. Before the interview begins you will be asked to provide some background information about yourself e.g., gender. The interview will be held at a convenient location and time agreed with you and should not last for more than an hour. With your permission the interview will be audio recorded. All information and data collected from you will be held in such a way that you cannot be identified (i.e., it will be anonymous).

Are there any expenses or payments involved?

You will not receive a payment for taking part in the study. As a thank you for taking part, we will also offer you a £10 gift voucher if you take part in your own time. We will not offer you a £10 gift voucher if you take part during your work time.

What if I change my mind during the study?

If you do take part and then decide to stop, you are free to withdraw from the study at any time without giving a reason by contacting the lead researcher Dolly Sud. You do not have to give a reason if you change your mind about taking part. You will be withdrawn from the study and this will not affect your usual treatment or care in anyway. It is not necessary but may be helpful for future study design if you could give the reason for withdrawal.

You can also withdraw any part or all your data at any point, up to 2 weeks after completion of your interview by contacting the lead researcher Dolly Sud.

Will my taking part in the study be kept confidential?

Yes. A code will be attached to all the data you provide to maintain confidentiality.

Your personal data (name and contact details) will only be used if the researchers need to contact you to arrange study visits or collect data by phone. Analysis of your data will be undertaken using coded data.

The data we collect will be stored in a secure document store (paper records) or electronically on a secure encrypted mobile device, password protected computer server or secure cloud storage device.

To ensure the quality of the research the study Sponsor and the NHS Organisation supporting the study may need to access your data to check that the data has been recorded accurately. If this is required your personal data will be treated as confidential by the individuals accessing your data.

What will you do with my information from the study?

We will use the information you provide to understand more about the experience of physical health (specifically cardiometabolic risk factors and metabolic syndrome) in severe mental illness, as well as the care and support that pharmacy/pharmacists can provide for these individuals. We will keep identifiable information about you for two weeks after the interview. You will have until the point at

which your data is anonymised two weeks after the interview to withdraw all or any of the information provided or discussed in the interview. Two weeks after the interview all your information will be anonymised so you cannot be identified. Your name will not appear on materials resulting from the study.

The findings from this research study will be used as part of the write up for the PhD and presented at appropriate conferences. We will write about the study in publications read by researchers and care providers as well as patients and their informal carers. We will also produce a summary of the findings to share with others, including our participants. The findings may also be used to help inform policy and/or further research.

A summary of the findings of the research will be available on completion of the study on the following webpage. This will not contain any identifiable information.

http://www.leicspart.nhs.uk/_InvolvingYou-CardioPhitnessResearchStudy.aspx

Who is organising this study and acting as data controller for this study?

Aston University is the sponsor for this study based in the United Kingdom. We will be using information from you (provided during the interview) to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at www.aston.ac.uk/dataprotection or by contacting our Data Protection Officer at dp_officer@aston.ac.uk

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

Our Data Protection Officer is Victoria Mee and you can contact her at: dp_officer@aston.ac.uk. . Leicestershire Partnership NHS Trust will collect information from you for this research study in accordance with our instructions.

Leicestershire Partnership NHS Trust will keep your name and contact details confidential and will not pass this information to Aston University. Leicestershire Partnership NHS Trust will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study.

Certain individuals from Aston University and regulatory organisations may look at your research records to check the accuracy of the research study. Aston University will only receive information that has been anonymised. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

Leicestershire Partnership NHS Trust will only keep anonymised information about this study for 6 years after the study has finished.

Who has reviewed the study?

All research involving NHS patients is reviewed by an independent group of people, called a Research Ethics Committee. This study was given a favourable ethical opinion by the West Midlands – Coventry & Warwickshire Research Ethics Committee.

What if I have a concern about the study?

If you have any concerns about anything to do with this study, please speak to the research team and we will do our best to answer your questions. Contact details can be found at the end of this information sheet.

If the research team are unable to address your concerns or you wish to make a complaint about how it is being conducted then you should contact the Aston University Director of Governance, Mr John Walter, at j.g.walter@aston.ac.uk or telephone 0121 204 4869.

You may also wish to speak to someone independent to the research by contacting the LPT Complaints Team; Tel: 0116 295 0831 email: complaints@leicspart.nhs.uk

If I want to take part or would like any further information, what do I do next?

Should you have any further questions about this study or wish to take part then please contact the researcher, Dolly Sud. Email: sudd@aston.ac.uk or call 0116 295 8989 option 2 then option 3 quoting CARDIOPHITNESS study.

The supervisor for the PhD is Dr Ian Maidment. Email: i.maidment@aston.ac.uk or on 0121 204 3002

Thank you for taking time to read this information sheet. If you have any questions regarding the study, please do not hesitate to ask one of the research team.

Dolly Sud
Researcher

Appendix 11: Topic guides

CARDIOPHITNESS Patient interview topic guide. IRAS project ID 233121

Topic Guide for interview with patients – ORIGINAL

(1) Introduction to interview

- Thank you for participating
- Introduction of lead researcher and others involved in the research (Aston University and LPT NHS Trust)
- Overview of research and purpose.
- Approximate duration of the interview is 45-60 minutes
- Proposed structure of interview - interested in what is important to them; no right or wrong answers, it is their perspective that we are interested in
- Consent to participate and approval to audio record the interview
- Confidentiality, anonymity of interview data and right to withdraw at any time
- Collection of basic demographic data and clinical data using the form at the end of this topic guide

(2) **Questions**

- Introduction [Note: The aim here is to get an idea of the person behind the story. Focus on the "now" – their current life. Also, to ease the person into the interview. Ask prompting questions to suit the person].

