# Delivering medicines optimisation through strategic leadership

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## Contents

**Abstract**

This thesis describes the author's journey as a researcher, a practicing pharmacist, and a leader and how they have delivered on the principles of medicines optimisation (MO). The first two chapters of the thesis provide a background on the author's career, areas of research interest, introduction to the literature and an overview of the research methodologies utilised. The thesis then proceeds to focus on the author's three key research themes of improving the quality of medicines reconciliation (MR) at hospital admission and at transfer of care, ensuring the safe and effective use of medicines in patients with mental health and learning disabilities and embedding the principles of MO through a multidisciplinary team (MDT) approach.

On the theme of MR, the author undertook one of the largest studies of its kind that provided an in depth understanding of the quality of medicines related information provided at discharge from hospital and how this information was acted upon in primary care. The author also developed a best practice resource and toolkit for MR that was endorsed by the Royal Pharmaceutical Society (RPS) which has been widely used nationally to improve the quality of MR at hospital admission. On the theme of mental health and learning disabilities, the author has developed and evaluated new innovative roles for pharmacists that have been cited as exemplar models for other organisations to follow, scoped opportunities for pharmacists and other health professionals to improve the physical health of people with a severe mental illness (SMI) and promoted the role of pharmacy in mental health practice. On the theme of embedding the principles of MO through a MDT approach, the author's collaborative leadership style is described throughout the thesis and is reflected in the breadth of professional journals that the author has published in. The scope of this theme was to

empower collaborative working between pharmacists and other healthcare professionals to optimise MO and therefore patients' health outcomes.

In conclusion, the thesis demonstrates the author's contribution to the MO agenda at a local, regional, and national level and how they translated strategic policy decisions into operational deliverables through a collaborative leadership style. It clearly outlines the importance of research and collaborative working to develop practical solutions and tools for wider implementation of MO and MR across care pathways to enhance medication safety.

## Chapter 1: Introduction

### 1.1 Outline of career history and development

The author qualified as a pharmacist in 2002 having completed a 5-year integrated undergraduate pharmacy degree that included a pre-registration year. The author was the first cohort of graduates of the newly designed four-year Masters of Pharmacy (MPharm) programme in the United Kingdom (UK). The first few years of the author's career were based in National Health Service (NHS) acute hospitals undertaking clinical roles that provided comprehensive training across hospital pharmacy specialisms. During the years 2005 to 2009, the author specialised in the discipline of psychiatry. Whilst undertaking these clinical roles, the author completed postgraduate qualifications in both clinical pharmacy and psychiatry.

From 2009, the author held increasingly more strategic roles across a variety of pharmacy sectors that included being appointed as a regional manager for the Centre for Pharmacy Postgraduate Education (CPPE) hosted by the University of Manchester, senior lecturer at the University of Hertfordshire (UoH) at their newly formed School of Pharmacy, lead for community health services across three greater London boroughs and as associate director at the medicines use and safety directorate of NHS Specialist Pharmacy Services (SPS). In 2016, the author was appointed as a Chief Pharmacist for a large mental health trust that covered services in Hertfordshire, Norfolk, Essex, and Buckinghamshire. Whilst undertaking these leadership roles, the author completed a Masters in Business Administration (MBA).

In addition to the formal employed positions the author has also held a variety of other appointments that include being a pharmacy advocate for the National Institute for

Health Research (NIHR) Greater London Primary Care Research Network, a member of the editorial advisory board for the Journal of Community Nursing, a peer reviewer for several health-related journals and a member of the Department of Health and Social Care (DHSC) community and mental health transformation steering group. The author's varied roles are detailed in the sections below and their career history and qualifications are outlined in their curriculum vitae (appendix 1).

### 1.1.1 Clinical roles

In the author's early career, they were employed in clinical roles across several NHS acute hospitals where they rotated through the various hospital pharmacy services such as technical services, medicines information, a range of clinical specialties, patient services, procurement, formulary, and therapeutic and drug monitoring. The training was structured around a competency framework that enabled a good understanding of the medicines use process along with an appreciation of the challenges faced by both patients and NHS services in obtaining the best value from medicines.

### 1.1.2 Academic roles

In 2009, the author was appointed as a senior lecturer at the newly formed School of Pharmacy at the UoH. In this role, the author developed a new clinical postgraduate course for secondary care pharmacists in collaboration with local secondary care NHS trusts. The aim of the programme was to equip early career hospital pharmacists with the core knowledge, skills and capabilities required to provide safe and effective pharmaceutical care to their patients. The postgraduate programme enabled the UoH to establish close relationships with local NHS trusts, support workforce planning and develop teacher practitioner posts.

In addition to the development and ongoing management of the postgraduate programme, the author taught students on topics such as critical appraisal skills, mental health therapeutics, change management and pharmacy practice.

### 1.1.3 Senior NHS roles

In 2010, the author was appointed to their first senior strategic role in the NHS where they were appointed to implement (with respect to medicines management) the transforming community services agenda (Department of Health (DH), 2011a). The appointment also coincided with a significant NHS reorganisation initiated by the then UK government in which Primary Care Trusts (PCTs) were dissolved and replaced with general practitioner (GP) led Clinical Commissioning Groups (CCGs), this resulted in the author managing (with respect to medicines management) the merger of Brent, Harrow and Ealing community health services with each other and their subsequent integration with the local acute hospital (Ealing Hospital) to create a newly formed integrated care organisation. In 2016, the author was appointed as a Chief Pharmacist for a large mental health and learning disabilities NHS trust. The role of a Chief Pharmacist encompasses responsibility for all medicines related matters and is integral to the senior leadership team that manages the NHS trust.

### 1.1.4 National appointments

The author has been appointed to two key national roles since 2009. The first appointment was as a regional manager for CPPE which is a national organisation that supports the continuing professional development (CPD) of the pharmacy workforce in England. A key function of this role was to ensure that the pharmacy profession was supported to acquire the knowledge, skills, and competencies to deliver the aspirations of the 2008 Pharmacy White Paper – Building on Strengths, Delivering the Future (DH, 2008).

The second appointment, in 2014, was as an associate director for the medicines use and safety directorate of the NHS SPS. SPS is a national organisation consisting of networks whose purpose is to support MO across the NHS. The primary purpose of the appointment was to improve the quality of medicines reconciliation (MR) at a national level.

## 1.2 Areas of interest

The author's areas of interest have developed in parallel since 2009 in part because of the roles that they have undertaken, national directives issued in relation to medicines and emerging evidence in the practice of pharmacy. The change from

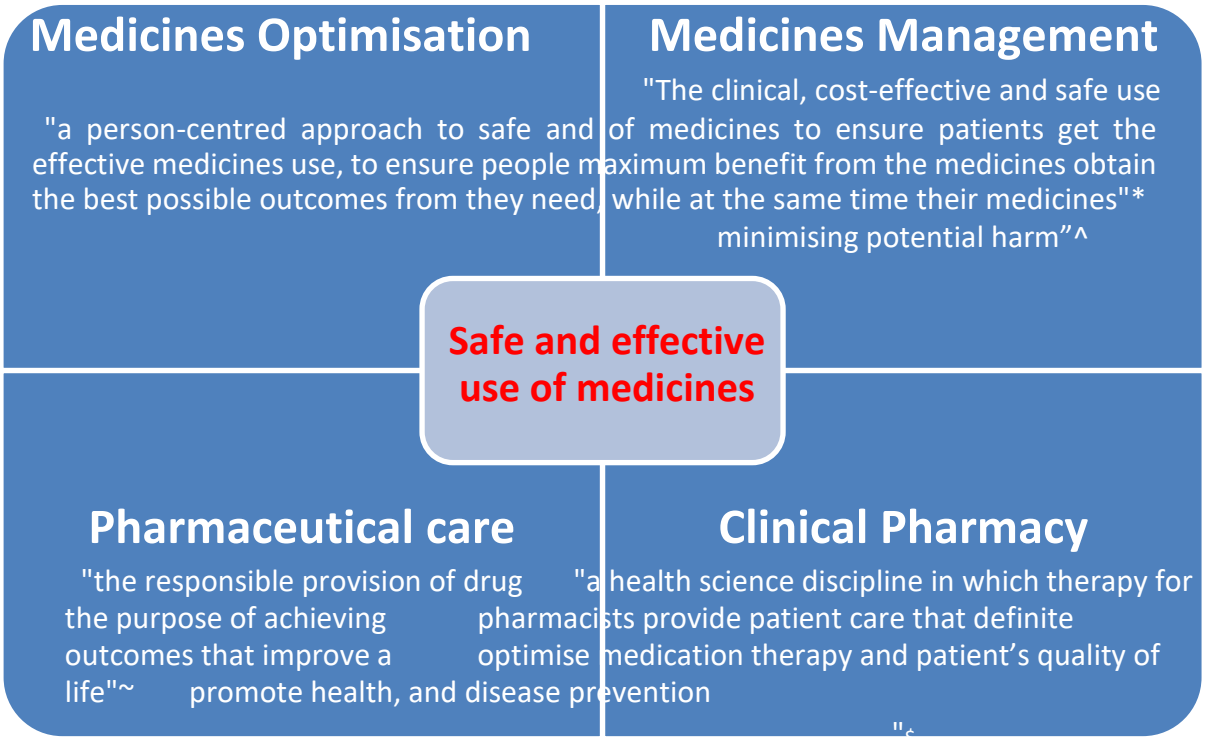
medicines management to medicines optimisation (MO) in early 2013 was a paradigm shift for the way in which medicines were viewed by health care professions that required important leadership from pharmacy leaders. As a result of the senior roles occupied by the author and their strategic leadership skills, they were able to influence the MO agenda locally, regionally, and nationally.

The author's published work and activities can broadly be considered as translating the principles of MO and medicines safety into practice through their strategic leadership skills. The author's work can be categorised more specifically into the following themes (i) improving the quality of MR, (ii) ensuring the safe and effective use of medicines in mental health and learning disabilities and (iii) engendering a multidisciplinary team (MDT) approach to MO. Each theme will be focussed on in more detail in chapters 3, 4 and 5 respectively.

### 1.3 Definitions and terminology

Internationally the key terms synonymous with the safe and effective use of medicines are MO, medicines management, pharmaceutical care, and clinical pharmacy. Fig 1a below describes the various terms and their definitions.

Fig 1a - Key definitions associated with the safe and effective use of medicines



* Definition from NICE. Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes. (NICE NG5, 2015).
^ Definition from the UK Medicines and Healthcare Products Regulatory Agency (MHRA)
~ Definition from Hepler CD, Strand LM. Opportunities and responsibilities in pharmaceutical care. Am J Hosp Pharm (Helper and Strand, 1990)
$ Definition from American College of Clinical Pharmacy (ACCP, 2021)

Prior to the introduction of the MO concept in 2013, the term that was most frequently used in the UK to describe the safe and effective use of medicines was “medicines management”. The key proponent of the medicines management approach in the UK was the Spoonful of Sugar report published in 2001 by the audit commission (Audit Commission, 2001). The publication defined medicines management in hospitals as “*encompassing the entire way that medicines are selected, procured, delivered, prescribed, administered and reviewed to optimise the contribution that medicines make to producing informed and desired outcomes of patient care*”. Although the Spoonful of Sugar report (Audit Commission, 2001) formally set out the medicines management approach, it could be argued that many of the principles in medicines management were already embedded in the practice of pharmacy in the UK. For example, in the descriptive study undertaken by Baker et al (1988), they described seventeen years of interventions to control rising expenditure on medicines that included policy changes for outpatient supplies, reducing waste, improving purchasing and the introduction of a tightly controlled formulary system. In the author’s opinion these practices were the backbone of the medicines management principles.

The key difference cited, by the Royal Pharmaceutical Society (RPS) between MO and medicines management, is that the former focuses on outcomes and patients whereas the latter focusses on processes and systems (RPS, 2013). The RPS proposed that the focus on improved outcomes for patients in MO is more likely to help ensure that patients and the NHS get better value from the investment in medicines (RPS, 2013).

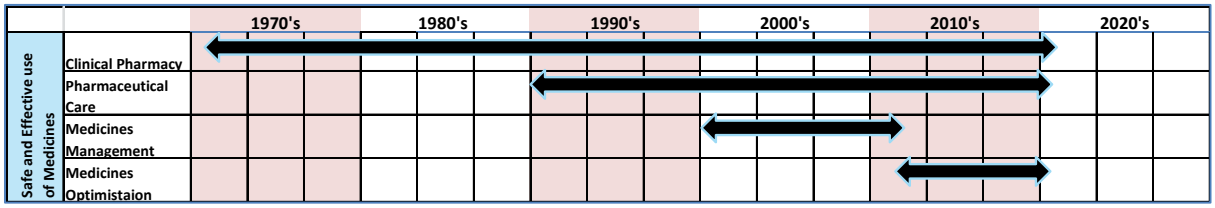
The two other key conceptual terms used in international practice particularly in the USA and the literature that encompass the safe and effective use of medicines are clinical pharmacy and pharmaceutical care. The term ‘clinical pharmacy’ was introduced in the early 1970s and encouraged and promoted for more patient-oriented clinical pharmacist roles to be developed and integrated into MDTs alongside doctors, nurses and other healthcare professionals (Hassali, Hashmi and Al-Tamimi, 2016).

The term ‘pharmaceutical care’ was introduced by Helper and Strand (1990) in which they described it as “*the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient’s quality of life*” and that it “*involves the process through which a pharmacist co-operates with a patient and other professional in designing, implementing and monitoring a therapeutic plan that will produce specific therapeutic outcomes for the patient*”.

In 2005, an interesting debate by Franklin BD (editorial board member) and Foppe JW (editor in chief) of the Journal Pharmacy World Science (PWS) occurred where the concepts of clinical pharmacy and pharmaceutical care were discussed (International Clinical Pharmacy Research Team, 2005). In the debate, they agreed that for the purposes of their journal, clinical pharmacy would be defined as that part of the practice of pharmacy that contributes directly to patient care and develops and promotes the rational and appropriate use of medicinal products and devices. They defined pharmaceutical care as the person-focused care relating to medication, which is provided by a pharmacist and the pharmacy team with the aim of improving the outcomes of therapy. They stated that the most important factor is that both definitions focus on the individual (usually a patient), whether they are in primary or secondary care. This suggests that the terms clinical pharmacy and pharmaceutical care are distinct from each other but also possess similarities especially when in the context of patient care.

From the author’s experience, there are overlaps between the terms MO, medicines management, clinical pharmacy, and pharmaceutical care. However, they are also quite distinct and have therefore influenced pharmacy practice nationally and internationally in their own individual ways. From the author’s perspective, the introduction of MO in 2013 had a significant impact on pharmacy practice particularly as it clearly mandated an MDT approach for successful delivery. It became evident that pharmacists were responsible for providing clear leadership on the MO agenda but the responsibility for its implementation did not solely rest with pharmacy staff. In the thesis the author demonstrates how they embedded the principles of MO through an MDT approach by providing strategic leadership. Fig 1b shows the evolution between the terms clinical pharmacy, pharmaceutical care, medicines management and MO.

Fig 1b: A timeline in the use of the terms clinical pharmacy, pharmaceutical care, medicines management and MO in the UK.




The introduction of MO in 2013 resulted in a paradigm shift in the practice of pharmacy in the UK. Much of the author's work focusses on implementing the principles of MO.

### 1.4 Medicines optimisation (MO)

In England, the concept of MO when launched was endorsed by NHS England, Royal College of General Practitioners, Royal College of Nursing (RCN), Academy of Medical Royal Colleges, and the Association of the British Pharmaceutical Industry. Similarly, the National Medical Director for England, the Chief Nursing Officer (CNO) and Chief Pharmaceutical Officer for England all provided their support at launch to ensure that MO principles were taken forward.

The four guiding principles for MO were set out by RPS in 2013 and were described as "(i) Aim to understand the patient's experience, (ii) Evidence based choice of medicines, (iii) Ensure medicines use is as safe as possible and (iv) Make MO part of routine practice" (RPS, 2013). In each of these principles, the RPS guidance detailed the types of positive outcomes that would be expected if the principles are implemented in practice.

In 2015, the National Institute for Health and Care Excellence (NICE) published its clinical guideline on MO which provided direction on how to implement MO (NICE NG5, 2015). The recommendations centred around the following themes (i) identifying, reporting and learning from medicines-related patient safety incidents, (ii) medicinesrelated communication systems when patients move from one care setting to another, (iii) MR, (iv) medication review, (v) self-management plans, (vi) patient decision aids used in consultations involving medicines, (vii) clinical decision support and (viii) medicines-related models of organisational and cross-sector working (NICE NG5, 2015). The guidance was supported with several implementation tools and data analytic resources. A MO dashboard was also established by NHS England that

allowed a time series analysis for trends to be monitored to address variation in practices.

During the period between 2013 and 2015, the key priority for all pharmacy leaders in NHS primary and secondary care organisations was to operationalise the RPS and NICE MO guidance into their organisations and local health economy.

### 1.5 Medication safety

One of the key principles of MO is to ensure medicines use is as safe as possible. The decision to prescribe medicines is based on careful balancing of perceived benefits versus potential harms and patient choice. Despite medicines clearly demonstrating many positive benefits for treating illness and preventing disease, they can sometimes cause serious harm. The medicines use process can be quite complex and generally begins with prescribing followed by dispensing, administration, and monitoring. The complexity of the process is due to a variety of factors such as the number of different health care professionals involved in the process, the patient being a core part of the process which may or may not reduce complexity depending on the patient's health literacy and cognition, the involvement of additional carers or external agencies involved in the provision of care and finally the process itself spanning through different care boundaries which inevitably involve different technological systems and processes. Errors can occur at all stages of the medication use process ranging from minor errors leading to no harm, through to major errors causing death.

There are a number of terms involved in defining medication errors and classifying their consequences e.g., error, failure, near miss, rule violation, deviation, preventable adverse drug event (ADE) and potential ADE (Lisby et al, 2010). Table 1a displays definitions of medication errors from a range of key national and international agencies:

Table 1a: Definitions of medication errors from a variety of authority bodies

| Reference | Definition |
|---|---|
| European Medicines Agency (EMA) (EMA, 2013) | *"A medication error is an unintended failure in the drug treatment process that leads to, or has the potential to lead to, harm to the patient. This includes the prescribing, storing, dispensing, preparation for administration or administration of a medicinal product."* |

| | |
|---|---|
| United States National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP, 2021). | *"Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures and systems including prescribing, order communication, product labelling packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring and use"* |
| United Kingdom National Reporting and Learning System (NRLS) (NPSA, 2007) | *"Patient safety incidents involving medicines in which there has been an error in the process of prescribing, dispensing, preparing, administering, monitoring, or providing medicine advice, regardless of whether any harm occurred".* |
| American Society of Health-System Pharmacists (AHSP, 2017) | *"episodes in drug misadventuring that should be preventable through effective systems controls involving, physicians and other prescribers, nurses, risk management personnel, legal counsel, administrators, patients and others in the organizational setting, as well as regulatory agencies and the pharmaceutical industry."* |

The World Health Organisation (WHO) indicates that errors occur when weak medication systems and/or human factors affect the various stages of the medication pathway. In 2017, the WHO launched its third global patient safety challenge which focussed on medication safety, the challenge aimed to reduce the global level of severe, avoidable harm due to medication by 50% over the next 5 years (WHO, 2017). The three areas prioritised by the WHO in this "Medication without Harm" challenge were to reduce medication errors in high-risk situations, reduce polypharmacy and improve communication at transitions of care.

To support the WHO campaign, the DHSC in the UK commissioned a rapid review of the evidence base on medication errors in England. The rapid review estimated that in England, 237 million medication errors occur at some point in the medication use process each year, of which 21.3% are prescribing errors, and 20% occur in secondary care (Elliot et al, 2018). In the review, interestingly only one study based on mental health was included which was an observational study that focussed on medication administration errors within the inpatient mental health setting (Cottney and Innes, 2015).

A significant proportion of the author's work presented in this thesis focusses on medication safety at transitions of care and medication safety in the mental health setting.

## 1.6 Strategic leadership in healthcare

There are many definitions of strategic leadership in the literature, the majority of which generally combine the definitions of strategic management and leadership of which there are also many definitions. In the author's opinion, a good example of the competencies required by a strategic leader are those described by Wooten et al (2006) in which they explain that strategic leadership involves an individual providing a focal point and guiding a group's behaviour by inducing compliance, discharging influence, personifying norms, and mobilizing efforts toward goal achievement. It also includes communicating a vision, developing organisational structures and processes, managing change initiatives, and creating capabilities.

The NHS has clearly stated that it requires high quality leaders at every level and in every area to ensure that it is able to deliver high quality compassionate care to the people it serves. In 2015, a review conducted by the Faculty of Medical Leadership and Management (FMLM), The King's Fund and the Centre for Creative Leadership showed the importance of leadership in the health service (FMLM,2015). The review concluded that 'there is clear evidence of the link between leadership and a range of important outcomes within health services, including patient satisfaction, patient mortality, organisational financial performance, staff well-being, engagement, turnover and absenteeism, and overall quality of care'. The author's learning on their MBA course has significantly impacted their approach to strategic leadership and management. The author's learning on complex adaptive systems has been particularly beneficial in the way they approach strategic challenges. The most common definition of a complex adaptive system is a dynamic network of agents acting in parallel, constantly reacting to what the other agents are doing, which in turn influences behaviour and the network as a whole (Holland, 1992). With respect to healthcare, the complexity arises due to the diversity of tasks involved in the delivery of patient care, the dependency of health-care providers on one another and the diversity of patients, clinicians, and other staff (WHO, 2012). It has been suggested that complex adaptive systems thinking is useful for helping to understand clinician leadership as well as managerial leadership and can be applied to many different facets of healthcare, from psychology and mental health services through to biology and neurology (Minas, 2005) (Martin and Felix-Bortolotti, 2010).The author's understanding that the interactions within a complex adaptive system are often more important than the discrete actions of the individual parts ensures that when leading

and planning change, they consider the unintended consequences as well as the desired outcomes of change.