  - Could you tell me a little about yourself – how would you describe yourself based on your current life? Prompts: – What do you do (as in work, keeping themselves occupied etc.)? – What are your interests and hobbies? – Family/community support and social networks
  - How is your health at the moment?

- What does health and well-being mean to you?
  (Idea of both physical health/wellbeing and mental health within this)

  - How would you describe your physical health/wellbeing at the moment?
  - Have you got any concerns about your physical health/wellbeing?
  - Tell me about the care you are getting for your physical health issue (use named example)
  - What things help your physical health? What things don't help your physical health?

- Role of the pharmacist or pharmacy
  (explore both community and hospital pharmacy/pharmacist)

  - How often to do you visit a pharmacy or speak to a member of the pharmacy team?
  - What are the main reasons for visiting the pharmacy/speaking to the pharmacist?
  - Does your pharmacy/pharmacist help you with your medicines?
  - Does your pharmacy/pharmacist support your physical health/wellbeing? Are any of these for health promotion or risk reduction (name example as appropriate e.g., diet, smoking cessation)?
  - Tell me about a time when the pharmacist has helped or given you advice about your physical health/wellbeing
  - What help or support would you like your pharmacist/pharmacy to provide?
  - What kind of relationship would you say you have with your pharmacist/pharmacy team?

- Potential barriers

  - What things get in the way of you developing/improving your physical health/wellbeing?
  - How do you think these might be overcome?
  - What do you think might get in the way of pharmacy/pharmacists supporting your physical health?
  - How do you think these might be overcome?

- Facilitators/enablers

  - What things help you to develop/improve your physical health/wellbeing?
  - How do they help you?
  - What would you like to make it easier to for you to do things for your physical health/wellbeing?
  - What would make it easier for you to get support from your pharmacy/pharmacist?
  - What would make it easier for pharmacies/pharmacist give you support for your physical health?

- Conclusions

  - Are there any other things you would like to add to these discussions?
  - Thanks for taking part in this research study and for your time.

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Please note that this document is for the Lead Researcher and their research team only and will not be given to participants.

CARDIOPHITNESS Patient interview topic guide. IRAS project ID 233121

Topic Guide for interview with patients – INCLUDES QUESTIONS AND COMMENTS THAT WERE ADDED DURING THE PROCESS OF GATHERING DATA AS PART OF THE ITERATIVE PROCESS

(3) Introduction to interview

- Thank you for participating
- Introduction of lead researcher and others involved in the research (Aston University and LPT NHS Trust)
- Overview of research and purpose.
- Approximate duration of the interview is 45-60 minutes
- Proposed structure of interview - interested in what is important to them; no right or wrong answers, it is their perspective that we are interested in
- Consent to participate and approval to audio record the interview
- Confidentiality, anonymity of interview data and right to withdraw at any time
- Collection of basic demographic data and clinical data using the form at the end of this topic guide

(4) **Questions**

- Introduction [Note: The aim here is to get an idea of the person behind the story. Focus on the "now" – their current life. Also, to ease the person into the interview. Ask prompting questions to suit the person.]

  - Could you tell me a little about yourself – how would you describe yourself based on your current life? Prompts: – What do you do (as in work, keeping themselves occupied etc.)? – What are your interests and hobbies? – Family/community support and social networks and groups
  - How is your health at the moment?

- What does health and well-being mean to you? And emotional well-being
  (Idea of both physical health/wellbeing and mental health within this)
  What does quality of life mean to you? Is it important to you?
  What do you see as the relationship/link between mental health and physical health?
  - How would you describe your physical health/wellbeing at the moment?
  - Have you got any concerns about your physical health/wellbeing?
  - Tell me about the care you are getting for your physical health issue (use named example). Quality and type of support if relevant and support with medication etc
  - What things help your physical health? What things don't help your physical health?
  - What has the impact of mental health medication or a change in mental health medication change been on your physical health, your quality of life, health, or well-being?
  - What information have you received about screening and management of your physical health in relation to your mental health medication?

- Role of the pharmacist or pharmacy
  (explore both community and hospital pharmacy/pharmacist)

  - How often to do you visit a pharmacy or speak to a member of the pharmacy team?
  - What are the main reasons for visiting the pharmacy/speaking to the pharmacist?
  - Does your pharmacy/pharmacist help you with your medicines?

- Does your pharmacy/pharmacist support your physical health/wellbeing? Are any of these for health promotion or risk reduction (name example as appropriate e.g., diet, smoking cessation)?
- Tell me about a time when the pharmacist has helped or given you advice about your physical health/wellbeing
- What help or support would you like your pharmacist/pharmacy to provide?
- What kind of relationship would you say you have with your pharmacist/pharmacy team?

- Potential barriers

  - What things get in the way of you developing/improving your physical health/wellbeing?
  - How do you think these might be overcome?
  - What do you think might get in the way of pharmacy/pharmacists supporting your physical health?
  - How do you think these might be overcome?

- Facilitators/enablers

  - What things help you to develop/improve your physical health/wellbeing?
  - How do they help you?
  - What would you like to make it easier to for you to do things for your physical health/wellbeing?
  - What would make it easier for you to get support from your pharmacy/pharmacist?
  - What would make it easier for pharmacies/pharmacist give you support for your physical health?

- Conclusions

  - Are there any other things you would like to add to these discussions?
  - Thanks for taking part in this research study and for your time.

_____

Please note that this document is for the Lead Researcher and their research team only and will not be given to participants.

CARDIOPHITNESS Informal carer interview topic guide. IRAS project ID 233121

Topic Guide for interview with informal carers – ORIGINAL

(5) Introduction to interview

- Thank you for participating
- Introduction of lead researcher and others involved in the research (Aston University and LPT NHS Trust)
- Overview of research and purpose.
- Approximate duration of the interview is 45-60 minutes
- Proposed structure of interview - interested in what is important to them; no right or wrong answers, it is their perspective that we are interested in
- Consent to participate and approval to audio record the interview
- Confidentiality, anonymity of interview data and right to withdraw at any time
- Collection of basic demographic data

(6) **Questions**

- Introduction [Note: The aim here is to get an idea of the person behind the story. Focus on the "now" – their current life. Ask prompting questions to suit the person.]

  - Could you tell me a little about yourself – Prompts: – What do you do (as in work, keeping themselves occupied etc.)? – What are your interests and hobbies? – Family and social networks?

- Considering the person you care for and the support you give them:
  (Idea of both physical health/wellbeing and mental health within this)

- How would you describe the physical health/wellbeing of the person you care for at the moment? Have you got any concerns about their physical health/wellbeing?
  - Tell me about the care they are getting for their physical health issue (used named example).
  - What things help the physical health of the person you care for? What things don't help?
- Role of the pharmacist or pharmacy
  (explore both community and hospital pharmacy/pharmacist in relation to the person they care for)

  - How often to do you visit a pharmacy or speak to a member of the pharmacy team?
  - What are the main reasons for visiting the pharmacy/speaking to the pharmacist?
  - Does the pharmacy/pharmacist help you with the medicines of the person you care for?
  - Does the pharmacy/pharmacist support their physical health/wellbeing? Are any of these for health promotion or risk reduction (name example as appropriate e.g., diet, smoking cessation)?
  - Tell me about a time when the pharmacist has helped or given you advice about the physical health/wellbeing of the person you care for
  - What help or support would you like the pharmacist/pharmacy to provide?
  - What kind of relationship would you say you have with your pharmacist/pharmacy team?

- Potential barriers

  - What things get in the way of the person you care for developing/improving their physical health/wellbeing?
  - How do you think these might be overcome?
  - What do you think might get in the way of pharmacy/pharmacists supporting the physical health of the person you care for?
  - How do you think these might be overcome?

- Facilitators/enablers

  - What things help develop/improve the physical health/wellbeing of the person you care for?
  - How do they help?
  - What would you like to make it easier for the person you care for to do things for their physical health/wellbeing?
  - What would make it easier for the person you care for get support from the pharmacy/pharmacist?
  - What would make it easier for pharmacies/pharmacist give the person you care for support for their physical health?

- Conclusions

  - Are there any other things you would like to add to these discussions?
  - Thanks for taking part in this research study and for your time.

_____

Please note that this document is for the Lead Researcher their research team only and will not be given to participants.

CARDIOPHITNESS Informal carer interview topic guide. IRAS project ID 233121

Topic Guide for interview with informal carers – INCLUDES QUESTIONS AND COMMENTS THAT WERE ADDED DURING THE PROCESS OF GATHERING DATA AS PART OF THE ITERATIVE PROCESS

(7) Introduction to interview

- Thank you for participating
- Introduction of lead researcher and others involved in the research (Aston University and LPT NHS Trust)
- Overview of research and purpose.
- Approximate duration of the interview is 45-60 minutes
- Proposed structure of interview - interested in what is important to them; no right or wrong answers, it is their perspective that we are interested in
- Consent to participate and approval to audio record the interview
- Confidentiality, anonymity of interview data and right to withdraw at any time
- Collection of basic demographic data

(8) **Questions**

- Introduction [Note: The aim here is to get an idea of the person behind the story. Focus on the "now" – their current life. Ask prompting questions to suit the person.]

  - Could you tell me a little about yourself – Prompts: – What do you do (as in work, keeping themselves occupied etc.)? – What are your interests and hobbies? – Family and social networks and groups?

- Considering the person you care for and the support you give them:
  (Idea of both physical health/wellbeing and mental health within this)

- How would you describe the physical health/wellbeing of the person you care for at the moment? And emotional well-being?
  - what do you see as the link between physical health and mental health? What does quality of life mean to you? In what way do you think it is important to the person you provide care for ?
  - Have you got any concerns about their physical health/wellbeing?
  - Tell me about the care they are getting for their physical health issue (used named example) Quality and type of support if relevant and support with medication etc.
  - What things help the physical health of the person you care for? What things don't help?
  - What has the impact of mental health medication or a change in mental health medication change been on the physical health, your quality of life, health, or well-being of the person you care for?
  - What information have you/they received about screening and management of your physical health in relation to your mental health medication? Are you aware of any regular physical health checks/appointments needed/attended?
  - How do you manage any physical health side-effects such as weight gain or diabetes (as relevant) for the person you care for? How does it impact your life/everyday life?