In chapters 3,4 and 5 the author demonstrates their strategic leadership skills in the context of delivering the principles of MO. In the summary section of these chapters, the author links the competencies required of a strategic leader as described by Wooten et al (2006) to their work.

## 1.7 Aim and objectives

The aim of this thesis is to describe and demonstrate the author's contribution to the MO agenda at a local, regional and national level. The aim can be illustrated by the contribution of the author's work in the context of the following objectives;

1. To improve the quality of MR at hospital admission and at transfer of care
2. To ensure the safe and effective use of medicines in patients with mental health and learning disabilities through MO
3. To embed the principles of MO through a multidisciplinary approach

## 1.8 Structure of the thesis

The thesis will aim to describe the author's journey as a researcher whilst in senior strategic leadership roles and how they translated strategic policy decisions into operational deliverables that impact patient care. The thesis will be divided into 6 chapters. Chapter 1 provides a background on the author's career and areas of interest coupled with an introduction to the literature of the key topic areas. Chapter 2 will summarise the research methodologies and methods utilised by the author in their research activities. Chapter 3 will focus on the author's activities in improving the quality of MR at hospital admission and at transfer of care (objective 1). Chapter 4 will focus on the author's activities in ensuring the safe and effective use of medicines in patients with mental health and learning disabilities through MO (objective 2). Chapter 5 will focus on the author's activities in embedding the principles of MO through a multidisciplinary approach (objective 3). Chapter 6 will summarise the impact of the author's research and activities on the practice of pharmacy. The author's list of research outputs in appendix 2 displays the author's research in the context of the

three objectives above. The research outputs do not necessarily follow a chronological pattern but tend to rather follow the senior leadership roles that the author has assumed between the years 2010 - 2021. Fig. 1c and 1d below display the author's research outputs for the period 2010 - 2021 and their categorisation according to the thesis objectives. The full list of research outputs including awards, grants, oral presentations, and invited lectures are available in appendix 2.

Fig 1c: Author's research activity during 2010 to 2021

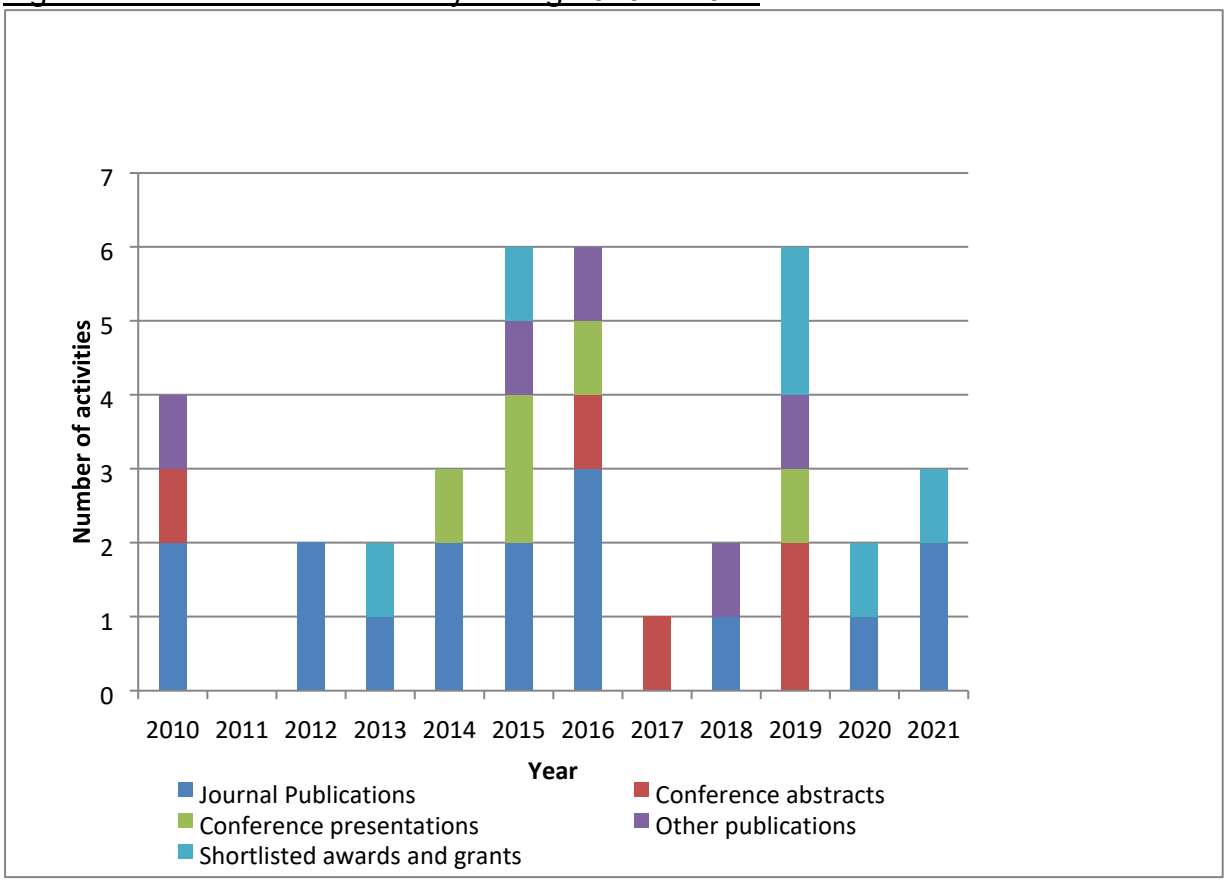
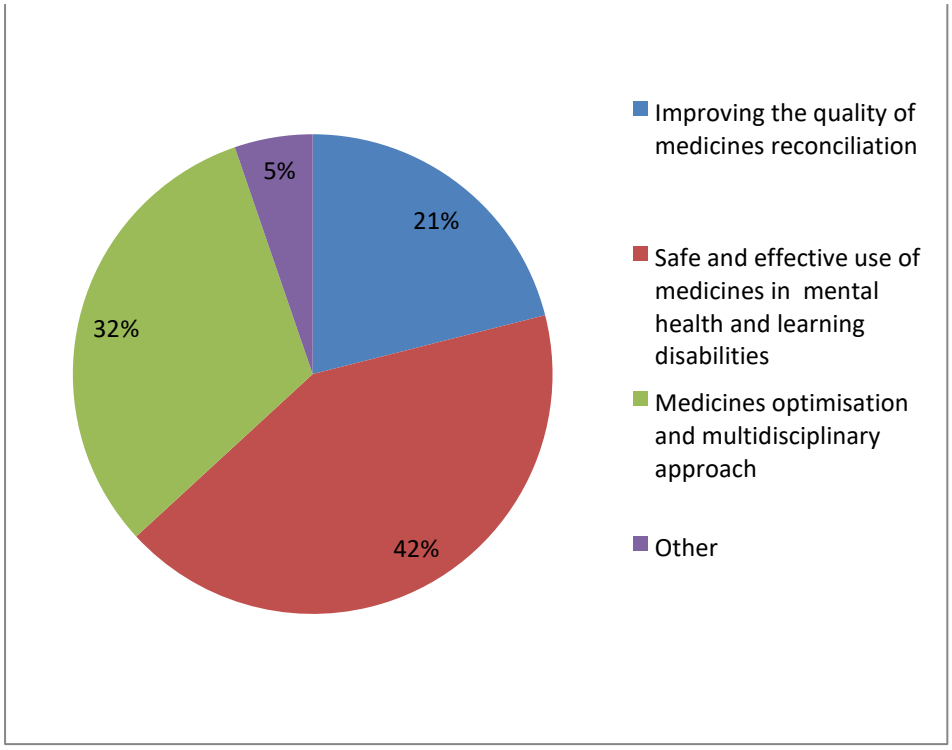



Figure 1d: The author's research activities categorised according to research theme.




# Chapter 2: Methodology

## 2.1 Introduction

Research methodology can broadly be categorised into either quantitative or qualitative methodologies. Quantitative research generally involves measuring or counting things that generate numerical data or data that can be converted into numbers that can be used to produce statistics and identify patterns. Qualitative research generally involves collecting data which is detailed, rich and complex and generates an in-depth understanding and explanation of processes and situations that are used to understand opinions, attitudes and motivations hence answering questions that cannot be quantified with numbers. Unlike quantitative research, qualitative data is mainly in the form of words, ideas, themes, patterns, and processes which are context specific.

The author's experience in research methodologies has evolved over time and consists primarily of quantitative methodologies. The author's training in a scientific discipline (pharmacy) predominantly included quantitative research methodologies. Qualitative methodologies are often more widely utilised in social sciences training. Combining quantitative and qualitative research methods is referred to as mixed methodology. A mixed methods research strategy can be defined as an approach whereby the researcher collects, analyses, and interprets both quantitative and qualitative data and integrates the two approaches in various ways (Creswell, 2015).

In their discussion, Doyle et al (2016) identified several strong justifications of using mixed methods research designs that included triangulation (using quantitative and qualitative methods so that findings may be mutually corroborated), expansion (the first phase has findings that require explanation qualitatively), exploration (where an initial phase is required to develop an instrument or intervention, identify variables to study or develop a hypothesis that requires testing), completeness (provides a more comprehensive account of phenomena under study), illustration (qualitative data are used to illuminate quantitative findings) and offset weaknesses (ensures that weaknesses of each method are minimised).

The fundamental purpose of undertaking research is to create and build knowledge. Research carried out scientifically should be based on several key fundamental philosophical assumptions and how these assumptions determine the selection of an appropriate methodology and methods. Ontological and epistemological philosophies are two such philosophies that underpin all types of research. Ontology is the study of being (Crotty, 1998, p. 10) and its assumptions are concerned with what constitutes reality. Researchers need to take a position regarding their perceptions of how things really are and how things really work. Epistemology is concerned with the nature and forms of knowledge (Cohen et al., 2007, p. 7) and its assumptions are concerned with how knowledge can be created, acquired, and communicated. In their research, the author approaches their work from both philosophical perspectives for example much of the work described in chapter 5 relates to an ontological perspective as it focusses on the reality of working together to deliver care in a complex healthcare system. The author's research into developing new roles described in chapter 4 originates from an epistemological philosophy where the focus is very much on creating new knowledge so that it can be shared more widely and utilised by other NHS trusts. With respect to other research philosophies such as positivism and interpretivism, the author's research lends itself much more towards interpretivism as in the majority it includes human involvement (healthcare staff and patients) and therefore encompasses the variables of cultures, circumstances, and different realities. The author's research does not lend itself to positivism as very little of their research considers pure data or facts that is not influenced by human interpretation which can often lead to introduction of bias.

The types of research methodologies used by the author in their work have been influenced by a variety of factors such as the type of study or research being conducted, the primary purpose of undertaking the research, time constraints, financial limitations, and the practice of pharmacy at the time. The author has primarily been employed in senior operational management roles that have often required them to undertake research in order to rapidly demonstrate proof of concept, feasibility, or impact of an intervention. Therefore, the author has utilised research methodologies with the purpose of evaluating new roles and service offerings, redesigning care pathways, identifying efficiency and productivity savings, managing the impact of policy and organisational changes and to demonstrate a return on investment with respect to pharmacy services. In order to achieve the desired outcomes of the research, the author has frequently utilised action research methodology as it allows data to be collected contemporaneously during a service change.

In addition to action research, the author has also utilised other research methodologies such as dialogic and collaborative methods, document analysis and narrative literature review. Table 2a below displays the methodologies used in the author's key publications that are discussed in chapters 3, 4 and 5.

Table 2a: Key author citations between 2010-2021 stratified against each objective

| Key Publication | Citation | Type of Publication | Research Methodology Used | Impact | Author Contribution |
|---|---|---|---|---|---|
| Objective 1: To improve the quality of medicines reconciliation at hospital admission and at transfer of care | | | | | |
| **1.** | **Shah C. (2015) *Improving the quality of Medicines Reconciliation: A national best practice resource and toolkit*. Medicines Use and Safety, Specialist Pharmacy Service. Available from: https://www.sps.nhs.uk/articles/medicinesreconciliation-best-practice-resource-and-toolkit/** | **NHS publication** | **1. Narrative literature review**<br>**2. Document analysis**<br>**3. Dialogic research methodology**<br>**Collaborative research**<br>**4. methodology** | **Endorsed by the Royal Pharmaceutical Society**<br>**Provided a national set of best practice standards**<br>**Google analytics show that the toolkit is still widely downloaded** | **Conception and design of the project**<br>**Drafting of publication**<br>**Critical review of publication**<br>**Submission of publication for RPS accreditation**<br>**Response to peer review from RPS** |

| | | | | | |
|---|---|---|---|---|---|
| **2.** | **Shah C, Hough J, Jani Y. (2020) Medicine's reconciliation in primary care: a study evaluating the quality of medication-related information provided on discharge from secondary care. *European Journal of Hospital Pharmacy.* 27, 137-142. Available from: 10.1136/ejhpharm-2018-001613** | **Journal article** | **1. Narrative literature review**<br>**2. Document analysis**<br>**3. Dialogic research methodology**<br>**4. Collaborative research methodology** | **Largest study of its kind in the UK**<br>**Study tools developed used by other organisations including Health Board of N. Ireland** | **Conception and design of the study**<br>**Data collection**<br>**Drafting of publication**<br>**Critical review of publication**<br>**Submission of publication** |
| | | | | **Findings presented across England to all Chief Pharmacist Groups**<br>**Findings presented at national and international conferences**<br>**Study reported on by the Pharmaceutical Journal** | **Response to peer review** |

| | | | | | |
|---|---|---|---|---|---|
| **3.** | **Butterworth S and Shah C. (2021) An audit of clozapine recording in primary care patient records. *The Pharmaceutical Journal*. 306 (7947). Available from: DOI:10.1211/PJ.2021.1.52708** | **Journal article** | **1. Action research methodology** | **Runner up in best poster prize at the 10th Annual International College of Mental Health Pharmacy (CMHP) Conference. United Kingdom. Study tools developed can be used across by all Mental Health NHS Trusts** | **Conception and design of the study<br>Critical review of publication<br>Response to peer review** |

| Citation | Type of Publication | Research Methodology Used | Impact | Author Contribution |
|---|---|---|---|---|
| Objective 2: To ensure the safe and effective use of medicines in patients with mental health and learning disabilities through medicines optimisation | | | | |

| | | | | | |
|---|---|---|---|---|---|
| **4.** | **Shah C, Umaru N, Adams E, Johal M, Faridi A, Kah M, Zia A and Magon R. (2021) Assessment of the impact of integrating pharmacist independent prescribers into child and adolescent mental health services. *The Pharmaceutical Journal. 306 (7948).* Available from: DOI:10.1211/PJ.2021.1.45513** | **Journal article** | **1. Action research methodology**<br>**2. Review of routine clinical data**<br>**3. Questionnaires**<br>**4. Focus group research methodology** | **Cited as a best practice example by Health Education England in their review of innovative and. extended roles within mental health services**<br>**Cited by NHS Getting It Right First Time (GIRFT) programme as a practice model to follow**<br>**Business case requested by several other Chief Pharmacists in England** | **Conception and design of the study**<br>**Data collection**<br>**Drafting of publication**<br>**Critical review of publication**<br>**Submission of publication**<br>**Response to peer review** |

| | | | | | |
|---|---|---|---|---|---|
| | | | | **Shortlisted for Health Services Journal (HSJ) Value Awards (2021)** | |

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| **5.** | **Vekaria S, Shah C, Barnett N et al. (2020) Implementing a pharmacist-led medicines optimisation clinic in a community mental health team. *Journal of medicines Optimisation*. 6 (2); 42-51.** | **Journal article** | **1. Action research methodology**<br>**2. Review of routine clinical data**<br>**3. Questionnaires** | **Shortlisted for Health Services Journal (HSJ) Patient Safety Awards (2020)**<br>**Shortlisted for Health Services Journal (HSJ) Value Awards (2021)** | **Conception and design of the study**<br>**Critical review of publication**<br>**Response to peer review** |
| **6.** | **Adams D and Shah C. (2016) Reducing antipsychotic prescribing in people with learning disabilities. *Clinical Pharmacist.* 8(10), 37-41. Available from: DOI:10.1211/CP.2016.20201751** | **Journal article** | **1. Document analysis,**<br>**2. Narrative literature review** | **Practical support to implement deprescribing in people with learning disabilities for Pharmacists**<br>**Published on the RPS Medicines Optimisation STOMP webpage (RPS, 2021) as a resource to support the profession** | **Conception and design of the publication**<br>**Critical review of publication** |

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| **7.** | **Adams D and Shah C. (2016) Prescribing of psychotropic medicines: the role of learning disability nurses. *Learning Disability Practice*. 19(8), 21-25. Available from: Doi: 10.7748/ldp.2016.e1763** | **Journal article** | **1. Document analysis,<br>2. Narrative literature review** | **Practical support for the nursing profession to implement deprescribing in people with learning disabilities** | **Conception and design of the publication<br>Critical review of publication** |
| **8.** | **Shah C and Aslanpour Z. (2010) A new year, new horizons and a new agenda for public mental health. *Pharmaceutical Journal.* 284, 77-78** | **Journal article** | **1. Document analysis,<br>2. Narrative literature review** | **Incorporated public mental health teaching into pharmacy undergraduate curriculum** | **Conception and design of the publication<br>Drafting of publication<br>Critical review of publication<br>Submission of publication<br>Response to peer review** |
| **9.** | **Shah C, Zia A, Aslanpour Z, Mehra Z. (2019) An evaluation on the role of Community and GP practice-based Pharmacists in supporting the physical health of patients with severe mental illness (SMI). The 10th Annual International College of Mental Health Pharmacy (CMHP) Conference. United Kingdom.** | **Conference poster** | **1. Questionnaire** | **Event was reported on by the Pharmaceutical Journal<br>Example of how mental** | **Conception and design of the event and questionnaire<br>Drafting of poster/abstract** |

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| | | | | **health NHS trusts can engage with the community pharmacy sector** | **Critical review of poster/abstract**<br>**Submission of poster/abstract**<br>**Response to peer review** |
| **10.** | **Shah C, Singh P, Matin S, Farrow J, Magon R, Zia A, Tatt-Smith P, Watson C and Smith A (2021). An evaluation of a physician associate led enhanced physical health clinic for people with severe mental illness (SMI) in the United Kingdom. *Journal of the American Academy of Physician Assistants*. 34(8), 1-6. Available from: DOI:10.1097/01.JAA.0000758220.38067.49** | **Journal article** | **1. Action research methodology**<br>**2. Review of routine clinical data**<br>**3. Questionnaire** | **Led to recruitment of additional physician associates within the NHS trust Led to the formation of a new model of care to manage physical health in combination with primary care led by physician associates** | **Conception and design of the study Data collection**<br>**Drafting of publication**<br>**Critical review of publication**<br>**Submission of publication**<br>**Response to peer review** |

| | Citation | Type of Publication | Research Methodology Used | Impact | Author Contribution |
|---|---|---|---|---|---|
| Objective 3: To embed the principles of medicines optimisation through a multidisciplinary approach | | | | | |
| **11.** | **Shah C, Lehman H and Richardson S. (2014) Medicine's optimisation: an agenda for community nursing. *Journal of Community Nursing*: 28(3):76-80. Available from: https://www.jcn.co.uk/journals/issue/3/06-2014/Prescribing** | **Journal article** | **1. Document analysis Narrative 2. literature review** | **Example of how the pharmacy and community nursing profession can work collaboratively to support MO** | **Conception and design of the publication Drafting of publication Critical review of publication Submission of publication Response to peer review** |
| **12.** | **Shah C, Devit R and Wong M. (2016) The use of common medications during breastfeeding. *Journal of Health Visiting*: 4(3); 150 – 154. Available from: https://www.independentnurse.co.uk/clinical-article/the-use-of-commonmedications-during-breastfeeding/118801/** | **Journal article** | **1. Document analysis Narrative 2. literature review** | **Example of how the pharmacy and health visitor profession can work collaboratively to support medicines use in breastfeeding mothers** | **Conception and design of the publication Drafting of publication Critical review of publication Submission of publication Response to peer review** |

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| **13.** | **Shah C and Coyne T. (2012) Medicines management programme for non-medical prescribers. Nursing Management. 19(8):34-37. Available from: DOI: 10.7748/nm2012.12.19.8.34.c9448** | **Journal article** | **1. Document analysis** | **A key publication cited in several** | **Conception and design of the programme** |
| | | | **2. Narrative literature review Questionnaire**<br>**3.** | **other publications Demonstrated the need for NHS organisations to support NMPs** | **Drafting of publication Critical review of publication Submission of publication Response to peer review** |
| **14.** | **Cassam J, Shah C, Lewis P, Al-Tahan S and Pickard K. (2014) Development of a community nursing drug chart. *Nursing Management*. 21(2):22-25. Available from: DOI: 10.7748/nm2014.04.21.2.22.e1215** | **Journal article** | **1. Review of routine clinical data Dialogic research**<br>**2. methodology Collaborative research methodology**<br>**3.** | **Several NHS trusts in England requested a copy of the drug**<br>**Methodology shared through the publication** | **Conception and design of the publication Critical review of publication Response to peer review** |
| **-** | **Shah C, Williams G, Joshi J and Aziz R. (2012) A retrospective study of fall risk factors.**<br>***Journal of Community Nursing*. 26(5):34-39.** | **Journal article** | **1. Review of routine clinical data**<br>**2. Document analysis** | **Highlighted the need for pharmacist inclusion into MDT falls risk assessment** | **Conception and design of the publication Critical review of publication** |