- Role of the pharmacist or pharmacy
  (explore both community and hospital pharmacy/pharmacist in relation to the person they care for)

  - How often to do you visit a pharmacy or speak to a member of the pharmacy team?

- Do you know how often does the person you care for visits a/their pharmacy or speak to a member of the pharmacy team?
- What are the main reasons for visiting the pharmacy/speaking to the pharmacist?
- Does the pharmacy/pharmacist help you with the medicines of the person you care for?
- Does the pharmacy/pharmacist support their physical health/wellbeing? Are any of these for health promotion or risk reduction (name example as appropriate e.g., diet, smoking cessation)?
- Tell me about a time when the pharmacist has helped or given you advice about the physical health/wellbeing of the person you care for
- What help or support would you like the pharmacist/pharmacy to provide?
- What kind of relationship would you say you have with your pharmacist/pharmacy team?
- If they say they don't go to the pharmacy at all ask – would you consider going to the pharmacy to ask for information or advice about medication the person you care for is taking/psychotropic medication?

- Potential barriers

  - What things get in the way of the person you care for developing/improving their physical health/wellbeing?
  - How do you think these might be overcome?
  - What do you think might get in the way of pharmacy/pharmacists supporting the physical health of the person you care for?
  - How do you think these might be overcome?

- Facilitators/enablers

  - What things help develop/improve the physical health/wellbeing of the person you care for?
  - How do they help?
  - What would you like to make it easier for the person you care for to do things for their physical health/wellbeing?
  - What would make it easier for the person you care for get support from the pharmacy/pharmacist?
  - What would make it easier for pharmacies/pharmacist give the person you care for support for their physical health?

- Conclusions

  - Are there any other things you would like to add to these discussions?
  - Thanks for taking part in this research study and for your time.

Please note that this document is for the Lead Researcher their research team only and will not be given to participants.

CARDIOPHITNESS Care professional and pharmacy professionals interview topic guide. IRAS project ID 233121

Topic Guide for interview with care professionals_ v 1.2 30/05/2018

Topic Guide for interview with care professionals/pharmacy professionals - ORIGINAL

(1) Introduction to interview

- Thank you for participating
- Introduction of lead researcher and others involved in the research (Aston University and LPT NHS Trust)
- Overview of research and purpose. Approximate duration of the interview is 45 - 60 minutes
- Proposed structure of interview - interested in what is important to them; no right or wrong answers, it is their perspective that we are interested in
- Verbal consent to participate and approval to audio record the interview
- Confidentiality, anonymity of interview data and right to withdraw at any time
- Collection of basic demographic data using the form at the end of this topic guide

(2) Questions

Broad question area	Specific questions/probes	Rationale
Background: Working within their setting.	**Can you tell me about your education and years of experience in your profession? (Brief overview)** - Years of practice - Types/area of practice - Duration of time spent/level of involvement working with individuals who have SMI - Postgraduate education and other training - Other (as relevant)	*To gain an insight into the professional background of the care professional or pharmacy professional*
Background: Experience with managing physical health of people with severe mental illness	**What physical health illnesses, do you encounter most often in patients with severe mental illness?** - Will include discussion around single and multiple morbidities - Average amount of time spent managing them **How do you support/manage physical health in your patients with SMI?** - Types of approaches taken to manage - Who else is involved in their care? - Continuity of care between healthcare settings	*These questions aim to obtain an understanding of current practices of managing and supporting cardiometabolic risk/metabolic syndrome of people with severe mental illness*
Knowledge and understanding of the care of cardiometabolic risk factors and metabolic syndrome for those with SMI	**Cardiometabolic risk represents the overall risk of developing type-2 diabetes and/or cardiovascular disease.** **Metabolic syndrome is a cluster of conditions — increased blood pressure, high blood sugar, excess body fat around the waist, and abnormal cholesterol or triglyceride levels.** **Individuals with SMI are at significantly elevated risk of both of these.(Explain these terms where needed depending on participant understanding).** **What do you see as the main elements for caring for cardiometabolic risk factors and metabolic syndrome for those with SMI?**	*This definition is aimed to provide an overview of cardiometabolic risk and metabolic syndrome*

	- What screening, interventions? - What resources are available? **How do you empower and/or encourage your patients to undertake and engage in screening and interventions?** - Can you provide an example - Who else is involved	
Confidence, willingness, barriers, and facilitators for pharmacy/pharmacists to undertake a role in the care for cardiometabolic risk factors and metabolic syndrome for those with SMI	**Views, opinions, and perceptions of pharmacy/pharmacists role in the care of cardiometabolic risk factors and metabolic syndrome in those with SMI** *Note for researcher conducting interview – bear in mind that professionals will have come from different backgrounds/practice in different settings e.g., community, hospital. Questions and explanations you give may need to be amended accordingly.* What are your thoughts on the view that pharmacists should or could have a role in providing cardiometabolic/metabolic risk assessment?	*The questions here aim to explore the general feeling of professional's attitudes and perceptions.*

(3) Conclusions

- Are there any other things you would like to add to these discussions?
- Thank you for your time.

_____

Please note that this document is for the Lead Researcher and their research team only and will not be given to participants.

CARDIOPHITNESS Care professional and pharmacy professional interview topic guide. IRAS project ID 233121

Topic Guide for interview with care professionals_ v 1.2 30/05/2018

Topic Guide for interview with care professionals and pharmacy professionals - INCLUDES QUESTIONS AND COMMENTS THAT WERE ADDED DURING THE PROCESS OF GATHERING DATA AS PART OF THE ITERATIVE PROCESS

(1) Introduction to interview

- Thank you for participating
- Introduction of lead researcher and others involved in the research (Aston University and LPT NHS Trust)
- Overview of research and purpose. Approximate duration of the interview is 45 - 60 minutes
- Proposed structure of interview - interested in what is important to them; no right or wrong answers, it is their perspective that we are interested in
- Verbal consent to participate and approval to audio record the interview
- Confidentiality, anonymity of interview data and right to withdraw at any time
- Collection of basic demographic data using the form at the end of this topic guide

(2) Questions

Broad question area	Specific questions/probes	Rationale
Background: Working within their setting.	**Can you tell me about your education and years of experience in your profession? (Brief overview)** - Years of practice - Types/area of practice - Duration of time spent/level of involvement working with individuals who have SMI - Postgraduate education and other training - Other (as relevant)	*To gain an insight into the professional background of the professional*
Background: Experience with managing physical health of people with severe mental illness	**What physical health diseases,** problems, risk factors **do you encounter most often in patients with severe mental illness?** - Will include discussion around single and multiple morbidities - Average amount of time spent managing them **How do you support/manage physical health in your patients with SMI?** - Types of approaches taken to manage - Who else is involved in their care? e.g., informal carers - Continuity of care between healthcare settings - motivation of patients and teams - referrals – discuss pathways and any challenges - do you think patients appreciate or understand the side-effects of medication on their CMR, MetS and related?	*These questions aim to obtain an understanding of current practices of managing and supporting cardiometabolic risk/metabolic syndrome of people with severe mental illness*
Knowledge and understanding of the care of cardiometabolic risk factors and metabolic syndrome for those with SMI	**Cardiometabolic risk represents the overall risk of developing type-2 diabetes and/or cardiovascular disease. Metabolic syndrome is a cluster of conditions — increased blood pressure, high blood sugar, excess body fat around the waist, and abnormal cholesterol or triglyceride levels. Individuals with SMI are at significantly elevated risk of both of these.(Explain these terms where needed depending on participant understanding).**	*This definition is aimed to provide an overview of cardiometabolic risk and metabolic syndrome*

	What do you see as the main elements for caring for cardiometabolic risk factors and metabolic syndrome for those with SMI? - What screening, interventions? - What resources are available? - information and support they provide including information leaflets and signposting **How do you empower and/or encourage your patients to undertake and engage in screening and interventions?** - Can you provide an example - Who else is involved	
Confidence, willingness, barriers, and facilitators for pharmacy/pharmacists to undertake a role in the care for cardiometabolic risk factors and metabolic syndrome for those with SMI	**Views, opinions, and perceptions of pharmacy/pharmacists role in the care of cardiometabolic risk factors and metabolic syndrome in those with SMI** *Note for researcher conducting interview – bear in mind that the professionals will have come from different backgrounds/practice in different settings e.g., community, hospital. Questions and explanations you give may need to be amended accordingly.* What are your thoughts on the view that pharmacists should or could have a role in providing cardiometabolic/metabolic risk assessment? Would you say your patients know what pharmacists do or what services pharmacy might be able to provide? What it your view on the notion that pharmacists are well positioned to provide cardiometabolic/metabolic risk assessment services for patients with severe mental illness in their sector of care e.g., primary care? What impact do you think that pharmacists providing cardiometabolic/metabolic syndrome risk assessment roles would have on patients with severe mental illness? What challenges (problems) do you think exist for pharmacists providing these services? (e.g., expense, time, space, equipment, quality assurance, negative reactions, lack of feedback)? How do you see these barriers being overcome? What could be done to encourage pharmacists to start specializing in some of these services? (Advertising, undergraduate training, further continuing education, remuneration, role-models-articles etc). What are yours and your staffs' needs for further training so your pharmacy can provide cardiometabolic/metabolic syndrome risk assessments service?	*The questions here aim to explore the general feeling of professional's attitudes and perceptions.* *This final question is for pharmacy professionals only.*

(3) Conclusions

- Are there any other things you would like to add to these discussions?
- Thank you for your time.

_____

Please note that this document is for the Lead Researcher and their research team only and will not be given to participants.

Appendix 12: Research Ethics Committee and Health Research Authority Approvals

West Midlands Coventry and Warwickshire Research Ethics Committee Approval (18th December 2018, REC reference: 17/EE/3057)

NHS
Health Research Authority

West Midlands - Coventry & Warwickshire Research Ethics Committee
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

18 December 2018

Dr Ian D Maidment
Senior Lecturer in Clinical Pharmacy
Aston University
Aston Triangle
Birmingham
B4 7ET

Dear Dr Maidment

Study title:	**Exploring the role of pharmacy and pharmacists in management of cardiometabolic risk factors and metabolic syndrome in severe mental illness.**
REC reference:	**18/WM/0291**
Protocol number:	**258-2018-DS**
IRAS project ID:	**233121**

Thank you for your letter of 19.11.2018, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact hra.studyregistration@nhs.net outlining the reasons for your request.

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, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System, at www.hra.nhs.uk or at 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 management permissions 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 publically 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 request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

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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).