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| - | **Shah C and Goundrey S. (2013) Managing the symptoms of urinary tract infection in women. *Journal of Community Nursing*. 27(4):88-92.** | **Journal article** | **1. Document analysis.**<br>**2. Narrative literature review** | **Highlighted the need for prudent use of antimicrobials** | **Conception and design of the publication**<br>**Critical review of publication** |

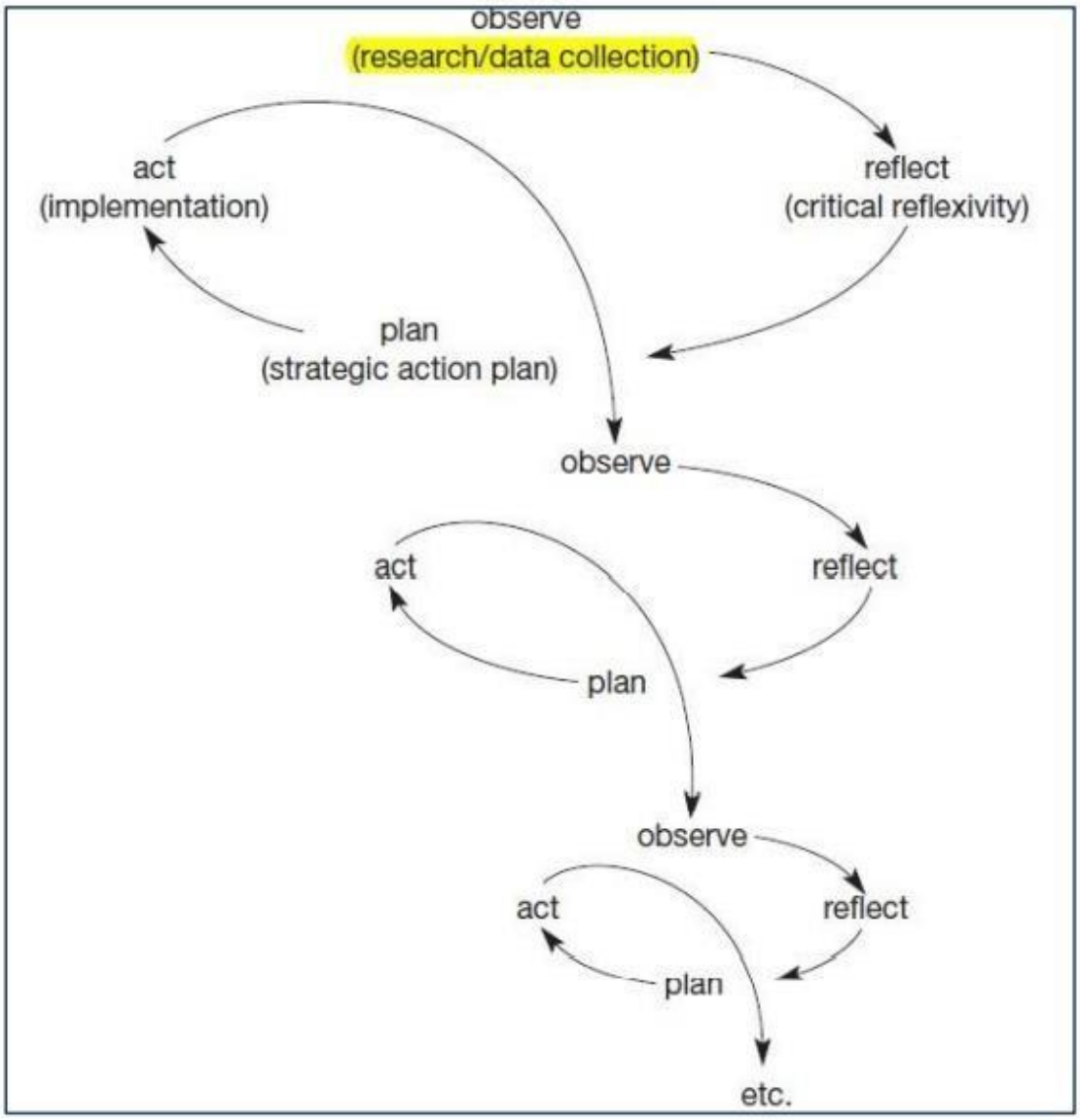
## 2.2 Action research methodology

Action research is an overarching approach to research, rather than a method itself, it can essentially be described as being concerned with generating knowledge about a social system, while, at the same time, attempting to change it (Meyer, 2000). Action research also adopts a system thinking approach, which is an area of interest for the author as they have previously studied this topic in their MBA and was the focus of their MBA thesis.

Action research is an approach often used within healthcare for improving clinical practice (Hughes, 2008). It involves healthcare practitioners conducting systematic enquiries in order to help them improve their own practices or clinical pathways, which in turn can improve their working environment, patient experience or pathway efficiency. The main features of action research are (1) its participatory nature (whereby researchers and practitioners work together in directing the course of change and the accompanying research), (2) its democratic impulse (whereby grassroots practitioners and their managers are empowered to change the contexts in which they work together) and (3) its contribution to social science and social change (as knowledge that is more meaningful to practice) (Bridges and Meyer, 2001). Action research uses a cyclical approach, whereby findings are fed back to practitioners as they are generated and are then used to inform further action and data collection (Bridges and Meyer, 2001).

The purpose of undertaking action research is to bring about change in specific contexts (Parkin, 2009). The benefits of action research methodology lie in its focus on generating solutions to practical problems and its ability to empower practitioners, by getting them to engage with research and the subsequent development or implementation activities (Meyer, 2000). There are a variety of action research cycles within the literature, Fig 2a below displays the action research cycle as described by O'Leary, 2004.

Fig 2a: Action research method cycle (O'Leary, 2004, cited in Koshy, 2005)




In O'Leary's model, the action research cycles converge to enable a better understanding of the issues which leads to a development of improved action implementation (Hughes, 2008). O'Leary describes action research as an experiential learning approach, to change, where the goal is to continually refine the methods, data, and interpretation in light of the understanding developed in each earlier cycle (Hughes, 2008). Action research draws on methodological approaches similar to that used in continuous quality improvement (CQI) but which can be distinguished from CQI because of its explicit focus on research and participation, its democratic basis

and its close proximity to practice (Norgaard and Sorensen, 2015). One of the key differences between CQI and action research is that CQI does not always involve the key elements of research such as articulating the research question at the outset, undertaking a robust review of the literature, designing a sampling strategy or considering a data collection and analysis strategy at the outset.

The author utilised the principles of action research in several of their publications. The author involved the healthcare clinicians delivering the care as participants in the action research cycle and collected patient experience outcomes to design the next stage of the research based on their learnings in previous stages. In the author's study on MR at transfer of care (Shah, Hough, and Jani, 2020) which is described in chapter 3, the action research methodology included several discussions and pilot activities with a practice–research engagement group that led to the development of study tools which included the audit protocol, data collection tool and a hints and tips tool. As the study progressed, the feedback allowed new supporting tools such as a frequently asked questions document to be developed and operational processes in the GP practice to be redesigned in response to any care issues identified. The principles of action research methodology were also used in the author's studies on the evaluation of integrating an independent prescribing pharmacist into Child and Adolescent Mental Health Services (CAMHS) (Shah et al, 2021) and the evaluation of a physician associate led enhanced physical health clinic (Shah et al, 2021b) which are described in chapter 4. In these studies, the author utilised patient experience and multidisciplinary feedback to evolve and modify the practices of the pharmacists and physician associates in their roles.

## 2.3 Data collection methods

Data collection is a systematic process of gathering observations or measurements in order to answer the research problem, test the hypothesis and evaluate the outcomes (Kabir, 2016). In their research, the author has primarily utilised data collection methods that include questionnaires, retrospective review of routine clinical data and focus groups.

### 2.3.1 Questionnaires

Questionnaires can be classified as both, quantitative and qualitative method depending on the nature of questions asked**.** In their research, the author where possible attempted to utilise validated questionnaires. Where this was not possible, the author designed questionnaires such that they were adapted or based on materials available in the published literature. For example, in their evaluation of the physician associate led enhanced physical health clinic (Shah et al, 2021b) the author used a patient experience questionnaire published by the Faculty of Physician Associates**.** In the design of questionnaires, the author used a variety of question types such as multiple choice, rating scale and Likert Scale questions and refrained from using closed dichotomous questions as they lack detail and provide little scope for respondents to supply answers which reflect their true feelings on a topic. The author utilised questionnaires in their research primarily in two main contexts: firstly, to understand the patient (or carer) experience and secondly to understand the attitudes and experiences of other healthcare professionals. For the author, the key advantage of using questionnaires as a data collection method was its speed of data collection, low cost, opportunity to obtain large amounts of information and access a large sample of people. The main disadvantage of questionnaires was the risk that respondents would answer questions without properly reading the question, may not be honest in order to present a preconceived image, not be able to express their additional thoughts, be unable to understand the questions due to language difficulties or be unable to use digital technologies. In order to mitigate some of the issues, the author ensured that all questionnaires were anonymised, where possible online and included an open-ended free-text question at the end of the questionnaire where respondents had the opportunity to add any comments which could then be analysed qualitatively. One limitation of the author's work is that they did not include strategies such as offering the questionnaires in different languages or alternative formats which may have increased the response rate.

### 2.3.2 Review of routine clinical data

Studies based on review of routine clinical data involve the use and analysis of existing data that has been acquired under real-life conditions, this type of research is increasingly popular among practitioners (Kennes, 2017). In day-to-day practice, a

vast amount of data is gathered under real life conditions that include for example detailed information on baseline characteristics, treatments, exposures, and outcomes at an individual level (Kennes, 2017). The opportunity to collect, centralise, aggregate, and store these data naturally presents a great solution to the problems involved with data acquisition in clinical trials which is often criticised as being artificial and unrealistic (Kennes, 2017).

The author utilised the principles of this research methodology in several of their publications. For example, in the author's evaluation of the physician associate led physical health clinic (Shah, 2021b), the author was able to collect and analyse routine clinical data such as body mass index (BMI), blood pressure, glycaemic control, ECG status, lipid profile, smoking status, medication adverse reactions and uptake of national public health screening programs. The author was then able to follow up on the outcome of any interventions undertaken by the physician associates based on that data. Similarly, many hospital pharmacy departments routinely collect pharmacist intervention data as a key performance indicator. The author was able to collect and analyse pharmacists' intervention data in their evaluations of pharmacist roles in CAMHS (Shah et al, 2021a).

### 2.3.3 Focus group

Focus groups are a common qualitative data collection method that allows the gathering of information in a group setting. Focus groups are considered an important qualitative health research technique (Morgan, 1997) due to their efficient and economical nature (Krueger and Casey, 2000). The key advantages of focus groups are that they facilitate interactions between participants, allow participants reactions to the comments and perspectives of others to be captured and they result in the sum of a group of people's experiences being captured rather than a single individual's experiences. Focus groups also yield large amounts of qualitative data and maximize face to face participant researcher contact compared to other qualitative methods such as structured interview methods (Parker and Tritter, 2006). The key disadvantage of focus groups is that they are resource intensive and lack anonymity which may lead participants to not voicing their opinions freely.

In the author's evaluation of pharmacist independent prescribers integrated into CAMHS (Shah et al, 2021a), a co-author utilised a focus group to understand and triangulate the perception and perspectives of the MDT staff on their pharmacist colleagues' roles and contributions. The focus group discussions were audiorecorded, transcribed to text, anonymised, and coded. The coding allowed categories, sub-themes, and overarching themes to be identified and discussed in the evaluation.

### 2.4 Dialogic and collaborative research methodology

In the author's research on MR, they heavily utilised the principles of dialogic research methodology in order to understand the complexity of the MR process at interfaces of care. The two key theories utilised by the author to frame a dialogical approach to their research were that of Freire's theory of dialogical action and teaching (Freire, 1970) and Bakhtin's dialogic imagination (Bakhtin, 1981). Freire's approach (Freire, 1970) proposed that dialogue is used to create processes that seek to (re)think and (re)create reality which is more than just an exchange of ideas. This focus is aligned with transformative scholarship and a critical intent that seeks to question and reflect on the reality from multiple viewpoints, fostering knowledge that in turn can advance transformation (Cannella, Pérez, and Pasque, 2015). Bakhtin (1981) similarly assumes that ideas, far from being abstract, are full of social constructions that reflect social reality. Bakhtin (1981) indicates that ideas exchanged through dialogue are formed in a continuing process of social interactions that shape one's own ideas as well as the ideas and assumptions of others. The use of a dialogic research methodology in a healthcare setting is presented in the work undertaken by Farias et al (2019) in which they discuss occupation-based social transformative work. Farias et al (2019) demonstrated the potential of dialogic research to generate reflection among people (e.g., scholars, practitioners, citizens) who want to better understand a topic as a first step to promote change.

In the author's research on MR, which is described in chapter 3, the dialogic research methodology helped the author understand the complex challenges associated with reconciling medicines at hospital admission, at discharge and post discharge in primary care. In both the development of the best practice toolkit for MR (Shah, 2015) and the study evaluating the quality of medication related information provided on

discharge from secondary care (Shah, Hough, and Jani, 2020), the author established a practice–research engagement group that consisted of a variety of pharmacy professionals from different healthcare sectors. The author established a design thinking workshop with the practice–research engagement group and created an environment that facilitated problem solving and idea generation. The design thinking workshop was structured into three phases: empathy, ideation, and prototyping. The phases are described below:

- **Empathy**: Developing a deep understanding of the problem that users face and empathising with them
- **Ideation**: Coming up with many ideas on how the user problem can be solved
- **Prototyping**: Creating a prototype of potential solutions and then testing it with real users.

The author utilised the principles of dialogic and collaborative research methodology with the practice research engagement group such that exchange of ideas could take place as informed by the participants' experiences as well as their interpretation of published guidance. Participants' ideas were in this sense understood as more than personal opinions, but rather as shaped by, and reflective of, their contexts and professional background. Through the design thinking workshops, the author was able to generate a shared understanding of the MR process, develop consensus statements, discuss ideas for improvement, understand risks and develop tools to be used in the study.

## 2.5 Document analysis

Document analysis is a form of qualitative research in which documents are interpreted by the researcher to give voice and meaning around a topic (Bowen, 2009). Document analysis can be used as a research method in its own right or alongside other research methods where it is used to triangulate findings gathered from other data sources**.** The document analysis research approach is particularly beneficial as it is an efficient and effective way of gathering data because documents are readily available and if produced by authoritative bodies can be considered as reasonably reliable. The disadvantage of using document analysis is that the documents are not created with data research agendas and therefore require some investigative skills. Additionally, a

document will not provide all of the necessary information required to answer the research questions.

In the application of the document analysis methodology, the author utilised the eight step process described by O'Leary (2014) in which the author was required to: (1) gather relevant texts, (2) develop an organisation and management scheme, (3) make copies of the originals for annotation (4) asses authenticity of documents, (5) explore documents' agenda, biases, (6) explore background information (e.g., tone, style, purpose), (7) ask questions about document (e.g., who produced it? why? when? type of data?) and (8) explore content.

In the document analysis undertaken by the author, they explored the content of documents using the interview technique in which they treated the document like an interview scenario i.e., the author asked the questions and then highlighted the answers within the document. The alternative technique for analysing the content would have been to undertake a thematic analysis by noting occurrences of particular words, phrases and concepts which is then organised into themes. The author's prior training in critical appraisal skills and the fact that the majority of documents reviewed were primarily policy documents published by reputable authorities provided a strong foundation for effective document analysis.

The document analysis approach was utilised by the author primarily to provide a summary and interpretation of policy papers. This allowed the author to translate policy directives into operational deliverables for the intended readership for example, in the author's publication on public mental health (Shah and Aslanpour, 2010) which is described in chapter 4, the author provided an interpretation of the 10-year strategy for mental health in England in which they were able to provide tangible examples of opportunities for the pharmacy profession to contribute to the aims of the strategy. In the author's two publications on Stopping Over-Medication of People with a Learning Disability (STOMPwLD) (Adams and Shah, 2016a) (Adams and Shah, 2016b) which are described in chapter 4, the author undertook a document analysis of the NHS England STOMPwLD programme materials and NICE guidance to provide an

interpretation of the policy along with practical implementation tips based on their expert clinical knowledge.

## 2.6 Narrative literature review

A literature review is a type of research article that is an objective report of the current knowledge on a topic, and which is based on a summary of previously published research (Helewa and Walker, 2000). The three basic types of literature reviews can be classified as narrative, qualitative systematic and quantitative systematic. Narrative literature reviews are usually presented as editorials, commentaries, or overview articles in published journals. The narrative literature review aims to provide the reader with a comprehensive overview of the topic and helps place that information into perspective whilst attempting to provide a new conclusion to the literature and not just simply presenting a summary of the literature (Green, Johnson and Adams, 2001).

In conducting narrative literature reviews, the author broadly used the following methodology. They firstly identified the appropriate keywords using MeSH (Medical Subject Headings) terms from the National Library of Medicine's controlled vocabulary thesaurus which is used for indexing articles. The author then conducted searches across the key healthcare databases such as PubMed, CINAHL (Index to Nursing and Allied Health Literature), EMBASE/Excerpta Medica, Cochrane Database of Systematic Reviews, DARE (Database of Abstracts and Reviews of Effectiveness) and MedLine. The search results were then reviewed for abstracts relevant to the review topic with relevant publications identified and critically appraised using the Critical Appraisal Skills Programme (CASP) tools (CASP, 2021). The author then synthesised the findings from the articles into a narrative review. The key limitation of narrative literature reviews is that they do not follow a systematic evidence-based criterion such as those used in systematic literature reviews. Therefore, narrative literature reviews do not mitigate against the introduction of selection bias by the author.

The author utilised the principles of narrative literature review methodology in several of their publications described in chapter 5. For example, in the author’s commentary piece on the role of MO and community nursing (Shah, Lehman and Richardson, 2014), the author presents the principles of MO in the context of community nursing

which is supported by examples from the literature of how community nursing can impact MO. In a similar fashion, the author's publication in the Journal of Health Visiting on the use of common medications during breastfeeding (Shah, Devit and Wong, 2016), they utilise the principles of a narrative literature review methodology to summarise the key issues that health visitors are likely to encounter in their practice with respect to medicines.

## 2.7 Mixed methods research

The author has utilised mixed methods approach where possible in their research to triangulate themes and patterns. In the author's evaluation of pharmacist independent prescribers integrated into CAMHS (Shah et al, 2021a), they triangulated findings from a focus group and an anonymous online questionnaire to understand the MDT perception of the pharmacist role within the community CAMHS team.

The author frequently utilised questionnaires in their research as it efficiently and effectively allows them to capture both quantitative and qualitative data that allows triangulation.

## 2.8 Summary

In summary, the author has utilised a range of research methods in their work often under the principles of action research in which they have attempted to address the key operational issues facing pharmacy leaders at that moment in time. The research methods chosen were frequently influenced by the intended purpose of the research which was often to demonstrate proof of concept in order to obtain financial resources to sustain interventions. The mixed methods approach has also supported triangulation of data leading to more reliable conclusions.

As outlined in chapter 1, the author's research outputs do not necessarily follow a chronological pattern therefore this limited the opportunity to apply learning from some publications to other research outputs. However, the author now has a range of research methodologies in their toolkit to support future research.

## Chapter 3: Improving the quality of Medicines Reconciliation

### 3.1 Background

Several national multicentre studies focussing on adverse events have documented that between 6.3 to 12.9% of hospitalised patients suffer at least one adverse event during their admission and that between 10.8 to 38.7% of these adverse events were caused by medicines (Council of Europe, 2006). Adverse events caused by medicines are one of the most common preventable adverse events in all settings of care, mostly because of the widespread use of prescription and nonprescription medications. In a study undertaken by Stausberg (2014), a review of routine hospital clinical data in the USA, England and Germany found an ADE prevalence rate of 3.22%, 4.78% and 5.64% respectively for hospital inpatient admissions. Medication errors are a frequent cause of ADEs despite only a small minority of medication errors causing ADEs. For example in one hospital inpatient study, the frequency of medication errors was 5.3 per 100 medication orders, much higher than the ADE rate of 0.25 per 100 orders (Bates et al, 1995).

There is a body of evidence that suggests that inaccurate MR at transfers of care is a major causative factor in patients experiencing an ADE (Cheema et al, 2018). It is estimated that more than 40 percent of medication errors are believed to result from inadequate reconciliation in handovers during admission, transfer, and discharge of patients of which approximately 20 percent are believed to result in patient harm (Rozich et al, 2004), (Gleason et al, 2004). MR is a significant factor that can affect medicines safety and is acknowledged as such by many patient safety organisations across the world such as the WHO, the Joint Commission (JC) and Institute for Healthcare Improvement (IHI) in the USA and NICE in England.