Ethical review of research sites

NHS 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).

Non-NHS sites

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Appendix 12- GP practices_GP lead _MH team leader introductory letter v 1.2]	1.2	09 July 2018
Copies of advertisement materials for research participants [Appendix 13 - Introductory email care professionals v 1.3]	1.3	09 November 2018
Copies of advertisement materials for research participants [Appendix 14 - Poster v 1.3]	1.3	
Covering letter on headed paper [Response to ethics (REC) and HRA queries]		18 November 2018
Evidence of Sponsor Insurance or indemnity (non NHS Sponsors only) [Aston EL PL 2018-19]	1.0	02 July 2018
Interview schedules or topic guides for participants [Appendix 9 - Topic guide for interviews with patients v1.2]	1.2	30 May 2018
Interview schedules or topic guides for participants [Appendix 10 - Topic guide for interviews with care professionals v1.2]	1.2	30 May 2018
Interview schedules or topic guides for participants [Appendix 11 - Topic guide for interviews with informal carers v1.2]	1.2	30 May 2018
IRAS Application Form [IRAS_Form_30082018]		30 August 2018
Letter from sponsor [233121-AstonU-Sponsorship-Provisional-Sud-13082018 (1)]	1.0	13 August 2018
Letters of invitation to participant [Appendix 4 - Letter of invitation to care professionals - v1.2]	1.2	14 July 2018
Letters of invitation to participant [Appendix 7 - Letter of invitation to informal carers v 1.3]	1.3	09 November 2018
Letters of invitation to participant [Appendix 1 - Letter of invitation to patients v 1.3]	1.3	09 November 2018
Participant consent form [Appendix 3 - Participant consent form_patient_informal_carer - v 1.3]	1.3	09 November 2018
Participant consent form [Appendix 6 - Participant consent form_care_professionals v 1.3]	1.3	09 November 2018
Participant information sheet (PIS) [Appendix 2 - Participant information sheet - patient v 1.3]	1.3	09 November 2018
Participant information sheet (PIS) [Appendix 5 - Participant information sheet - care professionals v 1.3]	1.3	09 November 2018

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Participant information sheet (PIS) [Appendix 8 - Participant information sheet - informal carers v 1.3]	1.3	09 November 2018
Research protocol or project proposal [CARDIOPHITNESS study protocol v 1.4_09.11.201]	1.4	09 November 2018
Summary CV for Chief Investigator (CI) [Ian Maidment CV - NRES v1.0]	1.0	22 March 2017
Summary CV for student [Dolly Sud CV- NRES v1.0]	1.0	22 April 2018
Summary CV for supervisor (student research) [Ian Maidment CV - NRES v1.0]	1.0	22 March 2017
Summary CV for supervisor (student research) [Eleanor Bradley CV - NRES v1.0]	1.0	25 June 2018

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 HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at
http://www.hra.nhs.uk/hra-training/

18/WM/0291	Please quote this number on all correspondence

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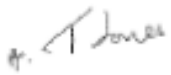
With the Committee's best wishes for the success of this project.

Yours sincerely



Dr Helen Brittain
Chair

Email:NRESCommittee.WestMidlands-CoventryandWarwick@nhs.net

Enclosures: "After ethical review – guidance for researchers" *[SL-AR2]*

Copy to: *Miss Dolly Sud*
Professsor Susan Corr, LPT NHS TRUST

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1231 **Health Research Authority Approval (18th December 2018, REC reference: 17/EE/3057)**

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Dr Ian D Maldment
Senior Lecturer in Clinical Pharmacy
Aston University
Aston Triangle
Birmingham
B4 7ET

Email: hra.approval@nhs.net
Research-permissions@wales.nhs.uk

18 December 2018

Dear Dr Maldment

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Exploring the role of pharmacy and pharmacists in management of cardiometabolic risk factors and metabolic syndrome in severe mental illness.**
IRAS project ID:	**233121**
Protocol number:	**258-2018-DS**
REC reference:	**18/WM/0291**
Sponsor	**Aston University**

I am pleased to confirm that HRA and Health and Care Research Wales (HCRW) Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

How should I continue to work with participating NHS organisations in England and Wales?
You should now provide a copy of this letter to all participating NHS organisations in England and Wales, as well as any documentation that has been updated as a result of the assessment.

Following the arranging of capacity and capability, participating NHS organisations should **formally confirm** their capacity and capability to undertake the study. How this will be confirmed is detailed in the "*summary of assessment*" section towards the end of this letter.

You should provide, if you have not already done so, detailed instructions to each organisation as to how you will notify them that research activities may commence at site following their confirmation of capacity and capability (e.g. provision by you of a 'green light' email, formal notification following a site initiation visit, activities may commence immediately following confirmation by participating organisation, etc.).

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IRAS project ID	233121

It is important that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details of the research management function for each organisation can be accessed here.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within the devolved administrations of Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) has been sent to the coordinating centre of each participating nation. You should work with the relevant national coordinating functions to ensure any nation specific checks are complete, and with each site so that they are able to give management permission for the study to begin.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?
The document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

I am a participating NHS organisation in England or Wales. What should I do once I receive this letter?
You should work with the applicant and sponsor to complete any outstanding arrangements so you are able to confirm capacity and capability in line with the information provided in this letter.