A variety of definitions for MR exist in the literature, the simplest definition found by the author is that from the Care Quality Commission (CQC) in England which defines MR as "*the process of accurately listing a person's medicines*" (CQC, 2020). Other definitions of MR are more nuanced for example the IHI define MR "*as the process of creating the most accurate list possible of all medications a patient is taking including drug name, dosage, frequency, and route and comparing that list against the physician's admission, transfer, and/or discharge orders, with the goal of providing*

*correct medications to the patient at all transition points within the hospital*". The JC define MR as '*the process of comparing a patient's medication orders to all of the medications that the patient has been taking'* (IHI, 2021). The WHO defines the MR process as '*the formal process in which health care professionals partner with patients to ensure accurate and complete medication information transfer at interfaces of care'* (WHO,2006). Although the underlying principles within the different definitions of MR tend to remain similar, in the author's opinion the differing definitions have led to the development of guidance documents that were open to interpretation for example the author found that some care sectors such as primary care and mental health did not embrace the principles of MR until the NICE MO guidance (NICE NG5, 2015) made a series of clearer recommendations. Therefore, a key aspect of the author's work has been to provide practical guidance to ensure safe MR processes in England.

The first major initiative to highlight the importance of MR and provide a directive to improve the process was in 2005 by the JC in the USA. In its directive, it set out a national patient safety goal "*to accurately and completely reconcile medications across the continuum of care*" (AHRQ, 2019). In the directive, the JC requested accredited organisations across the USA to develop and implement robust processes for MR by January 2006 (AHRQ, 2019). Similarly, in 2006, the WHO launched an objective to improve medication accuracy at transitions in care through its WHO "High 5s Project" (WHO, 2006) in which it aimed to standardise clinical processes. The first key national agency document published in England on MR was in 2007 by the National Patient Safety Agency (NPSA) and NICE titled "Technical patient safety solutions for Medicines Reconciliation on admission of adults to hospital" (NICE PSG1, 2007). There have been several further directives, initiatives, and improvement efforts at national and international levels to improve the quality of the MR process. In this chapter, the author describes their efforts to improve the MR process at both a local and national level.

## 3.2 Medicines reconciliation on admission to secondary care

### 3.2.1 Introduction

The NPSA/NICE guidance published in 2007 recommended that all healthcare organisations that admit adult inpatients should make sure that they have policies in

place for MR on admission. It indicated that the policy should specify standardised systems for collecting and documenting information about current medications, ensure that pharmacists are involved in the MR process as soon as possible after admission, that the responsibilities of pharmacists and other staff in the MR process are clearly defined and that strategies are incorporated to obtain information about medications for people with communication difficulties (NICE PSG1, 2007). The recommendations included in the guidance were predominantly based on the systematic review conducted by Campbell et al (2007) that included findings that pharmacy-led MR improved patient safety by reducing prescribing errors at admission, therefore the NICE/NPSA guidance heavily focussed on pharmacy leadership and involvement in implementing the recommendations.

Following the NPSA/NICE guidance in 2007, there was a significant effort by the pharmacy profession to not only implement the guidance but to continually improve the processes that underpin effective MR at admission to hospital. In England, much of this work has been led by the Medicines Use and Safety team within NHS SPS of which the author was employed from 2014 to 2016. In 2008, SPS established a small working group to develop a template policy for secondary care providers. In 2010, SPS undertook an audit to review the implementation of the NPSA/NICE guidance and in 2014 they employed the author to improve the quality of MR. The 2010 SPS audit included 50 NHS acute NHS trusts across East and South East of England covering 33,120 beds in which a total of 8621 MRs were audited (Dodds, 2010). The audit included a total of 49,099 admission drugs (average of 5.7 drugs per MR) and showed that 79.5% of inpatient beds had received a pharmacy led MR (Dodds, 2010). Of the 8621 MRs carried out by the pharmacy team, there were 11,366 unintentional discrepancies (UDs) identified between the medications prescribed on the medication chart at admission and what should have possibly been prescribed on the medication chart (mean 1.32 per MR) (Dodds, 2010).

In the 2015 NICE MO guidance (NICE NG5, 2015), the recommendations focussing on MR in hospitals were strengthened to include that MR must occur within 24 hours of admission to hospital or sooner if clinically necessary and recognise that MR may

need to be carried out on more than one occasion during a hospital stay for example, when the person is admitted, transferred between wards or discharged.

### 3.2.2 Key Publication 1: Improving the Quality of Medicines Reconciliation – A Best Practice Resource and Toolkit. NHS Specialist Pharmacy Service, Medicines Use and Safety.

Since the NPSA/NICE 2007 guidance, MR has formed a crucial element of a pharmacist's role in secondary care practice and has been designated as a key performance indicator (KPI) for hospital pharmacy services. The KPI is included in the NHS England medication safety thermometer, NHS England MO dashboard and in contract monitoring agreements between CCGs and secondary care providers. In 2014, the author was employed by SPS to review practices related to MR and develop a best practice resource and toolkit that would support, standardise, and improve the quality of MR in secondary care services in England.

In the development of the best practice resource and toolkit, the author utilised a range of research methodologies that included undertaking a narrative literature review and document analysis of key publications, guidance documents and NHS trust policies to identify and collate examples of good practice. The author also established a practice–research engagement group that consisted of individuals from across the NHS, academia, pharmacy educational organisations and a quality improvement health research group. The author utilised a dialogic and collaborative research methodology with the practice–research engagement group to generate a shared understanding of the optimal MR process, develop consensus on best practice, define key performance indicators, define audit standards, and develop tools for organisations to use in education, training, and audit. The activities allowed the author to develop and publish a best practice resource and toolkit that aimed to improve the quality of MR. The best practice resource and toolkit was divided into six chapters as follows: Making the Case for MR (chapter 1), Definition of MR and Process Sharing (chapter 2), Best Practice Standards (chapter 3), Audit and Evaluation (chapter 4), Education, Training and Competency (chapter 5) and Quality Improvement Methodology (chapter 6).

#### 3.2.2.1 Key findings and discussion

The author's narrative literature review and discussions from the practice–research engagement group suggested that MR had become a core part of secondary care pharmacist's role since 2007. Despite this, and the availability of widely published guidance documents and tools from national organisations such as the RPS, National Prescribing Centre (NPC) and CPPE, there were still significant variations in processes, standards, and performance around MR between NHS trusts. The underlying reasons for these variations from the author's research were the conflicting views on the optimal processes underpinning MR, the optimal skill mix of pharmacy staff utilised to deliver MR particularly around the delegation of duties to pharmacy technicians and resources provided to pharmacy departments to implement the NPSA/NICE 2007 guidance. In the best practice resource and toolkit, the author was able to address some of these issues by standardising best practices, highlighting the evidence supporting pharmacy led MR thus allowing Chief Pharmacists to develop business cases for additional funding, defining the optimal KPI for MR with NHS England and providing quality improvement and audit tools to improve the quality of MR.

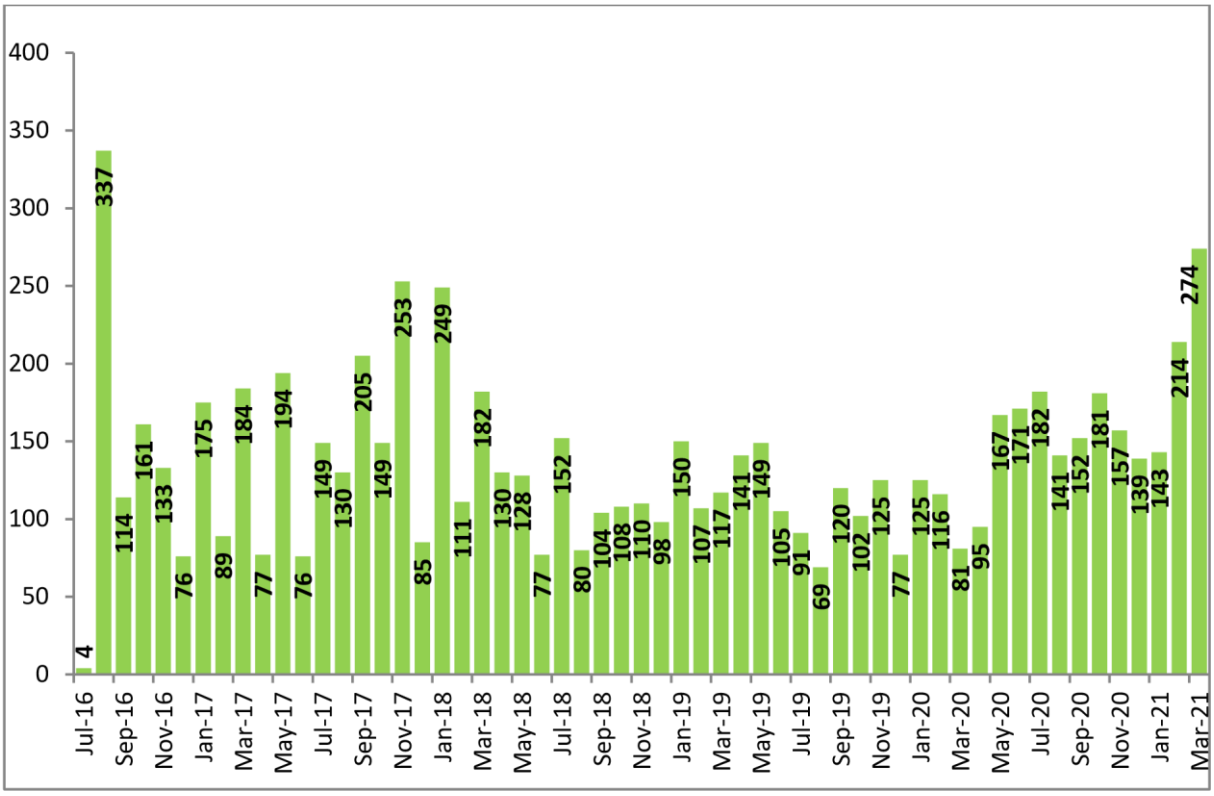
#### 3.2.2.2 Impact and associated outputs

The best practice resource and toolkit developed by the author was shared widely across the NHS through the SPS network and emailed directly to all Chief Pharmacists in England for review and implementation. The best practice resource and toolkit was also endorsed by the RPS through their accreditation process and shared through the RPS networks and communications. At the time of publication, the best practice resource and toolkit was utilised by the newly emerging Academic Health Science Networks (AHSN) to take forward quality improvement initiatives around MR. The Oxford AHSN also invited the author to be a member of its MR project steering group.

Fig 3a below displays the number of page views for the best practice resource and toolkit between 2016 and 2021. Over this five-year period, the resource has been viewed on 7811 occasions with each viewing lasting an average of 179 minutes. Five years post publication, the best practice resource and toolkit is projected to have its

most page views which demonstrates the relevance and impact of the resource developed by the author.

Fig 3a: Medicines reconciliation best practice resource and toolkit page views on SPS website.




Source: SPS data analytics, Mar 2021

Utilising the content developed in the best practice resource and toolkit, the author published two CPD articles aimed at improving the standards of MR practice amongst the medical and nursing professions. The author targeted primary care staff including GPs through a publication in the Prescriber Journal and provided the readership with guidance and tools to undertake effective MR (Shah and Barnett, 2015). Similarly, the author targeted senior nursing managers through a publication in the Nursing Management Journal with the aim of informing them of the need of robust MR practices when establishing nurse prescribing roles or services (Shah, Ishmael, and Wright, 2015).

## 3.3 Medicines reconciliation at transfer of care

### 3.3.1 Introduction

There is significant evidence that when patients move between care providers and interfaces (particularly from secondary care to primary care), the risk of miscommunication around changes to medicines poses a significant problem (Avery et al, 2011), (Grimes et al, 2011), (Barber et al, 2009), (RPS, 2012). In 2009, a report by the health and social care regulator-the CQC in England stated that acute NHS trusts (hospitals) need to improve the information they provide on changes to medication at discharge and made the following recommendation: *"Ensure that contracts with acute trusts set out the requirements and quality markers for both the timeliness and content of discharge summaries. Information on diagnosis, changes to medication and the reason for them must be included. They should put in place contract variations to set this in place at the earliest opportunity, including incentives through the commissioning for higher quality and innovation (CQUIN) system and penalties for poor contract performance"* (CQC, 2009). Prior to the CQC raising its concerns, several national organisations and Royal Colleges had developed standards focussing on what and how medicines related information should be communicated on the discharge summary when patients are transferred from secondary to primary care (NPC, 2008) (AMRC, 2008). In 2011, the UK DH developed a toolkit to support NHS organisations to improve communication of medicines-related information during transfer of care (DH, 2011b). The practice study by Avery et al, 2011 discussed some of the difficulties that GPs face when dealing with hospital discharge medications, for example in the study GPs highlighted the need for the wording of hospital correspondence to be clear and accurate with any medication changes clearly highlighted. Interestingly, in the same study, there was also evidence that primary care clinicians do not always act upon the information provided in the discharge summaries (Avery et al, 2011).

In the author's opinion, despite the evidence and efforts, the majority of the attention in England has been targeted on implementing and improving MR at admission to hospital with a much lesser focus on improving MR at the point of discharge from secondary care into primary care. A possible explanation for this is that unlike in 2007 when the NPSA/NICE issued standalone clear guidance to implement MR at

admission to hospital, there has been no such comparable discrete guidance issued for implementing MR at transfers of care. In 2015, the NICE MO Guidance (NICE NG5, 2015) recommended that secondary acute trusts must recognise that MR may need to be carried out on more than one occasion during a hospital stay for example, when the person is admitted, transferred between wards or discharged to primary care. The guidance also stated that MR must be conducted in primary care for all people who have been discharged from hospital or another care setting as soon as is practically possible, before a prescription or new supply of medicines is issued and within 7 days of the GP practice receiving the discharge information from secondary care (NICE NG5, 2015). In 2017, the WHO launched its third global patient safety challenge titled "Medication without Harm". The medication without harm challenge contained three priority areas of which one was medication safety in transitions of care (WHO, 2017).

### 3.3.2 Key Publication 2: Shah C, Hough J and Jani Y. Medicine's reconciliation in primary care: a study evaluating the quality of medication-related information provided on discharge from secondary care. European Journal of Hospital Pharmacy.

In order to understand the barriers and to support the implementation of the NICE 2015 guidance on MR at transfers of care, the author designed and implemented a study to investigate the quality of medicines related information provided to primary care at the point of discharge from secondary care and whether GPs acted on the information in a timely manner. The two key studies on this topic prior to the author's work were those undertaken by Hammad et al (2014) in the East of England and by Grimes et al (2011) in Ireland, however neither study followed up whether the GP had acted on the information received from secondary care. The study conducted by Hammad et al (2014) included approximately 3444 discharge summaries sent to GPs that were retrospectively reviewed for the quality of medicines related information contained within them. The study found that the majority of discharge summaries failed to fulfil the requirements set out by the NPC guidance, of significant concern was that only 48.9% of discharge summaries complied with standards set out by the NPC on the reporting of medication therapy changes (medicines initiated, discontinued or doses changed with a corresponding reason). The second study undertaken by Grimes et al (2011) investigated the quality of MR on discharge from two Irish acute hospitals. The

study found that medication details documented at discharge from acute hospital care in Ireland frequently contain prescription writing errors or failed to communicate information regarding changes made during inpatient care. For example, of the 1245 discharge summaries reviewed, 21.5% of discharges failed to document that a medicine that the patient had been taking prior to admission had been stopped during the inpatient stay. A limitation of both studies is that the discharge summaries reviewed were from a select few hospitals and therefore the results may not be representative of practice in all secondary care hospitals. In their study, the author addresses this limitation by reviewing approximately 1454 patient discharge summaries across 74 hospitals spanning all four NHS regions in England.

The author's success in using a dialogic and collaborative research methodology with a practice–research engagement group for the development of the MR best practice resource and toolkit led them to use the same method in this study. However, the composition of the practice–research engagement group for this study was amended to include pharmacists from NHS secondary and primary care, academia, and a member from the NICE medicines implementation team. Through the practice–research engagement group designed the author was able to develop, pilot and validate the study tools (study protocol, data collection form, hints and tips document and a collation of frequently asked questions). Data collection in the study was achieved through enlisting the network of pharmacists employed by the participating CCGs and requesting them to collect the data at GP practice level. All data was returned to the author who undertook the analysis centrally. The author's work resulted in it being the largest study of its kind in the UK. The study included 43 CCGs covering each of the four NHS Regions in England. The study included data for 1454 patients discharged from secondary care hospitals in England and 10,038 prescribed medicines and their subsequent MR in primary care.

#### 3.3.2.1 Key findings and discussion

The study found that the majority of medication details were stated in accordance with standards required with the exception of indication (11.7% compliance), formulation (60.3% compliance) and instructions of on-going use (72.5% compliance). The high compliance in discharge prescription writing standards was most likely due to the use

of electronic discharge templates which have set mandatory fields that must be completed when writing a discharge prescription. The low compliance in relation to documentation of drug indication reflects the challenges hospital clinicians may have of not always knowing the primary indication for established or chronic medicines, particularly if it has no bearing on the patient's admission. Recording an erroneous or assumed indication in the absence of certainty has the potential to lead to confusion for the patient and GP.

The study found that documentation about changes to medication regimes during the hospital inpatient stay was poor, only half, (49%, 1550/3164) of newly started medicines, 39% (186/477) of dose changes and 57% (420/738) of stopped medicines had a reason documented in the discharge summary. The findings from the author's study echo the findings of a systematic review conducted by Michaelsen et al (2015) on MR at discharge from hospital found that between 20% and 87% of patients encounter discrepancies at discharge. The novel aspect of the author's study was its investigation of MR in primary care. The results of the study were relatively positive in that only 12.5% of patients did not have their medicines reconciled within 7 days of receiving the discharge information from hospital.

In a recent qualitative study undertaken in Ireland attempted to understand the barriers and facilitators of MR at transitions of care, the study found that barriers included factors such as resistance from existing professional cultures, lack of staff interest and training, poor communication and poor information and communications technology (ICT) support (Redmond et al, 2020). Solutions suggested included supporting effective MDTs, greater involvement of pharmacists in MR, ICT solutions (linked prescribing databases, decision support systems) and increased funding to provide additional MR (e.g., admission and discharge reconciliation) and more advanced services (e.g., community pharmacist delivered medicines use review) (Redmond et al, 2020).

### 3.3.2.2 Impact and associated outputs

The study highlighted the significant medication safety issue at a national level and at individual hospital and CCG level. The results were presented to Chief Pharmacist Groups across England, included in press reports by the RPS in the Pharmaceutical Journal (Pharmaceutical Journal, 2016) and presented at conferences such as the International Society for Quality in Healthcare Annual (ISQUA) conference.

Each participating CCG was provided with its own report that compared its data to the national dataset. This allowed CCGs and local secondary care providers to collaborate to review the local hospital discharge template to ensure that it meets the needs of all involved. The author is aware that post publication several CCGs developed local quality targets or action plans to improve on the issues identified in the study.

One of the recommendations in the study by the author was for consideration to be given to designating the responsibility of MR in primary care to the growing number of clinical pharmacists employed within GP practices. The RPS included this recommendation when they designed a job description template for GP practice-based pharmacists and included the following statement in the job description "*reconcile medicines following hospital discharge and work with patients and community pharmacists to ensure patients receive the medicines they need post discharge"* (RPS, 2016).

In 2021, NHS England launched the NHS discharge medicines service (DMS) under the community pharmacy contractual framework. The service has been established to ensure better communication of changes to a patient's medication when they leave hospital and to reduce incidences of avoidable harm caused by medicines. As an essential service, it must be provided by all community pharmacy contractors in England. Although not cited, it is highly probable that the author's work contributed to the development of the DMS as it addresses many of the issues identified in the author's study.

As a result of this study and other outputs related to MR, the author has been recognised as a knowledgeable individual in this research area and has been requested to peer review several articles for journal publications. The Northern Ireland

Regulation and Quality Improvement Authority (RQIA) sought permission from the author to utilise the study tools to conduct their own regional audit of MR on discharge documentation (RQIA, 2017) and in 2020 they requested the author to peer review their follow up audit (RQIA, 2020).

## 3.4 Medicines reconciliation and clozapine

### 3.4.1 Introduction

Within England, there are many medicines that are often prescribed and supplied by secondary care services either due to the specialist nature of the medicine, monitoring requirements, cost, or all of these factors. For example, medicines for Human Immunodeficiency Virus (HIV), certain immunosuppressant medicines for organ rejection, biologic medicines and oncology medicines are, in the majority of cases, prescribed by secondary care clinicians and supplied either through the hospital pharmacy or a homecare medicines delivery provider. A homecare medicine delivery provider is a service that delivers ongoing medicine supplies and, where necessary, associated care, initiated by the hospital prescriber, direct to the patient's home with their consent.

In these circumstances, the GP is generally made aware of the medicines being prescribed by the secondary care clinician through their clinic letters. If the secondary care services have not furnished the GP with the medicines related information or the GP has not updated their clinical systems with the information provided, the details of these medicines will not appear in the GP clinical system which will impact the GP clinical decision-making software and patient summary care record (SCR).