The sponsor contact for this application is as follows:

Name: Nichola Seare
Telephone: 01212043325
E-mail: n.seare@aston.ac.uk

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **233121**. Please quote this on all correspondence.

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IRAS project ID	233121

Yours sincerely

Sharon Northey
Senior Assessor

Email: hra.approval@nhs.net

Copy to: *Miss Dolly Sud - Student*
Professsor Susan Corr, LPT NHS TRUST – R&D contact
Nichola Seare – Sponsor contact

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Appendix 13: Research Ethics Committee and Health Research Authority Approvals for substantial amendments

West Midlands Coventry and Warwickshire Research Ethics Committee Approval for substantial amendment #1 (10th March 2019, REC reference: 17/EE/3057)

NHS
Health Research Authority

West Midlands - Coventry & Warwickshire Research Ethics Committee
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

10 March 2019

Miss Dolly Sud
Pharmacy Department
BRADGATE SITE, GROBY ROAD
Glenfield, Leicester, Leicestershire
LE3 9EJ

Dear Miss Sud

Study title:	Exploring the role of pharmacy and pharmacists in management of cardiometabolic risk factors and metabolic syndrome in severe mental illness.
REC reference:	18/WM/0291
Protocol number:	258-2018-DS
Amendment number:	1
Amendment date:	13 February 2019
IRAS project ID:	233121

The above amendment was reviewed 28 February 2019 by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Make it clear in the Participant Information Sheet that by not taking part would not have any effect on the participant's care.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Copies of advertisement materials for research participants [Appendix 14 - Poster v1.2.docx]	1.2	09 July 2018
Interview schedules or topic guides for participants [Appendix 9 -	1.3	30 December 2018

Topic guide for interviews with patients v1.3 _30.12.2018.docx]		
Interview schedules or topic guides for participants [Appendix 11 - Topic guide for interviews with informal carers v1.3 30.12.2018.docx]	1.3	30 December 2018
Notice of Substantial Amendment (non-CTIMP) [AmendmentForm_ReadyForSubmission_14.2.2019_233121.pdf]	1	13 February 2019
Participant information sheet (PIS) [Appendix 2 - Participant information sheet - patient - v 1.4 _09.02.2019.docx]	1.4	09 February 2019
Participant information sheet (PIS) [Appendix 5 - Participant information sheet - care professionals v 1.4_ 09.02.2019.docx]	1.4	09 February 2019
Participant information sheet (PIS) [Appendix 8 - Participant information sheet - informal carer v 1.4 09.02.2019.docx]	1.4	09 February 2019
Research protocol or project proposal [CARDIOPHITNESS study protocol v 1.5 30.01.2019.docx]	1.5	30 January 2019

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

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.

We are pleased to welcome researchers and R & D staff at our Research Ethics Committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

18/WM/0281: Please quote this number on all correspondence

Yours sincerely

P.P

Dr Helen Brittain
Chair

E-mail: NRESCommittee.WestMidlands-CoventryandWarwick@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Professsor Susan Corr, LPT NHS TRUST*
Miss Dolly Sud

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West Midlands - Coventry & Warwickshire Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 28 February 2019

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Helen Brittain (Chair)	Clinical Psychologist Retired	Yes	
Dr Karen Schofield	Retired Consultant Haematologist	Yes	

Name	*Profession*	*Present*	*Notes*
Teagan Allen	REC Assistant		

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West Midlands Coventry and Warwickshire Research Ethics Committee Approval for substantial amendment #2 (2nd August 2019, REC reference: 17/EE/3057)

A Research Ethics Committee established by the Health Research Authority

NHS
Health Research Authority

West Midlands - Coventry & Warwickshire Research Ethics Committee
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Tel: 02071048016

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

02 August 2019

Miss Dolly Sud
Pharmacy Department
BRADGATE SITE, GROBY ROAD
Glenfield, Leicester, Leicestershire
LE3 9EJ

Dear Miss Sud

Study title:	**Exploring the role of pharmacy and pharmacists in management of cardiometabolic risk factors and metabolic syndrome in severe mental illness.**
REC reference:	**18/WM/0291**
Protocol number:	**258-2018-DS**
Amendment number:	**2**
Amendment date:	**26 June 2019**
IRAS project ID:	**233121**

The above amendment was reviewed at the meeting of the Sub-Committee held on 26 July 2019 by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

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The Committee was content to approve this Amendment on the grounds that a carer has no legal confidentiality responsibilities and therefore the Committee stated that they can be recruited independently.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Copies of advertisement materials for research participants [Appendix 14 - Poster v 1.4 26.06.2019]	1.4	26 June 2019
Notice of Substantial Amendment (non-CTIMP) [Notice of amendment 26.6.2019]	2	26 June 2019
Research protocol or project proposal [CARDIOPHITNESS study protocol v 1.6 26.06.2019]	1.6	26 June 2019

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

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.