In the discipline of psychiatry, the two medicines rarely transferred to primary care for prescribing are the antipsychotic clozapine and long-acting antipsychotic injections. A key implication of a lack of record of clozapine treatment recorded on GP clinical systems are that any drug interactions between clozapine and other drugs prescribed by the GP will not be alerted through the GP clinical decision-making software. This presents a significant risk as clozapine is predominantly metabolised by the cytochrome P450 isoenzyme 1A2 (CYP1A2) and therefore has many clinically significant drug interactions mediated by CYP1A2 inhibitors which are frequently

prescribed in primary care for example the antibiotic ciprofloxacin. Another key implication is that patients presenting with physical health concerns such as constipation, infection, development of diabetes or cardiovascular disorders may not be recognised as a potential adverse effect of clozapine treatment and thus misdiagnosed. For example, the gastrointestinal adverse effects of clozapine are extremely serious and potentially fatal such that in 2017 the MHRA issued a drug safety alert requesting that all healthcare professionals should advise patients to report constipation immediately, actively treat any constipation that occurs and to exercise particular care in certain patient groups (MHRA, 2017). A further key implication of not recording clozapine on GP clinical systems is that it will not appear on the patient's SCR. Healthcare professionals in secondary care, particularly in acute services rely heavily on the SCR to complete MR at admission to hospital. Omission of clozapine doses for more than 48 hours can lead to the need for re-titration of clozapine dosing which may possibly lead to deterioration of the patient's mental health.

In 2017, the author planned a series of quality improvement activities with respect to the clozapine pathway in their NHS trust. As part of this quality improvement programme, the author aimed to improve the recording of clozapine medication in primary care systems.

### 3.4.2 Key Publication 3: Butterworth S and Shah C. An audit of clozapine recording in primary care patient records. The Pharmaceutical Journal.

A series of medication incidents within the author's local area led to concerns about the lack of records of clozapine treatment on GP clinical systems. Over a period of several months, patients who were well maintained on clozapine were admitted to the local general acute hospital for medical issues unrelated to their mental health or clozapine treatment. On admission to hospital, the MR undertaken had not identified that patients were maintained on clozapine treatment because clozapine was not listed in the patient's SCR. Unfortunately, in two cases, interruption in clozapine treatment led to the patient's mental health deteriorating to an extent such that it warranted an inpatient admission to a mental health ward.

As a result of the incidents and the quality improvement programme, a short study was undertaken with all GP practices in the locality with the support of the local CCG. The

methodology for the study included the development of a data collection tool that was sent to GP practices with known clozapine patients on their registers. The GP was requested to complete the data collection tool following a review of the patient's clinical notes. For each identified patient maintained on clozapine, the GP was requested to ascertain whether clozapine treatment was documented in the patient's clinical notes and SCR. Additionally the GP was requested to identify whether any prescriptions were issued for laxatives in the previous six months and/or if the patient had presented with constipation in the previous three years and whether this had been attributed to clozapine treatment. The purpose for the information regarding laxative use or presentation of constipation symptoms was due, as outlined earlier, to the serious gastrointestinal side effects of clozapine treatment which often go unnoticed. For every 1000 patients treated with clozapine, between 300 and 600 will develop constipation and four will develop serious gastrointestinal complications (including paralytic ileus, bowel obstruction, bowel ischemia and necrosis) from which one will die (EveryPalmer et al., 2016).

#### 3.4.2.1 Key findings and discussion

Of the 160 patients (85% response rate) for whom data collection forms were returned, 54% (n=86) of GP records clearly showed that the patient was taking clozapine and 51% (n=82) had clozapine recorded on their SCR. These results are similar to those found in a study conducted in 2010 in which only 55% of patients had a clear documentation in their GP records that they were prescribed clozapine (Parker and Somasunderam, 2010). A national study conducted by the Prescribing Observatory for Mental Health (POMH-UK) also found similar results where only 58% of patients (n=3,902) treated with clozapine had their clozapine treatment recorded in their SCR (Barnes et al, 2020) indicating this is an area that still requires improvement.

With regards to the issue of clozapine and constipation, the study found that onequarter (n=40) of patients were prescribed a laxative by the GP and that 28% (n=45) had complained of constipation in the last three years. Of those prescribed laxatives, 29% (n=13) were directly as a result of clozapine induced constipation.

#### 3.4.2.2 Impact and associated outputs

Although a somewhat simple study design, it focused on an extremely important issue that impacts patient care and safety. The findings demonstrate that for a significant number of patients, GP medication records are not fully complete with regards to specialist medicines which subsequently have implications on medication safety. For example, an incomplete GP medication record can affect clinical decision making, affect MR processes in secondary care that rely on an accurate SCR and lead to confusion at transfers of care. A key output of this study was that the author had provided the GPs with an up-to-date record of the patient's clozapine treatment regime when sending the data collection tool and GPs were requested to update their clinical systems with the information following the data collection exercise.

The key impact of this study was its simplicity and reproducibility that could be replicated by all mental health NHS trusts in England if supported by their CCG.

## 3.5 Summary

This chapter demonstrates the activities undertaken by the author to improve the quality of MR at a local and national level. The chapter describes how the author strategically assembled a range of experts from across academia and healthcare including front line practitioners and using dialogic and collaborative research methodologies led them to develop a set of best practice standards and research tools that have subsequently been used nationally to improve the quality of MR. The author's experience in MR has also led them to being recognised as a national expert in this area.

## Chapter 4: Delivering medicines optimisation to ensure the safe and effective use of medicines in patients with mental health and learning disabilities

### 4.1 Background

There is a universal acknowledgement in the UK that there has been a historical underinvestment in mental health services that has impacted access to services and the quality of care delivered (Kings Fund, 2019). In addition to the lack of historical investment, mental health services in England have also been the subject of significant change as a result of changing healthcare policy over the past 30 years. During this period mental health care provision has changed from principally hospitalising people with mental health problems into psychiatric institutions to treating patients in community-based settings. Between 1987/8 and 2016/17 there was a fall of 72.1% and 96.4% overnight mental health beds and learning disability beds respectively in England (Kings Fund, 2017). This equated to the number of inpatient mental health beds in England decreasing from 67,112 to 18,730 (Kings Fund, 2017). In 2012, the UK government committed to achieving 'parity of esteem' between mental and physical health services in the Health and Social Care Act 2012 (DH, 2012), pledging

to ensure that people experiencing mental health problems get the same access to safe and effective care as those with physical health conditions services (Kings Fund, 2019).

The role of medicines in treating mental health disorders gathered prominence in the 1950s with the introduction of medications such as chlorpromazine. An analysis of prescribing data between 1998 and 2010 showed that antidepressant and antipsychotic prescriptions increased by 10% and 5.1% respectively on average per year during the period of analysis (Ilyas and Moncrieff, 2012). Patients with mental illness often encounter many barriers to recovery including stigma, poor insight, complex medication regimens, and serious adverse reactions, which may lead to poor treatment outcomes (Compton et al, 2005). There are several unique factors to consider when applying the principles of MO in patients with mental illness. For example patient adherence can be significantly lower due to a variety of factors such as the lack of insight into the illness, the high number and range of intolerable adverse effects associated with psychotropic medications particularly antipsychotics, a higher propensity of toxicity due to high dose and combination antipsychotic prescribing, the number of high risk drugs (e.g. lithium, clozapine) that require close monitoring and the high number of psychotropic medications metabolised by the cytochrome P450 isoenzyme system which lead to a greater propensity for drug interactions. In addition, forced medication administration under the Mental Health Act 1983 can negatively impact the clinician and patient therapeutic relationship.

The author has been working in mental health services since 2003. From their observations, despite the significant efforts by successive governments to ensure parity of esteem between mental and physical health services, there are still significant gaps in resources to achieve this aim. In the author's opinion, the gap in resources extends to mental health pharmacy services which creates a significant barrier to deliver on the ambitions of the MO agenda. In addition, mental health research (including mental health pharmacy practice research) has lagged behind many other areas in terms of priority, funding, and therefore discoveries (DH, 2017). The author's research and activities are focussed on three key issues (i) MO in mental health, (ii)

stopping inappropriate psychotropic prescribing in people with learning disabilities and (iii) improving the physical health of people with severe mental illness (SMI).

## 4.2 Medicines optimisation in mental health

### 4.2.1 Introduction

The complexity of mental illness, the unique characteristics of psychotropic medicines described above and the shifting way that care is delivered pose a challenge to embed the four principles of MO described in chapter 1 in the mental health setting. A 2007 healthcare commission report (Healthcare Commission, 2007) found that "levels of medicines management support available within mental health trusts tended to be less than those found in acute trusts". The report cited "*that for mental health inpatients, 24 per cent of wards received no visits from pharmacy staff, compared to only 14 per cent in acute trusts, and only 14 per cent of mental health wards received more than five hours of pharmacy staff time each week, compared to 64 per cent in acute trusts*". The report also cited "*that there were noticeably fewer pharmacy staff in mental health trusts, and the staff mix is also different, with fewer pharmacy assistants and technicians*". In the author's opinion, despite the 2007 healthcare commission report, significant variance still remains in the resources provided to and the way in which pharmacy service are delivered in mental health NHS trusts when compared to acute trusts.

In 2017 and 2018, the author was a member of a NHS steering group that informed the Lord Carter of Coles report to the UK government on the operational productivity review of unwarranted variations in mental health services and community health services (NHS England, 2018). Through the author's involvement in the steering group and review of the subsequent report, the author believes that mental health pharmacy services are not resourced adequately or designed well enough to deliver fully and consistently on the principles of MO. For example, through the steering group dialogue and analysis, it was apparent that on average 80% of the clinical pharmacy resources in mental health and community health NHS trusts are allocated to bed-based care despite the majority of clinical care actually being delivered in community settings (NHS England, 2018). In the author's opinion, the limited pharmacy resource available needs to be rebalanced such that MO activities are proportionally targeted to

community based mental health settings. The author has attempted to undertake this rebalancing within their own NHS trust and some examples are discussed below.

**4.2.2 Key Publication 4: Shah C, Umaru N, Adams E et al. Assessment of the impact of integrating pharmacist independent prescribers into child and adolescent mental health services. The Pharmaceutical Journal.** Despite many pledges and objectives set out since 2010, child and adolescent mental health services (CAMHS) in England have struggled to meet expectations due to high demand for services and staff recruitment challenges which have led to long waiting times and restricted access to services (NHS benchmarking, 2018). The author's employing NHS trust faced a similar challenge, therefore in conjunction with senior clinicians, management and commissioners, the author discussed the feasibility of recruiting pharmacist independent prescribers firstly to support workload pressures and secondly to improve the medicines related aspect of the care pathway. The author proposed that pharmacists would be integrated within the community CAMHS MDT with the aim for them to be trained as independent prescribers to manage a delegated caseload of children and young people with attention deficit hyperactivity disorder (ADHD).

There is limited published literature on the role of pharmacists working as independent prescribers within mental health settings especially in disciplines such as CAMHS. The two key references found on the use of pharmacist independent prescribers in the CAMHS setting were by Lyon and Brown (2018) that described a naturalistic evaluation on the deployment of a dedicated pharmacist to support CAMHS to optimise medicines use through working with medical staff and managers and a conference abstract by O'Brien (2019) that reported the benefits of establishing a pharmacist led ADHD titration clinic. Both publications reported a range of benefits to including specialist pharmacists within community CAMHS.

In order, to add to the limited literature base, the author decided to evaluate their project through an action research methodology approach. The action research methodology was designed to:

- Understand the contributions to care made by specialist pharmacists integrated into the community CAMHS MDT
- Identify pharmacists' contributions within a pharmacist independent prescriber led ADHD clinic
- Understand the service user experience
- Understand the acceptance of the specialist pharmacist and pharmacist independent prescriber role within CAMHS by other healthcare professionals.

The author utilised a variety of research methods in this evaluation such as a questionnaire with children and young people and their families to understand their experience of a pharmacist led ADHD clinic and a questionnaire to understand healthcare professionals' experience of working with the pharmacists' within their MDTs. In order to gain a more in-depth understanding of the value of having a pharmacist within the MDT, a focus group interview that included psychiatrists, psychologists, nurses, social workers, and administrative staff was also undertaken.
To identify the pharmacists' contributions to care, the author developed a data collection tool based on the work undertaken by Rogers et al (2016), the tool allowed the pharmacists to capture data on their routine clinical activity and interventions. The study used the overarching principles of action research methodology as care delivery, practices and, processes were iterated and evolved throughout the study period based on results and feedback.

#### 4.2.2.1 Key findings and discussion

Over a 2-month period, the pharmacists' self-reported a total of 322 contributions to care that encompassed pharmaceutical activities such as medication review, provision of medication related advice, monitoring of physical health parameters and transcribing activities. The number and breadth of contributions reflected the varied duties and responsibilities that the pharmacists' had assumed. In the evaluation of the pharmacist led ADHD clinic, the pharmacists' made changes to children and young people's medication regime in 46% of consultations (dose changes in 26%, new medication started in 14% and medication stopped in 6% of cases). With respect to

physical health monitoring, the pharmacists' identified concerns in six (12%) patients of which four centred on growth related issues. The family/carer experience survey of the pharmacist led ADHD clinic had a 40% response rate and was extremely positive with only one family indicating that they would have preferred to have had a consultation with a Dr instead of the pharmacist.

The results from the electronic survey undertaken to identify the acceptance of MDT colleagues on the role of the pharmacist was extremely positive. In total 13 MDT staff (4 psychiatrists, 3 psychologists, 3 administrative staff, 2 nurses and 1 social worker) responded to the electronic survey and over 90% of the respondents thought that the introduction of the pharmacist role was either very or extremely beneficial for the team. The positive impact of the pharmacist's roles was further affirmed by members of the CAMHS team during the focus group discussions in which they communicated specific descriptions of the pharmacists' contributions and their value.

#### 4.2.2.2 Impact and associated outputs

Through the evaluation, the author was able to demonstrate and share that a pharmacist can be recruited, trained, and integrated into an MDT CAMHS team and that they can be managed and supervised by a consultant psychiatrist in a similar manner to a speciality doctor. The work also demonstrated that pharmacists could develop a defined scope of practice that allows them to manage a delegated caseload of patients safely and effectively such as in ADHD and that they can add value to the wider CAMHS MDT with their pharmaceutical expertise. The evaluation demonstrated that by having such roles, medicines related issues within the CAMHS pathway including interface problems can be resolved more effectively and efficiently. In general, the evaluation found that the addition of pharmacist independent prescribers into a community CAMHS MDT and their contributions are highly accepted by other health professionals, children, young people, and their families.

The robust evaluation of the project has led to organisations such as Health Education England (HEE) and the NHS Improvement Getting It Right First Time (GIRFT) programme citing the work as a potential solution to support the increasing challenge faced by CAMHS services across England in meeting demand for services (HEE,

2019). Similarly, through network discussions and conversations at conferences, the author has been asked to share the project model, recruitment strategy and business case with three other NHS Trusts (Oxford Health NHS Trust, South West London and St George's Mental Health NHS Trust and Lincolnshire Partnership NHS Foundation Trust). The author also organised a CAMHS pharmacist network meeting in September 2019 to support pharmacists working in similar roles to collaborate, share experiences, support each other, and develop their roles further. The project was shortlisted for the 2021 Health Services Journal (HSJ) Value Awards in the Pharmacy and MO Category.

### 4.2.3 Key publication 5: Vekaria S, Shah C, Barnett N et al. Implementing a pharmacist-led medicines optimisation clinic in a community mental health team. Journal of Medicines Optimisation.

The CQC conducts a comprehensive annual survey of community mental health patients experience of care, the survey contains 4 questions related to medicines which are described below:

- Involvement in decisions - for those receiving medicines and whether they were involved as much as they wanted in decisions about medicines received
- Purpose of medication - for those receiving medicines to establish whether a discussion has taken place with someone from NHS mental health services on the purpose of the medication
- Side effects - for those receiving medicines to establish whether a discussion about the possible side effects has occurred with someone from NHS mental health services
- Medicine review - for those receiving medicines for 12 months or longer to explore whether a mental health worker checked how they are getting on with their medicines

The 2018 CQC community mental health survey reported that people's experiences of community mental health services had deteriorated across the four areas described above and, in some respects, represented a continued negative trend since 2014 nationally (CQC, 2018). Despite the clear evidence that patients do not feel involved as much as they wanted in decisions about medicines received, shared decision

making (SDM) is not yet standard clinical practice in mental health care (Royal College of Psychiatrists, 2014) and research around SDM in mental health is still lacking. For example, a systematic review of SDM interventions in mental health found only two eligible studies that concluded that further research was urgently needed (Duncan, 2010).

As described earlier in the chapter, the author foresaw a need for mental health pharmacy departments to rebalance the limited clinical pharmacy resource available such that it is proportionally distributed between bedded mental health services and community mental health services. In line with this view, the author planned a series of interventions in their NHS trust to improve service user's experience of medicines especially in community mental health settings that included a trust wide initiative to embed a culture of SDM to medicines use. One of the interventions included piloting a formal pharmacist led MO clinic in a community mental health setting. The concept of a MO clinic for patients with mental illness in a community setting has been established and proved to deliver successful outcomes in a variety of publications (Bell et al, 2007, Raynsford, 2018).

The aim of the MO clinic was to provide patient centred MO consultations to improve patient experience and reduce potential harm. The evaluation of the pilot was designed to:

- Understand the medicines related issues experienced by service users
- Identify pharmacist contributions in a community mental health MO clinic
- Understand the service users' experience

The study included the development of a tool that allowed the pharmacists to capture data on their routine clinical activity and interventions, use of a patient experience questionnaire and development of a questionnaire for use with the referring clinician to identify whether the pharmacist contributions directly improved care. All data generated was quantitative and therefore analysed descriptively.

#### 4.2.3.1 Key findings and discussion

The MO clinic received 30 referrals from several psychiatrists, of the 30 referrals, 23 (77%) patients attended the MO clinic. Most patients were referred to the MO clinic for more than one reason with the most common reasons being side effects and information about alternative treatments. In total, 83 interventions were made across the 23 patients with 6 patients switching treatment to an alternative medication. An intervention that potentially avoided severe harm, was the identification of clozapine induced gastric hypomotility (CIGH) which is a serious life-threatening adverse effect of clozapine.

In total, 11 (48%) patient experience questionnaires were returned and indicated that the MO clinic was well received by patients. Similarly following each appointment, the referring clinician was sent an online questionnaire to obtain their satisfaction on the outcome of the clinic appointment, from the 23 questionnaires sent, 6 (26%) were returned of which 83% found the pharmaceutical support provided extremely beneficial in managing the care of the patient.

The pilot demonstrated the positive impact of a MO clinic for patients with mental illness in a community setting particularly if the principles of SDM are used. However, the pilot also identified that a significant amount of time is required to operate such a clinic as on average approximately 3 hours and 34 minutes (range: 90-430 minutes) was spent on each of the referred patients with half of this time spent preparing for the consultation.

#### 4.2.3.2 Impact and associated outputs

The MO pilot provided strong evidence for the role of specialist mental health pharmacists in a community mental health setting. As a result of the pilot success, the author was able to secure funds to establish a substantive pharmacist role in a community setting which they were able to position into the newly formed integrated NHS structure (Secretary of State for Health and Social Care, 2021). A key focus of the role is to support the emerging Primary Care Networks (PCNs) which are the cornerstone of the new integrated NHS structure with specialist mental health medicines advice.

The work undertaken in the MO clinic and the initiatives to embed the principles of SDM into medicines related consultations resulted in a significant improvement in the 2020 CQC community mental health survey medicines related questions for the author's NHS trust. This improvement resulted in the author's NHS trust being placed in the top 20% of NHS trusts nationally. The MO pilot was shortlisted for the 2020 HSJ Patient Safety Awards in the Pharmacy and MO Category.

## 4.3 Stopping inappropriate psychotropic prescribing in learning disabilities

### 4.3.1 Introduction

In 2016, NHS England launched a campaign to **St**op the **O**ver **M**edication of **P**eople with a learning disability, autism, or both (STOMP) (NHS England, 2021). The STOMP programme was based on a key report published by Public Health England (PHE) that highlighted more psychotropic medicines are prescribed for people with learning disabilities than in the general population, that nearly one third of adults known to have a learning disability were receiving one or more psychotropic medicine of which more than half did not have a mental health diagnosis documented in their clinical notes and finally that medicines were not reviewed regularly (Public Health England, 2015).

In 2019/20 the Learning Disabilities Mortality Review (LeDeR) Programme which aims to improve the quality of care and health outcomes for people with a learning disability made a recommendation for clinical pharmacists to be deployed across PCNs to undertake structured medication reviews for high-risk patients to address issues such as over-medication (NHS England, 2020).

Although the evidence indicating that people with learning disabilities are prescribed psychotropic medication inappropriately is strong, a recently published longitudinal prospective cohort study that investigated psychotropic prescribing rates in people with intellectual disabilities over a 10-year period found that the rate of antipsychotic prescribing in people with intellectual disabilities had decreased from 24.5% in 200204 to 16.7% in 2014 (Henderson, 2020). The study did however find that the rate of antidepressant prescribing had increased from 11.2% to 19.1% during the same period. The study did not evaluate the appropriateness of prescribing or whether

medications were reviewed regularly therefore requires some caution when interpreting findings.

### 4.3.2 Key Publication 6: Adams D and Shah C. Reducing antipsychotic prescribing in people with learning disabilities. Clinical Pharmacist. Key publication 7: Adams D and Shah C. Prescribing of psychotropic medicines: the role of learning disability nurses. Learning Disability Practice.

Despite the programmes endorsement by The Royal Colleges of Nursing, The Royal Colleges of Psychiatry, GPs, the RPS and the British Psychological Society at the initial launch of the NHS England STOMP campaign, there were few published tools or guidance documents to provide practical support to clinicians to stop psychotropic medications in people with learning disabilities. The lack of such tools or guidance was considered a significant gap by the author, therefore, along with a colleague the author developed a range of supportive tools for clinicians. The author used a combination of document analysis, narrative literature review and their expert knowledge of psychotropic medication to develop a guidance document for clinicians to use internally within the author's NHS trust. This guidance document was also translated into CPD publications so that the information could be shared more widely. The publications were also used as tools to engage clinicians locally to raise awareness and implementation of the STOMP campaign.

#### 4.3.2.1 Key findings and discussion

In the production of the guidance document and publications, the author was able to provide a number of hints and tips on how to withdraw psychotropic medication safely and how to manage the consequences of stopping psychotropic medications. For example, one of the factors rarely considered when stopping an antipsychotic is that it may lead to a reduction in antipsychotic induced raised prolactin levels, this reduction in prolactin levels may lead to a normalisation of the menstruation cycle in women which would require considerations such as contraception if the person was sexually active or support around symptoms related premenstrual syndrome to ensure they are not conflated as challenging behaviour. Another key consideration often overlooked that was highlighted in the publications was that the removal of the sedating effects of

psychotropic medication may result in people with learning disabilities to be more alert and engaged in activities. Therefore, carers, support workers, families and social workers need to ensure that appropriate programmes of social activities are in place to prevent boredom and provide stimulation.

#### 4.3.2.2 Impact and associated outputs

Through the publications, the author was able to engage clinicians within their NHS trust and local primary care leads to raise awareness of the NHS England STOMP campaign and to work collaboratively to achieve the aims of the campaign. The author with the support of a colleague was able to develop a toolkit that facilitated GPs and specialist mental health clinicians to review psychotropic medication in people with learning disabilities with an aim to de-prescribe where possible in a safe and cautious manner. The toolkit assisted GP practice managers to identify people with a learning disability that were prescribed a psychotropic medication, supported the GP to undertake a medication review through a custom designed medication review template and if required seek prompt support from the specialist learning disabilities staff at the author's NHS trust. In addition, the author in conjunction with the consultant psychiatrists developed a local registry of people with learning disabilities who were prescribed a psychotropic medication. The register was designed to track the outcomes of a quarterly medication review. An analysis of the registry found that between April 2017 and March 2018 out of the 347 patients who were prescribed psychotropic medications, 41 patients were successfully discontinued a psychotropic medication.

The author's publication (Adams and Shah, 2016a) is cited on the RPS Medicines Optimisation STOMP webpage (RPS, 2021) and CPPE learning disabilities hub (CPPE, 2021) as a resource to support the wider pharmacy profession to review psychotropic medication in people with learning disabilities. The author is also part of a team that is currently undertaking a systematic review into the de-prescribing (reduction or withdrawal) of psychotropic medicines in people with intellectual disabilities for challenging behaviours. The systematic review has been registered with the international database of prospectively registered systematic reviews (NIHR, 2021) and is planned for submission to a high impact journal in 2021.

## 4.4 Improving the physical health of people with severe mental illness

### 4.4.1 Introduction

People with a diagnosis of SMI experience significant health inequalities that contribute to a life expectancy that is up to 20 years shorter than the general population (NHS England, 2016a). In addition to the shorter life expectancy, in comparison to the general population, people aged under-75 in contact with mental health services in England have death rates that are 5 times higher for liver disease, 4.7 times higher for respiratory disease, 3.3 times higher for cardiovascular disease and 2 times higher for cancer (Public Health England, 2017). The mechanisms through which these health inequalities, increased burden of physical ill-health and reduced life expectancy arise are complex and involve interrelated factors that include (1) wider social factors such as unemployment and poverty, (2) increased behaviours that pose a risk to health such as smoking and poor diet, (3) lack of support to access care and support, (4) effects of medication which include weight gain, (5) stigma, discrimination, isolation and exclusion preventing people from seeking help and (6) diagnostic overshadowing which is the misattribution of physical health symptoms to part of an existing mental health diagnosis (NHS England, 2016b).

Although improving the physical health of people with SMI extends beyond MO, there is a strong relationship between the cardio metabolic side effects of antipsychotic drugs and poor physical health (Del Campo et al, 2018). Second generation antipsychotics are known to increase cardiovascular risk through several physiological mechanisms that include insulin resistance, hepatic steatosis, hyperphagia, and accelerated weight gain (Del Campo et al, 2018). Antipsychotics have also been directly linked to adverse vascular effects such as increased or reduced blood pressure, increased risk for thrombosis and endothelial alterations (Kahl, WesthoffBleck and Kruger 2018). Frequently there are limited prophylactic interventions to prevent these side effects in partly due to a lack of understanding of the molecular mechanisms that cause these side effects (Del Campo et al, 2018). The unpalatable side effects of antipsychotic medication are a significant contributor to the high level of non-adherence amongst people with a SMI which is estimated to be at least as high as 40%–50% (Lacro et al, 2002) (Sajatovic et al, 2006).

### 4.4.2 Key Publication 8: Shah C and Aslanpour Z. A new year, new horizons and a new agenda for public mental health. The Pharmaceutical Journal. Key publication 9: Shah C, Zia A, Aslanpour Z, Mehra Z. A evaluation on the role of Community and GP practice-based Pharmacists in supporting the physical health of patients with severe mental illness (SMI). The 10th Annual International College of Mental Health Pharmacy (CMHP) Conference. United Kingdom.

In 2010, the author published an opinion piece on the role that the pharmacy profession could play in public mental health (Shah and Aslanpour, 2010). The publication was based on the new government strategy for mental health "New Horizons" in England. The author utilised a combination of document analysis and narrative literature review as the research methods to draft the publication. The documents reviewed were primarily UK government policy documents along with guidance from professional pharmacy bodies. The author reviewed the selected documents using the eight-step process as described by O'Leary (2014) which included outlining emerging themes from the UK government strategy and reviewing the literature to identify examples of how the pharmacy profession could contribute to delivering those strategic objectives through their everyday practice.

One of the key reasons for the publication was because the author noted a paradigm shift towards a more preventative approach to mental health and wellbeing in the new horizons strategy (2010-2020) when compared to the previous 10-year strategy. The author believed that this change in approach presented a real opportunity for the pharmacy profession to make a significant contribution to mental health as it aligned strongly to the deliverables set out in the 2008 UK government pharmacy white paper "*Pharmacy in England Building on strengths – delivering the future*" (DH,2008). The author strongly believed that pharmacists could play a pivotal role in delivering the public mental health aspirations of the new horizons strategy particularly helping remove the stigma associated with mental illness through talking about mental health issues and making brief interventions where possible.

Although progress on the role of pharmacists in mental health continued to be made, it was not until 2018 that momentum was generated across the profession on the full contribution that pharmacy can make to mental health care. In 2018, the RPS held a roundtable discussion event to identify how pharmacy can support people with mental health problems (RPS, 2018) and in 2020 the RPS published their guidance document titled *"Improving care of people with mental health conditions: how pharmacists can help"* (RPS, 2020). The RPS efforts were supported by CPPE who launched a national mental health campaign to raise the profile of mental health conditions and to explore how pharmacy professionals can improve their support for people living with mental health conditions. In 2019, the author in collaboration with CPPE and RPS hosted the Hertfordshire and Bedfordshire Local Practice Forum (LPF) to discuss how community pharmacists locally could best support the physical health of patients with SMI. During the event which was reported on by the RPS (Pharmaceutical Journal, 2019), the author developed and utilised a questionnaire with the attendees to identify their confidence in supporting various aspects of physical health for people with SMI.

#### 4.4.2.1 Key findings and discussion

Despite the author not being employed in the mental health sector between 2010 and 2016, from their perspective, it was not until 2018 that real momentum occurred in the pharmacy profession to support the physical health of patients with mental illness despite there being a clear role for pharmacists in this domain. The results of the questionnaire conducted by the author at the RPS LPF event demonstrated that pharmacists in general feel confident in supporting the physical health of patients with mental illness particularly around cardiovascular interventions, contraceptive advice, smoking cessation and advocating for public health screening programmes. This confidence is likely to have arisen due to the increasing number of public health services commissioned from community pharmacy since the UK government 2008 pharmacy White Paper (DH, 2008). For example, in a literature review conducted by Agomo et al (2018) they describe how community pharmacy based public health interventions have shown to be effective in smoking cessation, health promotion, disease screening and preventive activities, provision of emergency hormonal contraceptive, and vaccination services. In the survey completed by the author, participating pharmacists indicated they felt less confident in advising patients on

dental and bowel health hygiene. This is an important finding as the anti-muscarinic side effects- such as dry mouth and constipation of psychotropic medications can significantly impact the dental and bowel health of patients which as previously outlined, in clozapine treated patients can be extremely serious as articulated in the 2017 MHRA national drug safety alert (MHRA, 2017).

#### 4.4.2.2 Impact and associated outputs

In recognition of the need to increase the role of pharmacists within public mental health, the author at the time of writing the 2010 opinion piece whilst in an academic role at the UoH was able to integrate the concepts of public mental health into the 4th year public health module of the undergraduate pharmacy course. The focus of the teaching was on the promotion of mental health wellbeing, prevention of mental illness and prevention of disability due to mental illness which was delivered through a series of lectures, workshops, and simulation. Although the impact of this teaching on students was not evaluated formally, it was incorporated into the summative assessments for the module. The author therefore had incorporated an extremely important topic into the undergraduate pharmacy curriculum at a critical stage of the pharmacy student's development.

### 4.4.3 Key publication 10: Shah C, Singh P, Matin S et al. An evaluation of a physician associate led enhanced physical health clinic for people with severe mental illness (SMI) in the United Kingdom. Journal of the American Academy of Physician Assistants.

Physician associates (PAs) are medically trained, generalist healthcare professionals, who work alongside doctors and provide medical care as an integral part of the MDT (Royal College of Physicians, 2021). In the UK, the PA profession is considered as reasonably 'new' and even newer in the discipline of psychiatry (Royal College of Physicians, 2021). In 2018, the UK had approximately 1000 graduate PAs, 1200 PAs in training with only 20 known to be employed in mental health settings (Royal College of Psychiatrists and Health Education England, 2019). The role and duties of PAs working in mental health has been considered and defined in an implementation toolkit developed by the Royal College of Psychiatrists and Health Education England (Royal College of Psychiatrists and Health Education England, 2019). In this toolkit, it

suggests that physician associates can carry caseloads under supervision, carry out full psychiatric and risk assessments, and liaise with other services, as well as (1) prepare reports and discharge summaries, (2) undertake basic psycho-therapeutic interventions, (3) perform service quality improvement and audit activities, (4) deliver education to service users and other staff, (5) assist the consultant by writing letters, chasing referrals/treatments, and prepare medical notes and (6) undertake physical assessments and procedures.

Although in general outside the scope of a Chief Pharmacist role, in their NHS mental health trust, the author was requested to support the deployment of two PAs in conjunction with two consultant psychiatrists that were designated to line manage the PAs. The request was due to the author's previous activities and interest in improving the physical health of people with SMI coupled with their philosophy of an MDT working approach to care delivery (see chapter 5). The author along with medical colleagues designed a PA led enhanced physical health clinic for people with a SMI that aimed to review and where appropriate intervene on (1) body mass index, (2) blood pressure, (3) glycemic control, (4) ECG findings, (5) lipid profile, (6) smoking status, (6) medication side effects and (7) uptake of national public health screening programmes such as cervical, breast and bowel cancer and abdominal aortic aneurysm.

The author evaluated the PA led clinic through an action research methodology whereby a tool was developed to capture data on the routine clinical activity undertaken by the PAs within the clinic. A validated patient experience questionnaire from the Faculty of Physician Associates was used in addition to a follow up telephone questionnaire to identify the outcomes of any interventions.

#### 4.4.3.1 Key findings and discussion

A total of 72 patients accessed the PA led enhanced physical health clinic during the study period. The findings of the study are purposely described at patient level as they present a powerful narrative of how the interventions impacted each patient's health and wellbeing. The PA interventions led to one patient being diagnosed with diabetes who was subsequently commenced on the anti-diabetic medication metformin and similarly two patients who were diagnosed with pre-diabetes and were commenced on

the NHS diabetes prevention programme. One patient was diagnosed with hyperlipidaemia and commenced on the cholesterol lowering medication simvastatin. One patient was persuaded to switch from cigarettes to e-cigarettes. One patient had their medication changed from olanzapine to aripiprazole due to metabolic adverse effects. One patient whose blood tests showed haematological abnormalities was referred to secondary care. Three service users that were eligible for NHS cancer screening services but had not accepted the invitations were supported to do so by the PA.

The key findings from this evaluation were that PAs can be integrated into a community mental health MDT, can operate a physical health clinic for SMI patients and deliver meaningful interventions that support the physical health of people with a SMI.

#### 4.4.3.2 Impact and associated outputs

The findings from the evaluation have led to an expansion of PA led enhanced physical health clinics in the author's NHS trust including the development of new integrated models of care whereby the clinic is delivered in a primary care setting in conjunction with the GP practice nurse. The tools used in the evaluation have been developed into a physical health toolkit that is now used across the author's NHS trust and primary care therefore providing a consistent approach to supporting the physical health of people with a SMI.

The following comments were received from the peer review process during the submission of the publication to the Journal of the American Academy of Physician Assistants:

*"The authors are to be commended for their effort, as the topic is important and of interest to PAs internationally. In the US, PAs have been historically underutilized in psychiatry".*
*"Creation of just the sort of service the authors describe has been proposed or attempted in a limited fashion, even in the relatively mature practice environment of the US".*
*"This is also an important initiative in the UK that could benefit the NHS and SMI patients more broadly"*

These comments demonstrate the impact of the evaluation which can hopefully encourage mental health trusts in England to consider developing roles for PAs in their workforce planning.

## 4.5 Summary

This chapter demonstrates the activities undertaken by the author to improve the safe and effective use of medicines and physical health within the mental health and learning disabilities setting. Using action-based research methodologies, the author designed, implemented, evaluated, and published innovative interventions that have led to safer and more effective use of medicines and improved the physical health of people with SMI. The author's strategic leadership has led to the development of new roles for pharmacists and PAs in mental health on a national level. Document analysis research methods have allowed the author to translate strategic directives issued by the UK government into practical operational deliverables for the pharmacy profession.

## Chapter 5: Embedding the principles of medicines optimisation through a multidisciplinary approach

### 5.1 Background

The prescribing of medicines is the most common intervention that occurs in the NHS across all sectors of care and is the second highest area of spending in the NHS after staffing costs (NHS Digital, 2020). In 2019/20, the NHS spent approximately £20.9 billion on medicines which is an increase of 9.9% from the previous year, of this the secondary care hospital drug expenditure accounted for just over half (55.9%) of the total at £11.7 billion (NHS Digital, 2020). Despite the significant investment into medicines, there is a substantial body of evidence to indicate that medicines use can be suboptimal in various ways or can even cause harm. For example, it has been estimated that between 30% and 50% of medicines prescribed for long-term conditions are not taken as intended (NICE QS120, 2016), up to £300 million worth of medicines are wasted each year in primary care (York Health Economics Consortium, 2010) and adverse drug reactions account for 6.5% of hospital admissions (Pirmohamed, 2004). In general, over or under use of medicines leads to diminished benefits, greater costs and increased harm (Kings Fund, 2013).

The medicines use process is a complex process, but which can be broadly classified into four key phases as follows: (1) prescribing, (2) dispensing, (3) administering, and (4) monitoring. The key health related professional groups involved in the medicines use process in a hospital or healthcare managed settings such as a nursing home are usually medical, pharmacy and nursing staff. For the medical profession, the prescribing and monitoring of medicines part of the medicines use process is a core part of their role. The good practice in prescribing and managing medicines and devices guidance issued by the General Medical Council (GMC) (GMC, 2013) encompasses all four principles of MO as described by the RPS. For the nursing profession, the administration of medicines and supporting people to take their medicines correctly forms a significant part of their professional role. In addition, increasing number of nurses are now qualified as independent prescribers and therefore undertake prescribing and monitoring duties too. The RCN has a dedicated webpage on medicines related practice that contains numerous resources that support

the implementation of MO. The RPS MO guidance recognises the need for a multiprofessional approach to deliver the ambitions of the MO agenda and as such states *"the medicines optimisation approach will require multidisciplinary team working to an extent that has not been seen previously"* (RPS, 2013). Similarly, the 2015 NICE MO guidance, recommends that "*organisations should consider a multidisciplinary team approach to improve outcomes for people who have long-term conditions and take multiple medicines*" (NICE NG5, 2015). This multi-professional approach is increasingly more relevant as over time independent prescribing rights have been gradually extended to a range of other healthcare professionals such as physiotherapists, optometrists and most recently paramedics in 2018.

In this chapter, the author describes their activities to support the implementation of MO principles through a multidisciplinary approach. The structure of this chapter differs slightly in that, the author's publications address distinct topics that were reflective of the author's role in the NHS at that time and therefore each publication is discussed individually rather than under a theme.

## 5.2 Key publication 11: Shah C, Lehman H, Richardson S. Medicines optimisation: an agenda for community nursing. Journal of Community Nursing.

The community nursing sector includes a large breadth of specialisms, roles, and settings for example specialist nurses in diabetes, respiratory, palliative care or specific roles such as community matrons, district nurses, tissue viability nurses or targeted services such as rapid response, admission avoidance teams and heart failure. In general community nurses provide care in or close to people's homes rather than in hospital settings, this often results in them working alone and without the support of an MDT at the point of care delivery. In the NHS five year forward view policy document published in 2014 (NHS England, 2014), a strong direction was set to deliver more healthcare out of acute hospitals and closer to home with the aim of providing better care for patients, cutting the number of unplanned bed days in hospitals, and reducing net costs. In the author's opinion the impact of this policy decision on the community nursing workforce was that a more skilled and competent workforce would be required as community nurses would be required to undertake

increasingly more complex medicines administrations such as intravenous (IV) therapy, manage increasingly complex medicines regimes and be managing more complex patients.

In order to manage the impact of these policy decisions, the author in collaboration with senior community nursing leaders in their NHS trust undertook a range of activities. These included delivering education and training sessions, redesigning the community drug chart, increasing support for non-medical prescribes, establishing a multidisciplinary community health services MO group which ensured that pharmaceutical support was included in new service developments or care pathway design. In their publication in the Journal of Community Nursing, the author discussed this approach and provided an overview on the impact of the care closer to home agenda on community nursing practice with respect to medicines administration and the principles of MO. The publication described the author's collaborative approach with nursing leaders in their NHS trust on how they addressed some of the issues they faced using a combination of narrative literature review, document analysis and their expert pharmaceutical knowledge.

### 5.2.1 Key findings and discussion

The publication clearly demonstrated the significant challenges that community health services were under due to mergers with other providers, pressure to rapidly transform services to deliver the care closer to home agenda and the significant instability due to many services being tendered out to the market. The latter was in line with the sentiments of the 2012 Health and Social Care Act which encouraged competition in the NHS (DH, 2012). During this turbulent period, it was vital that pharmacy leaders undertook a collaborative approach with other professions to manage the medicines related issues. The article also discussed the author's experience of establishing a multidisciplinary community health services MO group that included medical, nursing, allied health professionals and pharmacists and which they considered a significant enabler in delivering the principles of MO.

### 5.2.2 Impact and associated outputs

The primary purpose of the publication was to raise awareness of the care closer to home agenda and its impact on nursing practice with respect to medicines administration and secondly to encourage senior nurses and pharmacists to collaborate with each other to implement the principles of MO. One of the initiatives delivered by the author was their development of a MO e-learning programme for community healthcare staff which was shortlisted for the innovation showcase at the 2015 RPS conference.

The author's work also led them to be invited to present at several meetings organised by the SPS Community Health Service Network and be appointed to the editorial advisory board member for the Journal of Community Nursing.

## 5.3 Key publication 12: Shah C, Devit R and Wong M: The use of common medications during breastfeeding. Journal of Health Visiting.

Health visitors are qualified and registered nurses or midwives who work with families to promote good health and prevent illness in pre-school age children. In general the activities of a health visitor include (i) providing ante-natal and post-natal support, (ii) supporting parents in bringing up their young children, (iii) providing advice on feeding babies and children, (iv) assessing a child growth and development needs, (v) supporting children with special needs, (vi) advising on behavioural management techniques, (vii) advising how to reduce risks and prevent accidents and reduce injuries and (vii) providing information on local services (NHS, health careers, 2021).

Through close working with health visitors, the author became aware that health visitors frequently provided advice to families of infants on childhood immunisations, how to manage minor ailments such as nappy rash, fever, teething, constipation, and dry skin, how to manage medicines use in breastfeeding and in more complex cases understanding the effect of medicines excreted in breastmilk on the feeding, growth and development of the infant. It also became apparent to the author that although the majority of health visitors in the UK were qualified as independent prescribers, very few utilised their prescribing skills and qualifications. This view is supported by a review undertaken in Scotland that found that a significant number of health visitor

prescribers did not actively prescribing for their clients (Coull et al, 2013). It also became evident to the author that many health visitors received queries from mothers on the use of medicines on breastfeeding. The queries ranged from whether to stop breastfeeding when prescribed medicines such as antibiotics and painkillers or in some cases concerns on the impact of breastfeeding on the infant whilst on long term medicines such as antidepressants. The NHS patient advice website encourages breastfeeding mothers to talk to their midwife, health visitor, a pharmacist or GP if they have any questions on medicines in breastfeeding, however, the feedback from health visitors to the author was that in most cases they referred the mothers to the GPs as they were unsure of what to advise.