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: https://www.hra.nhs.uk/planning-and-improving-research/learning/

18/WM/0291:	**Please quote this number on all correspondence**

Yours sincerely

Chair

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Miss Dolly Sud*

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A Research Ethics Committee established by the Health Research Authority

Attendance at Sub-Committee of the REC meeting on 26 July 2019

Committee Members:

Name	Profession	Present	Notes
Mrs Louise Harmer	Senior Medical Education Manager	Yes	
Dr Ronald Jubb	Retired Consultant Rheumatologist	Yes	Chair

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Appendix 14: Aston University Aston Health Research and Innovation Cluster Ethics Approval

1st February 2019. Aston University Reference: 258-218-DS

Aston University
1st February 2019

Dr Ian Maidment
Research Student: Dolly Sud
School of Life and Health Sciences

Aston Triangle
Birmingham
B4 7ET
United Kingdom
Tel: +44 (0)121 204 5069
www.aston.ac.uk

Dear Dr Maidment,

Study title:	Exploring the role of pharmacy and pharmacists in management of cardiometabolic risk factors and metabolic syndrome in severe mental illness.
IRAS project ID:	233121
Protocol number:	258-2018-DS
REC reference:	18/WM/0291
Aston reference:	258-2018-DS
NHS Research Sites:	1) Leicestershire Partnership NHS Trust Riverside House Bridge Park Plaza, Bridge Park Road, Thurmaston, Leicester Leicestershire LE4 8PQ Generic Approval for: 2) CRN East Midlands NHSP, C Floor South Block Nottingham University Hospitals NHS Trust QMC Campus Nottingham NG7 2UH Note in accordance with Debbie Wall's Email dated 18 January 2019 GP Practices will need to confirm their participation on an individual basis. These must also be approved by Aston prior to undertaking any research.
	3) Personal and professional networks

I am writing to confirm permission for your project to proceed on behalf of the Sponsor, Aston University.

This approval is subject to the project being undertaken in accordance with:

- The HRA Approval Letter dated 18th December 2018 and documents listed therein
- Delegation of Duties and Authorised Persons Logs (Appendix 1)
- Aston University Quality Management System requirements as outlined in the site file standard operating procedures and if applicable the Aston University Quality Manual: Acquisition, Storage, Use and Disposal of Human Tissue.
- Appropriate approvals for each Research Site being in place and given Governance Approval from Aston
- The UK Policy Framework for Health and Social Care Research

Continued Sponsorship is subject to the following, post-approval:

Reporting

- Submission of Annual Reports to the NHS Ethics Committee that gave a favorable opinion to the study and a copy of the report being sent to research_governance@aston.ac.uk.

Protocol amendments

Any protocol amendments being submitted for approval according to SOP AHRIC107 before they are implemented.

Changes to study personnel

Updated Delegation of Duties Logs and Authorized Persons Logs being submitted to research_governance@aston.ac.uk with associated supporting documents for approval prior to personnel changes being made.

Adverse Event Reporting

Any Adverse Events being reported according to SOP AHRIC104

Study Closure

At the end of data collection (and if applicable data cleansing) an end of study report being is submitted to the REC and research_governance@aston.ac.uk . Note: data analysis can continue after submission of this report.

Archiving

Archiving of the study in according to SOP AHRIC106.

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Failure to comply with the terms of this approval will result in withdrawal of approval and indemnity for the project.

May I take this opportunity to wish you well with your study.

Yours sincerely,

Professor James Wolffsohn
Associate Pro-Vice Chancellor

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Appendix 15: Aston University Aston Health Research and Innovation Cluster Ethics Approval for Substantial Amendments

10th March 2019. Approval for Substantial Amendment

Aston University
5th April 2019

Dr Ian Maidment
Research Student: Dolly Sud
School of Life and Health Sciences

Aston Triangle
Birmingham
B4 7ET
United Kingdom
Tel: +44 (0)121 204 5069
www.aston.ac.uk

Dear Dr Maidment,

Study title:	Exploring the role of pharmacy and pharmacists in management of cardiometabolic risk factors and metabolic syndrome in severe mental illness.
IRAS project ID:	233121
Protocol number:	258-2018-DS
REC reference:	18/WM/0291
Aston reference:	258-2018-DS

On behalf of the Sponsor, Aston University, I am writing to confirm approval to implement Substantial Amendment #1 dated 13th February 2019 in accordance with the following (Appendix 1):

- HRA Approval dated 2nd April 2019
- REC Favourable Opinion dated 10th March 2019 (and document set detailed therein)
- Capacity and Capability from Trust dated 3rd April 2019

With best wishes with your continuing research.

Yours sincerely,

Professor James Wolffsohn
Associate Pro-Vice Chancellor

20th August 2019. Approval for Substantial Amendment

Aston University
20 August 2019

Dr Ian Maidment
Research Student: Dolly Sud
School of Life and Health Sciences

Aston Triangle
Birmingham
B4 7ET
United Kingdom
Tel: +44 (0)121 204 5069
www.aston.ac.uk

Dear Dr Maidment,

Study title:	Exploring the role of pharmacy and pharmacists in management of cardiometabolic risk factors and metabolic syndrome in severe mental illness.
IRAS project ID:	233121
Protocol number:	259-2018-DS
REC reference:	19/WM/0291
Aston reference:	259-2018-DS

On behalf of the Sponsor, Aston University. I am writing to confirm approval to implement Substantial Amendment #1 dated 13th February 2019 in accordance with the following (Appendix 1):

- HRA Approval dated 19 Aug 2019;
- REC Favourable Opinion dated 2 Aug 2019 (and document set detailed therein);
- Capacity and Capability from Trust dated 19 Aug 2019.

With best wishes with your continuing research.

Yours sincerely,

Professor James Wolffsohn
Associate Pro-Vice Chancellor