In the author's opinion and experience, despite health visitors undertaking significant medication related activities, there was very little collaborative working between the health visitor and pharmacy professions. In order to support health visitors to gain knowledge and have confidence in managing medication related issues, the author in conjunction with the lead health visitor held a series of educational sessions in their NHS trust with a particular focus on medicine use in breastfeeding. The sessions were extremely well received such that the lead health visitor who was also a member of the editorial advisory board of the Journal of Health Visiting suggested to the author that they develop a CPD article on medicine use in breastfeeding to share across the profession. In order to develop the publication, the author used a combination of narrative literature review, document analysis and their expert pharmaceutical knowledge.

### 5.3.1 Key findings and discussion

The author formulated the CPD article around three key themes, the first was to provide baseline knowledge on the pharmacokinetics of medicines and how medicines enter breastmilk, the second was to provide practical guidance around commonly used medicines in breastfeeding and thirdly to encourage a multidisciplinary approach to managing medicines use in breastfeeding.

A key point in the article was the discussion around the role of the MDT and its functions in helping mothers decide on whether to continue or discontinue long term

medication during breastfeeding. From the author's experience, the two key long-term conditions that require robust care planning with respect to medicines and breastfeeding are HIV and SMI. In HIV, the advice in most developed countries is to completely avoid breastfeeding, regardless of antiretroviral treatment and maternal viral load however, this advice differs in less developed countries where access to clean water and affordable replacement feeding (infant formula) is not always available and HIV infected mothers are encouraged to exclusively breastfeed for the first 6 months of life and continue breastfeeding for at least 12 months (WHO, 2019). In the author's experience, this different guidance between developed and less developed countries has caused confusion amongst mothers especially in localities that have high migrant populations. In mothers with long term SMI, the decision to breastfeed, to use formula feed, to continue or to discontinue medication requires individual care planning. This must consider the many benefits of breastfeeding, the known and unknown risks of medication exposure for the baby via breast milk, the effects of untreated illness in the mother, and the benefits of and maternal preferences for breastfeeding.

The need for a MDT developed care plan involving the prescribing clinician, specialist pharmacist, and midwife and health visitor is pivotal to support the new mother. Each of these professionals has contact with the breastfeeding mother at different stages of care and therefore need to work collaboratively to deliver a consistent reassuring message.

### 5.3.2 Impact and associated outputs

Through the publication, the author was able to support health visitors to deliver better care to breastfeeding mothers and ensure the safe use of medicines. The publication also encouraged health visitors to seek out their pharmacist colleagues so that they can work together to provide evidence-based information to breastfeeding mothers. A recent initiative by SPS has been to develop a dedicated page on their website that contains training, guidance and resources to help healthcare professionals with decision making about the use of medicines in breastfeeding (SPS, 2021). This initiative endorses many of the principles of collaborative working outlined in the author's publication.

### 5.4 Key publication 13: Shah C and Coyne T. Medicines management programme for non-medical prescribers. Nursing Management.

In the NHS, the prescribing of medicines is a role historically and predominantly performed by medical and dental professionals, however two seminal reports challenged this view; the Cumberlege report (DHSS, 1986) which paved the way for limited prescribing by health visitors and district nurses, and the Crown report (Crown, 1999), which recommended extending prescribing rights to other healthcare professionals.

In 2003, supplementary prescribing by nurses and pharmacists was introduced in the UK, this allowed a voluntary partnership between the supplementary prescriber, the doctor looking after the patient, and the patient to be formed in which the supplementary prescriber became responsible for managing the condition(s) and prescribing the medication(s) listed in an agreed clinical management plan. In 2006, independent prescribing was introduced for nurses and pharmacists that removed some of the complexity and constraints of supplementary prescribing and allowed nurse and pharmacist prescribers to be fully accountable for the care of the patient, including examination and prescribing. An evaluation of independent prescribing commissioned by the DHSC concluded that non-medical prescribing (NMP) practice was well established and integrated in the NHS and had increased patients' access to medicines (Latter et al, 2011). Over time, as stated previously, independent prescribing rights gradually extended to a range of other healthcare professionals such as physiotherapists, optometrists and most recently paramedics in 2018.

Whilst employed within community health services, it became apparent to the author that there was very little formal support provided to independent prescribers in the author's NHS trust compared to that available for medical colleagues. Therefore, the author in conjunction with nursing and allied healthcare professional leads developed a programme of education sessions for independent prescribers across the trust to support them in their prescribing practice. The key challenge was to develop a programme that would meet the needs of the breadth of independent prescribers employed that included specialist nurses in diabetes, palliative care, specialist physiotherapists in musculoskeletal and respiratory services and pharmacists

specialising in anticoagulation. The author in conjunction with the leads designed a programme that encompassed key prescribing related issues such as prescribing in an evidence-based manner, managing adverse effects, managing drug interactions and pain management.

The publication described the process of developing the education sessions, the feedback received on the programme via questionnaires and the issue of supporting the disparate range of independent prescribers in the NHS trust with medicines education.

### 5.4.1 Key findings and discussion

In total 61 independent prescribers (all were nursing professionals with the exception of two pharmacists and one physiotherapist) from across secondary, primary and community health sectors attended the CPD sessions. The cohort of independent prescribers attending the programme reported a range of practice disciplines such as cardiology, respiratory and diabetes demonstrating the breadth of independent prescribing occurring across the healthcare sector. Approximately 60% of attendees were actively prescribing, which is a rate consistent with other studies (Latter, 2011). The feedback from the questionnaires indicated that the programme was well received. The author's thematic analysis of free text comments indicated that the sessions on evidence-based resources and critical appraisal skills were particularly well received by the participants which in the author's opinion is pivotal in practicing evidence-based prescribing and is regarded as one of the four key principles in MO. The evaluation also found that independent prescribers frequently accessed training opportunities and materials from a range of sources that included pharmaceutical companies, websites, their manager, their pharmacist colleagues, and newsletters circulated by the trust pharmacy team.

### 5.4.2 Impact and associated outputs

The author identified an opportunity for the pharmacy profession to support the growing number of independent prescribers in NHS trusts with their CPD needs. The work was evaluated and shared in a nursing journal to encourage nursing leaders to

work with their pharmacist colleagues to develop similar supportive frameworks in their own NHS trust.

### 5.5 Key publication 14: Cassam J, Shah C, Lewis P et al. Development of a community nursing drug chart. Nursing Management.

Medicines administration is one of the core responsibilities of registered nurses in a managed healthcare setting and can be one of the most complicated and timeconsuming aspect of a nurse's role (Shepherd and Shepherd, 2020). In addition to medicines administration, nurses are frequently the final professional to check to see that the medication is correctly prescribed and dispensed before administration (Shepherd and Shepherd, 2020). The evidence surrounding medication errors in hospital settings suggests that administration errors make up the most common type of medication error reported (41%) followed by prescribing errors (32%) (NPSA, 2007). In a systematic review by Keers et al (2013), they identified a variety of factors that can lead to medicines administration errors. These included misidentification of a medicine, misidentification of a patient, lack of knowledge, poorly written prescriptions, documentation and/or transcription, medicine supply and storage problems, staff inexperience and lack of training, high workload and problem of fatigue and stress among staff, inappropriate skill mix among staff and lack of ward-based equipment and interruptions/distractions.

Nursing staff administering medicines in a hospital setting generally do so against the instructions written on a drug chart by a prescriber. The drug chart serves as a communication tool between doctors, nurses, pharmacists, other health professionals and hospitals regarding the patient's medicines. It is used to direct how and when drugs are to be administered and as a record of their administration. One of the key priorities during the organisational changes described earlier in the chapter was for the author to develop a harmonised community drug chart across the newly merged organisation to support the safe prescribing and administration of medicines. In order to develop the harmonised community drug chart that would meet the needs of all the service lines, the author undertook a review of routine clinical data to identify the most commonly prescribed medicines, sought opinions and knowledge of operational practices from a small MDT group using dialogic and collaborative research

methodologies. The author ensured that the newly developed chart met the appropriate national standards. Once developed and in use, the author proceeded to share their methodology on the development of the drug chart along with the drug chart itself in a nursing journal. The primary purpose of sharing the approach was to support other community health service organisations that faced similar challenges following merger with other organisations.

### 5.5.1 Key findings and discussion

During the development of the community drug chart several interesting findings and variations between services became apparent. For example, the type of clinical activity undertaken by each community health service differed considerably hence resulting in a variety of medicines being administered. The relationship between community nurses and GPs in different services varied significantly. In some services the GP prescribed directly onto the drug chart where in others the community nurses had to transcribe the information from the GP referral form and the skill set of the nurses could vary significantly depending on the specialisms.

During the development, it became clear that the complexity of medicines being administered by community nurses in the home setting was increasing. For example, the administration of high dose insulin, intravenous (IV) furosemide, IV antibiotics, low molecular weight heparins, high dose opioids and erythropoietin were all recent developments. Of the 227 medicines audited by the author during development of the drug chart, approximately 50% were for the treatment of diabetes or end of life care thus necessitating particular requirements in the drug chart design. An additional finding from the audit was the low completion of the allergy field and a lack of a second patient identifier such as a date of birth.

A particular finding of concern in the audit was the unclear prescribing/transcribing associated with insulin prescriptions, for example almost 27% of insulin prescription entries on the drug chart in the review failed to clearly state the word ‘units’ which was in breach of the main recommendations set out in the NPSA rapid response report on insulin prescribing (NPSA, 2010). These findings added to concerns that had already been identified through the error reporting system in the author’s NHS trust around the

community nursing management of insulin patients. The author in conjunction with the director of nursing established a task and finish group to address these safety concerns and ensure that the recommendations set out in the NPSA safer administration of insulin (NPSA, 2010) were embedded in community nursing practice.

The findings discussed above strongly influenced the design of the new community drug chart for example a specific section for insulin prescriptions was included that contained the word ‘unit’ as a pre-print so that use of IU or U could not occur. The new drug chart also included a prompt for noting the type of insulin device to be used, a specific pre-printed section for medicines administered by a syringe driver and a section where a photo of the patient could be attached (to prevent mistaken identity) with their consent.

### 5.5.2 Impact and associated outputs

The newly designed drug chart was well received by community nursing teams and by GPs who agreed to complete the chart at the point of referral. The revised drug chart designed to improve the safety of insulin administration with respect to community nursing practice was presented at the inaugural RCN/RPS summit (RCN/RPS, 2014). In addition, following publication of the article, the author received a request from a community health organisation in Yorkshire to share a hard copy of the drug chart so that they could use it to develop a similar one for themselves.

## 5.6 Other publications

### 5.6.1 Medicines and falls

**Shah C, Williams G, Joshi J and Aziz R. 2012 A retrospective study of fall risk factors. Journal of Community Nursing. 26(5), 34-39**.

In the elderly, falls are associated with major morbidity and mortality, they can cause injuries, fractures, loss of confidence and independence, depression, and death. Recurrent falls and fear of falling are the most common reasons for an older person to require nursing home care. Approximately 1 in 3 adults over 65 and half of people over 80 suffer at least one fall a year (NHS Falls, 2021). There are a variety of factors that increase the risk of falling in older people which can be classified as either intrinsic

(person-specific) or extrinsic (environmental). Some of the factors that are strongly linked to increasing the risk of falls in elderly people are gait and balance impairment, cognitive impairment, visual impairment, dizziness, and certain chronic diseases such as Parkinson's and Alzheimer's disease. Medicines can also increase the risk of falls for example psychotropic drugs are often linked with an increased risk of falls, several cardiovascular medicines are associated with a higher risk of falls particularly through their hypotensive effects and patients who use insulin have also been shown to be at increased risk of falls, due to hypoglycaemia. Prevention of falls is usually based on assessing multiple risk factors including those described above. In hospital settings, a robust falls risk assessment depends on accurate history taking and examination that is undertaken through a multidisciplinary team assessment. The role of the pharmacist in such an assessment is often to undertake a medicine use review to improve patient education and optimise medicines use to reduce the risk of falls.

In their work, the author retrospectively reviewed case notes of 62 patients that had suffered approximately 78 falls over a period of 6 months in a community hospital. In their study, the author aimed to identify any patterns or risk factors amongst the cohort of patients that had suffered a fall including any possible contribution of medicines. The author found that 78% of patients who had suffered a fall had a history of falls but only 57% of patients that had fallen were graded as high risk on admission using the Morse Falls Risk Assessment tool (Morse, 1997). The author found that a significant number (49%) of patients were prescribed anticoagulants which increases the risk of bleeding and bruising following a fall. A key finding of the study was a lack of documented contribution from a pharmacist in the MDT falls risk assessment despite a high level of polypharmacy. This highlighted at the time the need for integrating MO into the falls prevention practice and for pharmacists to be apart of the MDT in conducting falls risk assessments.

### 5.6.2 Prescribing in urinary tract infections

**Shah C and Goundrey S. Managing the symptoms of urinary tract infection in women. Journal of Community Nursing. 013; 27(4):88-92**. Diagnosing and managing upper and lower urinary tract infections (UTI) are a significant challenge due to their high prevalence, risk of recurrence and inappropriate treatment. In addition, inappropriate diagnosis, and subsequent treatment due to the use of urine

dipsticks is often a problem in older people, particularly those in long stay care facilities. For example, a positive result for ‘nitrite’ (bacterial marker) or ‘leucocyte’ (white blood cell marker) may be a normal finding because of the high proportion of older people that have bacteria in the urine but may lead to an inappropriate diagnosis of a UTI and treatment with antibiotics. The increase in worldwide antibiotic resistance necessitates the need for proper antibiotic stewardship.

Whilst in their role within community health services, the author was responsible for supporting community nurses. Through discussions with senior nursing leaders and procurement data, it became apparent to the author that community nurses in patient facing roles often undertook urine dipsticks in their patients as routine which possibly could lead to inappropriate diagnosis and treatment with antibiotics. As a result of this information, the author developed a short guideline to support community nurses on how and when to use urine dipsticks and manage UTIs particularly in elderly women as UTIs are twice more likely to occur in females compared to males. The guideline was extremely well received such that it was translated into a CPD article for the Journal of Community Nursing to support the wider profession.

### 5.7 Summary

This chapter demonstrates the author’s activities to encourage collaborations between pharmacists and other healthcare professionals to implement and embed the principles of MO into care delivery. The author’s collaborative and collective leadership style has enabled them to influence and work in partnership with senior leaders form other healthcare disciplines to deliver on the principles outlined in the MO approach. The author has strategically taken the additional step to disseminate their activities and outcomes in non-pharmaceutical journals to act as exemplars of MO implementation in a variety of different clinical scenarios. In this chapter, the author relies heavily on research methodologies such as document analysis and narrative literature review.

## Chapter 6: Summary and conclusions

### 6.1 Synopsis

In this final chapter of the thesis, the author aims to reflect on their journey both as a practitioner and a researcher. The author will revisit and critically discuss the aims, objectives, impact, limitations, and conclusions of their research along with their future plans.

### 6.2 Revisiting thesis aim and objectives

The overall aim of the thesis was to describe and demonstrate the author's contribution to the MO agenda at a local, regional, and national level. The author's contribution is primarily described in the context of their strategic job roles in the NHS at that moment in time. Therefore, this has involved research primarily undertaken to gain new knowledge or to improve practice that positively impacts patient care.

The author's contribution to the MO agenda in the thesis was described through the three main themes: MR, the safe and effective use of medicines in patients with mental health and learning disabilities and embedding the principles of MO through a MDT approach. The thesis discussed each theme individually in chapters 3, 4 and 5. The research methodologies utilised by the author were described in chapter 2 and were

linked to the individual research outputs described in each chapter. For each objective, the author was able to demonstrate their contribution and impact to the MO agenda.

### 6.3 Impact of research

The author has been an active researcher since 2010 and has published multiple articles in peer reviewed journals, presented their work at national conferences and published resources that have been utilised nationally. In addition, they have presented at national meetings as an expert, taught on university courses, applied successfully for grants (appendix 2), had projects shortlisted for national awards, advised editorial boards, acted as a peer reviewer for high impact journals and have been invited to contribute to national steering groups that have advised the UK government.

In the research area of MR, the author successfully undertook one of the largest studies of its kind in England that provided in depth understanding of the medication safety issues faced at transfers of care across England. From the author's personal communication with other pharmacy leaders, many regions in England developed action plans in response to the national report and localised reports that the author was able to provide. The author's study was replicated in Northern Ireland by the Northern Ireland Regulation and Quality Improvement Authority (RQIA) using the tools and methodology developed by the author. The author's work has contributed to the body of literature that has led to the development of the NHS DMS that was launched in 2021 in which all community pharmacies in England were contracted to support patients with any medicines related issues following discharge from secondary care.
A successful roll out of the DMS addresses many of the issues identified in the author's study. A key contribution by the author to improve the quality of MR was the development of the MR best practice resource and toolkit which was endorsed by the RPS. Since 2016, the resource has been viewed on 7811 occasions. In England, the author has been regarded to have a considerable level of expertise on the topic of MR and has been requested to act as a peer reviewer for several journals, provide advice on quality improvement projects and review national training packages.

In the research area of safe and effective use of medicines in patients with mental health and learning disabilities, the author, as a Chief Pharmacist of a large mental health and learning disabilities NHS trust is able to influence decision making and implement initiatives both locally and nationally.. The author's work on developing new roles such as independent prescribing pharmacists within CAMHS services has been cited by HEE as a model for other NHS trusts to consider following. Similarly, the work undertaken by the author on improving the physical health of people with SMI through the pharmacy and physician associate professions addresses some of the underlying health inequalities faced by people with SMI which contribute to a life expectancy that is up to 20 years shorter than the general population. Some of the most important part of the author's work has been their efforts to publish and promote the role of pharmacy in mental health practice as this is an area where there is lack of research. These efforts have been recognised through the author's work being shortlisted for national awards. The impact of author's research is strengthened as it has often been delivered in a challenging and complex practice environment.

In the research area of embedding the principles of MO through a MDT approach, the author has published several examples of their collaborative leadership style in a variety of journals targeting disciplines such as community nursing, health visiting, nursing leadership, learning disability nursing and general practice. In addition, the author has presented at nursing conferences, taught on nursing programmes, and provided advice to local GP leads meeting. The author has recently extended this collaborative approach to the new emerging profession of PAs where they supported the establishment of a PA led physical health clinic. These examples of MDT working demonstrate how pharmacy can lead and influence the MO agenda in collaboration with other health professions.

### 6.4 Limitations

MO has a broad scope and impacts all care pathways thus requiring health professionals working in different sectors and disciplines to embrace and implement its principles. Although the author's work and experience encompass a wide range of sectors that include acute, community and mental health, there is a limited focus on

primary care. This could be considered as a limitation as the majority of the care provided in the NHS is in primary care.

A significant proportion of the research undertaken by the author has been undertaken whilst in leadership roles and in contexts where additional resources have been made available to the author. Therefore, in certain circumstances the author's research may be less generalisable.

Although the author utilised a variety of research methodologies in their studies to triangulate and corroborate findings, they relied heavily on action research methodology which although has multiple advantages can be susceptible to the introduction of bias as the researcher is effectively evaluating services under their leadership, can have limitations in its ability to distinguish between cause and effect of interventions and sometimes lack rigour of measurement and validity.

A limitation in the author's research is that their activities were not undertaken chronologically and therefore may have limited the opportunity from learning from each research method deployed and building on it. A higher usage of qualitative research methodologies such as focus groups or structured interviews particularly with patients and carers would have yielded a more in depth understanding of the impact of interventions made by the author.

### 6.5 Future work

The author has plans to build on some of their existing research themes and develop new areas of interest, some of these are described below:

The COVID-19 pandemic in the UK has highlighted that people who already suffer from existing inequalities, disadvantage, and discrimination such as those with anSMI have been impacted to a far greater degree from the harms of the pandemic. For example, a 20.1% decrease has been observed in the proportion of patients living with SMI that had undergone a full physical health check following the first COVID-19 lockdown in England (Armitage, 2021). This has also been confounded by a substantial decrease in face-to-face appointments in primary care. There are

significant concerns that these issues will result in poorer outcomes in physical health for those with SMI. In order to address these concerns, the author plans to build on their work undertaken with PAs by utilising the different healthcare practitioners available in the care pathway to support different aspects of physical health for people with SMI at different points of the care pathway. For example, by making use of PCN and GP practice pharmacists to prescribe social and pharmacological interventions and facilitating community pharmacists in making brief interventions and promoting self-care through access to public health interventions and training and education programmes. The author anticipates greater opportunities to do this as a result of the closer working between care providers in the new integrated NHS structure.

The author intends to explore mechanisms that can reduce the risk of severe harm due to clozapine induced constipation. The author's current experience of practice is that the risk remains high despite the drug safety alert issued by the MHRA in 2017. Through utlilising their experience of establishing practice research engagement groups and the use of dialogic and collaborative research methodologies, the author hopes to engender a national system wide approach to address this difficult and serious adverse effect of clozapine treatment.

At the time of writing this thesis, the author is in the process of securing funding to evaluate the implementation of electronic prescribing and medicines administration (ePMA) in their NHS trust. The author plans to use their knowledge and experience of systems dynamics to build a simulation model that reflects the medicines use process which can then be utilised to evaluate the impact of ePMA on practice, processes and performance.

### 6.6 Conclusions

This thesis describes and demonstrates how the author has delivered MO through strategic leadership. It reflects the author's journey as a researcher, a pharmacist increasing in their skills and competence, a leader, and their multidisciplinary approach to working. The research presented in this thesis and its impact on pharmacy practice in particular and patient care in general, was a result of the breadth of roles adopted by the author.

The author's collaborative leadership approach has been central to the work described throughout the thesis and is demonstrated with multiple examples such as the establishment of practice–research engagement groups, publications within journals of other health care disciplines and supporting newly emerging professions such as PAs. This therefore emphasises the importance of collaborative work to embed research within daily healthcare practice and provision.

This thesis demonstrates the importance and value of leadership-driven collaborative practice research. The author's work illustrates how action research is an effective mean for providing evidence and establishing the pivotal role of pharmacists within MDTs as experts in MO and MR and thus the whole agenda of medication safety.

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**1: Curriculum vitae**

# Chetan Shah

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|---|---|
| **Personal Profile** | A conscientious and strategically minded individual with excellent problem solving and leadership skills with a track record of managing and delivering projects and change |

**Appendix**

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| **Professional Experience** | **Jan 2016 – on going** **Hertfordshire Partnership University NHS Foundation Trust Chief Pharmacist (AfC Band 9)**<br>• Responsible and accountable for all aspects of Pharmacy and Medicines optimisation for the NHS trust<br>• Trust Controlled Drugs Accountable Officer (CDAO)<br>• Member of the trust senior leadership team<br><br>**Sept 2014 – Apr 16** **Medicines Use and Safety, NHS Specialist Pharmacy Services (Associate Director (AfC Band 8c)**<br>• Managed a quality improvement project focussed on Medicines Reconciliation<br>• Conducted a national audit on transfer of care that has led to changes in practice nationally<br><br>**Sept 10 – Jan 2016** **London Northwest Integrated HealthCare NHS Trust Principal Pharmacist (AfC Band 8c)**<br>• Responsible for all community health medicines management related issues for the trust (covering the boroughs of Ealing, Harrow and Brent)<br>• Responsible for ensuring compliance with local, regional and national standards/directives and ensuring good clinical governance<br><br>**Sept 09 – Sept 2014** **The University of Hertfordshire Principal Lecturer in Pharmacy Practice and Public Health**<br>• Programme tutor for MSc in Pharmacy Practice (MSc for Hospital Pharmacists)<br>• Teaching and Research activities; public health, public mental health and clinical Pharmacy<br>• Co-chair of the East of England Joint Programmes Board (JPB)<br><br>**Jan 09 – Sept 09** **The University of Manchester CPPE Regional Manager (Band 8b)**<br>• Managed 18 CPPE tutors across North London and East of England<br>• Project managed development of new learning programmes<br>• Developed collaborations between CPPE and other Pharmacy organisations and educational providers<br><br>**Apr 08 – Aug 09** **Central North West London (CNWL) NHS Foundation Trust Locum Medicines Information Pharmacist (Band 8a)**<br>• Responsible for the day to day running of enquires within the unit<br>• Supervision and training of pre-registration students<br>• Lecturing undergraduate nursing students at Thames Valley University<br><br>**Apr 07 – Apr 08** **Career break travelling across S.E Asia**<br><br>**July 05 – Apr 07** **CNWL NHS Foundation Trust Senior Mental Health Pharmacist (Grade D)**<br>• Responsible for delivering a clinical Pharmacy service to adult psychiatric wards<br><br>**June 03 – June 05** **North West London Hospitals NHS Trust Rotational Basic Grade Pharmacist (Grade B/C)**<br>• 3 month rotations within medicines information, therapeutic drug monitoring, patient services, aseptic manufacturing, cardiology, gastroenterology, general medicine and surgery.<br><br>**July 02– June 03** **Royal Brompton NHS Trust, Mersey Care NHS Trust Locum Pharmacist**<br>• Clinical and dispensary duties<br><br>**July 01– July 02** **Kings College Hospital NHS Trust, Denmark Hill Pre-registration Pharmacist**<br>• Successfully completed 52 week pre-registration programme that included aseptic manufacturing, medicines information, cardiology, hepatology, general medicine and surgery. |

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| **Other Achievements** | • Awarded £10K grant from Health Education England to evaluate CAMHS prescribing project<br>• HSJ Patient Safety Award 2020 Finalist - Medicines Optimisation Clinic in Mental Health<br>• HPFT Staff Awards (Innovation Category) 2019 Winner – Redesign of Clozapine Pathway and Introduction of Point of Care Testing<br>• RPS Innovation Showcase 2015 Finalist – Development of a e-learning programme on medicines optimisation<br>• RPS Pharmaceutical Care Award 2013 Finalist - Development of a clinical Pharmacy service to an intermediate care team delivering care closer to home |
| **Selected Publications**<br><br>**Over 40 publications in peer reviewed journals and conferences (Full publication list is available on request)** | • Shah C, Hough J, Jani Y. Medicine's reconciliation in primary care: a study evaluating the quality of medication-related information provided on discharge from secondary care. Eur J Hosp Pharm 2018;0:1–6<br>• Shah C and Barnett N. *Medicines reconciliation: A patient safety priority*. Prescriber. 2015; 26(2):23-26<br>• Shah C, Ishmael N, Wright J*. How nurses contribute to Medicines Reconciliation*. Nursing Management. 2015;22(2):18-22.<br>• Shah C, Lehman H, Richardson S. *Medicines optimisation: an agenda for community nursing.* Journal of Community Nursing. 2014; 28(3):76-80.<br>• Cassam J, Shah C, Lewis P et al. *Development of a community nursing drug chart*. Nursing Management. 2014; 21(2):22-25.<br>• Shah C and Coyne T. Medicine's management programme for non medical prescribers. Nursing Management. 2012; 19(8):34-37<br>• Shah C, Williams G, Joshi J and Aziz R. *A retrospective study of fall risk factors.* Journal of Community Nursing. 2012;26(5):34-39.<br>• Adams D and Shah C. Reducing antipsychotic prescribing in people with learning disabilities. Clinical Pharmacist 2016; 8(10): 37-41. |
| **Academic Qualifications** | Oct 2021 **Doctor of Philosophy (PhD) degree** Kingston University<br>April 2015 **Masters in Business Administration (MBA)** University of Hertfordshire<br>Sep 2009 **Diploma in Clinical Pharmacy** Queens University, Belfast<br>Mar 2007 **Certificate in Psychiatric Therapeutics** Aston University<br>Jul 2002 **Masters of Pharmacy** Liverpool John Moore's University |

**Appendix**

**2: Full publication list**

# Chetan Shah

## Full Publication List

### Improving the quality of medicines reconciliation at hospital admission and at transfer of care

**Journal Publications**

1. Shah C, Hough J, Jani Y. Medicine's reconciliation in primary care: a study evaluating the quality of medicationrelated information provided on discharge from secondary care. Eur J Hosp Pharm 2018; 0:1–6.
2. Shah C and Barnett N. Medicines Reconciliation: A Patient safety priority. Prescriber 2015; 26(22): 23-26.
3. Shah C, Ishmael N, Wright J. How nurses contribute to Medicines Reconciliation. Nursing Management. 2015; 22(2):18-22.

**Conference Abstracts and presentations**

4. Jani Y, Shah C, Hough J. Medicines reconciliation in primary care following hospitalisation. International Society for Quality in Healthcare conference 2017.
5. Shah C. Oral Presentation - Reconciling Medication Post Hospital Discharge for Patients with Long Term Conditions. Primary Care and Public Health Conference 2016.
6. Shah C. Oral Presentation - Improving the Quality of Medicines Reconciliation. Medicines Optimisation Conference. Sep 2015.HealthCare Conferences UK

**Other Publications**

7. Shah C, Hough J and Jani Y. Collaborative audit across England on the quality of medication related information provided when transferring patients from secondary care to primary care and the subsequent medicines reconciliation in primary care. Medicines Use and Safety, Specialist Pharmacy Service, NHS England.
8. Shah C. Improving the quality of Medicines Reconciliation: A national best practice resource and toolkit. Medicines Use and Safety, Specialist Pharmacy Services. Endorsed by the Royal Pharmaceutical Society of Great Britain.

### Ensuring the safe and effective use of medicines in patients with mental health and learning disabilities through medicines optimisation

**Journal Publications**

**9.** Shah C, Singh P, Matin S et al. (2021) An evaluation of a physician associate led enhanced physical health clinic for people with severe mental illness (SMI) in the United Kingdom. Journal of the American Academy of Physician Assistants. 34(8), 1-6. Available via DOI:10.1097/01.JAA.0000758220.38067.49

**10.** Shah C, Umaru N, Adams E et al. (2021) Assessment of the impact of integrating pharmacist independent prescribers into child and adolescent mental health services. The Pharmaceutical Journal, Online: DOI:10.1211/PJ.2021.1.45513.

**11.** Vekaria S, Shah C, Barnett N et al. (2020). Implementing a pharmacist-led medicines optimisation clinic in a community mental health team. Journal of medicines Optimisation. 6 (2); 42-51

**12.** Adams D and Shah C. Reducing antipsychotic prescribing in people with learning disabilities. Clinical Pharmacist 2016; 8(10): 37-41.

**13.** Adams D and Shah C. Prescribing of psychotropic medicines: the role of learning disability nurses. Learning Disability Practice 2016; 19(8):21-25.

**14.** Karia A, Kravitz, Shah C. Schizophrenia: Helping patients adhere to long term management plans. CPD Update Module 1523. Chemist and Druggist April 2010

**15.** Shah C and Aslanpour Z. A new year, new horizons and a new agenda for public mental health. Pharmaceutical journal 2010;284:77-78

**Conference Abstracts and presentations**

**16.** Shah C, Zia A, Aslanpour Z, Mehra Z. An evaluation on the role of Community and GP practice based Pharmacists in supporting the physical health of patients with severe mental illness (SMI). 10th Annual International College of Mental Health Pharmacy (CMHP) Conference 2019.

**17.** Tang E, Smith A and Shah C. An evaluation of the implementation and outcomes of Paliperidone 3- monthly LAI (Trevicta®) at Hertfordshire Partnership University NHS Foundation Trust. 10th Annual International College of Mental Health Pharmacy (CMHP) Conference 2019.

**Invited Lectures**

**18.** Royal Pharmaceutical Society, Hertfordshire and Bedfordshire Forum 2019. We need to talk about severe mental illness.

**19.** University of Padova (Italy) 2011. The U.K Health System and Support for Drug Users**.**

**Other Publications**

**20.** Shah C, Zia A, Sawnhey I and Smith A. Drug shortages, price increases and market turbulence through the lens of mental health in England. Royal College of Psychiatry Easter Division Newsletter 2019.

## Embedding the principles of MO through a multidisciplinary approach

**Journal Publications**

**21.** Shah C, Devit R and Wong M: The use of common medications during breastfeeding. Journal of Health Visiting 2016; 4(3): 150 – 154.

**22.** Shah C, Lehman H, Richardson S. Medicines optimisation: an agenda for community nursing. Journal of Community Nursing. 2014; 28(3):76-80.

**23.** Cassam J, Shah C, Lewis P et al. Development of a community nursing drug chart. Nursing Management. 2014; 21(2):22-25.

**24.** Shah C and Goundrey S. Managing the symptoms of urinary tract infection in women. Journal of Community Nursing. 2013; 27(4):88-92.

**25.** Shah C and Coyne T. Medicine's management programme for non-medical prescribers. Nursing Management. 2012; 19(8):34-37

**26.** Shah C, Williams G, Joshi J and Aziz R. A retrospective study of fall risk factors. Journal of Community Nursing. 2012; 26(5):34-39.

**Conference Abstracts and presentations**

**27.** Bhachu H.K and Shah C. Evaluating prescribing and discontinuing medication for patients under the Intermediate Care Ealing (ICE) Team by a Clinical Pharmacist (CP). Pharmacy Congress 2016.

**28.** Shah C, Bhachu H and Kirkwood. Oral Presentation - Delivering a clinical Pharmacy service closer to home. Medicines Optimisation Conference Mar 2015. NW London Academic Health Science Network.

**29.** Shah C and Lehman H. Oral Presentation – Improving the safety of Insulin administration in the community nursing services. Working together to help patients make the most of medicines - A summit for nurses and pharmacists. Dec 2014. Royal College of Nursing and Royal Pharmaceutical Society.

**30.** Aslanpour Z, Shah C, Flynn R. Evaluation of Pharmacy student's knowledge of competencies required for public health specialists. 70th International congress of the international pharmaceutical federation. Lisbon 2010

**Appendix**

| **Other Publications** |
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| **31.** Shah C, Crotty S and Gilbert A. Hertfordshire and West Essex Pharmacy Workforce Review 2018. |
| **32.** Shah C (Reviewer). HIV – Learning at Lunch. Centre for Pharmacy Postgraduate Education (CPPE). The University of Manchester 2010 |
| **Awards and grants** |
| **33.** HSJ Value Awards 2021 Finalist - CAMHS pharmacist independent prescriber's integration into Child and Adolescent Mental Health Services (CAMHS). |
| **34.** HSJ Patient Safety Award 2020 Finalist - Medicines Optimisation Clinic in Mental Health |
| **35.** £10K grant from Health Education England to evaluate CAMHS pharmacist independent prescribers integration into Child and Adolescent Mental Health Services (2019). |
| **36.** HPFT Staff Awards (Innovation Category) 2019 Winner – Redesign of Clozapine Pathway and Introduction of Point of Care Testing |
| **37.** RPS Innovation Showcase 2015 Finalist – Development of a e-learning programme on medicines optimisation for community health services professionals |
| **38.** RPS Pharmaceutical Care Award 2013 Finalist - Development of a clinical Pharmacy service to an intermediate care team delivering care closer to home |
| **Other responsibilities** |
| **39.** Peer reviewer - European Journal of Hospital Pharmacy (A BMJ Publication)**,** Clinical Pharmacist. Pharmaceutical Press. |
| **40.** Editorial advisory board member for the Journal of Community Nursing (2012-2017) |
| **41.** Pharmacy representative (2010-2012) on the Primary Care Research Network for Greater London - National Institute for Health Research **(NIHR)** |

## 3 Statements of contribution from co-authors

I, Sally Butterworth, confirm that Chetan Shah contributed to the cited paper below in the following way:

- Aided design of the study
- Critical review of publication
- Response to peer review

Butterworth S and Shah C. (2021) An audit of clozapine recording in primary care patient records. The Pharmaceutical Journal. 306 (7947). Available from: DOI:10.1211/PJ.2021.1.52708

To whom it may concern

I, Zoe Aslanpour, confirm that *Chetan Shah* contributed to the cited paper below in the following way:

- **Conception and design of the study**

- **Critical review of publication**
- **Response to peer review**

**Shah C and Aslanpour Z. (2010) A new year, new horizons and a new agenda for public mental health. *Pharmaceutical Journal.* 284, 77-78**

**Shah C, Zia A, Aslanpour Z, Mehra Z. (2019) An evaluation on the role of Community and GP practice based Pharmacists in supporting the physical health of patients with severe mental illness (SMI). The 10th Annual International College of Mental Health Pharmacy (CMHP) Conference. United Kingdom.**

To whom it may concern,

I, Nkiruka Umaru, confirm that ***Chetan Shah*** contributed to the cited paper below in the following way:

- Conception and design of the study
- Drafting of manuscript
- Critical review of manuscript before submission
- Submission of manuscript to Journal
- Review and revision of manuscript following peer reviewer's comments
- Final submission to Journal

**Shah C, Umaru N, Adams E, Johal M, Faridi A, Kah M, Zia A and Magon R. (2021) Assessment of the impact of integrating pharmacist independent prescribers into child and adolescent mental health services. *The Pharmaceutical Journal. 306 (7948).* Available from: DOI:10.1211/PJ.2021.1.45513**

Authorship Statement

I, *CO AUTHOR*, confirm that *Chetan Shah* contributed to the cited papers below in the following ways:

- Conception and design of the paper
- Critical review of manuscript pre publication
- Response to peer review

Adams D and Shah C. (2016) Reducing antipsychotic prescribing in people with learning disabilities. *Clinical Pharmacist.* 8(10), 37-41. Available from: DOI:10.1211/CP.2016.20201751

Adams D and Shah C. (2016) Prescribing of psychotropic medicines: the role of learning disability nurses. *Learning Disability Practice.* 19(8), 21-25. Available from: Doi: 10.7748/ldp.2016.e1763

[Redacted]

Danielle Adams DipPsychPharm MRPharmS 20th September 2021

## Appendix

I, *Reena Devit*, confirm that *Chetan Shah* contributed to the cited paper below in the following way:

- **Conception and design of the study**
- **Drafting of publication**
- **Critical review of publication**
- **Submission of publication**
- **Response to peer review**

**Shah C, Devit R and Wong M. (2016) The use of common medications during breastfeeding. *Journal of Health Visiting*: 4(3); 150 – 154. Available from: https://www.independentnurse.co.uk/clinical-article/the-use-of-commonmedications-during-breastfeeding/118801/**

I, Philippa Lewis, confirm that Chetan *Shah* contributed to the cited paper below in the following way:

- **Conception and design of the publication**
- **Critical review of publication**
- **Response to peer review**

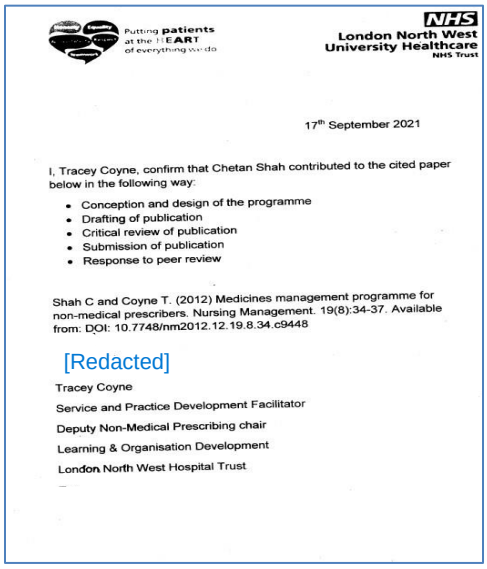
**Cassam J, Shah C, Lewis P, Al-Tahan S and Pickard K. (2014) Development of a community nursing drug chart. *Nursing Management*. 21(2):22-25. Available from: DOI: 10.7748/nm2014.04.21.2.22.e1215**

I, *Stuart Richardson, Co-author*, confirm that *Chetan Shah* contributed to the cited paper below in the following way:

- **Conception and design of the study**

- **Drafting of publication**
- **Critical review of publication**
- **Submission of publication**
- **Response to peer review**

**Shah C, Lehman H and Richardson S. (2014) Medicines optimisation: an agenda for community nursing. *Journal of Community Nursing*: 28(3):76-80. Available from: https://www.jcn.co.uk/journals/issue/3/06-2014/Prescribing**



Putting patients at the HEART of everything we do

NHS
London North West University Healthcare
NHS Trust

17th September 2021

I, Tracey Coyne, confirm that Chetan Shah contributed to the cited paper below in the following way:

- Conception and design of the programme
- Drafting of publication
- Critical review of publication
- Submission of publication
- Response to peer review

Shah C and Coyne T. (2012) Medicines management programme for non-medical prescribers. Nursing Management. 19(8):34-37. Available from: DOI: 10.7748/nm2012.12.19.8.34.c9448

[Redacted]

Tracey Coyne
Service and Practice Development Facilitator
Deputy Non-Medical Prescribing chair
Learning & Organisation Development
London North West Hospital Trust

I, Yogini Jani, confirm that you, Chetan Shah, contributed to the cited paper below in the following way:

Conception and design of the study
First draft of publication
Critical review of publication
Finalising the publication for submission
Submission of publication
Response to peer review

Shah C, Hough J, Jani Y. (2020) Medicine's reconciliation in primary care: a study evaluating the quality of medication-related information provided on discharge from secondary care. European Journal of Hospital Pharmacy. 27, 137-142. Available from: 10.1136/ejhpharm-2018-001613

I, Dr Pratima Singh, confirm that *Chetan Shah* contributed to the cited paper below in the following way:

- **Conception and design of the study**
- **Drafting of publication**
- **Critical review of publication**

- **Submission of publication**
- **Response to peer review**

**Shah C, Singh P, Matin S, Farrow J, Magon R, Zia A, Tatt-Smith P, Watson C and Smith A (2021). An evaluation of a physician associate led enhanced physical health clinic for people with severe mental illness (SMI) in the United Kingdom. *Journal of the American Academy of Physician Assistants*. 34(8), 1-6. Available from: DOI:10.1097/01.JAA.0000758220.38067.49**

I, *Seema Vekaria*, confirm that *Chetan Shah* contributed to the cited paper below in the following way:

- **Conception and design of the study**
- **Critical review of publication**
- **Response to peer review**

**Vekaria S, Shah C, Barnett N et al. (2020) Implementing a pharmacist-led medicines optimisation clinic in a community mental health team. *Journal of medicines Optimisation*. 6 (2); 42-51.**

**Appendix 4: Key publication 8 in print (as not accessible otherwise)**
[REDACTED]

**Appendix 5: Key publication 9 (in print as not accessible otherwise)**
[REDACTED]