Advancing Clinical Pharmacy Practice

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M00475644

January 2019

Volume I

Context Statement submitted to Middlesex University in partial fulfilment of the requirements for the degree of Doctorate in Professional Studies (Health) by Public Works

Foreword

Stand upright, speak thy thoughts, declare the truth thou hast, that all may share. Be bold. Proclaim it everywhere. They only live who dare.

- Voltaire

Acknowledgements

I would never have made it this far without the untiring encouragement, advice and mentoring of my academic supervisors, Professor Hemda Garelick and Dr. Sandra Appiah. Thank you for lifting me when I faltered, for inspiring me, and most importantly, believing in me.

Many thanks also to Professor Martin Stephens and Dr. Gordon Weller for always being available to answer my questions and provide advice.

To my collaborators and research partners, without whom I would not have anything to write about – thank you for working with me. Special mention to Reena Mehta, my long-term research partner and friend – you were there at the beginning, and stayed, even when we weren't sure we knew what we were doing. I'm so grateful that we are still riding together.

All my friends and colleagues who have cheered me on over the years and willed me to succeed – your encouragement has meant so much to me.

Marm, Mum, Mayowa, Dara - thank you for appreciating how important this is for me. Ola – always there when I call. Best big brother ever.

Deinde, you have endured my absences and inattention, never sure when it would all be over. Your love and understanding have carried me through.

Abstract

This Context Statement contains critical descriptions of my academic and professional outputs as a hospital clinical pharmacist and senior pharmacy leader, over the period 2007 to 2017, with some antecedents prior to 2007. Clinical Pharmacy has a main aim of optimising safe, appropriate and effective medicines use, for individual patients and organisations as well as system-wide. The Public Works presented here centre around four interrelated themes regarding clinical pharmacy – measuring and improving standards and quality of care; prescribing, prescribing practices and prescribing safety; innovative practice within legal and ethical frameworks; the impact and outcomes of clinical pharmacy. A unifying premise is my aim of advancing clinical pharmacy practice.

The concept of measuring to improve standards and quality of clinical care has progressed considerably over the past 15 years. I present my contributions to this - developing, implementing, measuring and disseminating clinical pharmacy quality and performance indicators, as well as benchmarking and quality improvement initiatives.

The chapter on prescribing encompasses the impact of electronic prescribing on pharmacy practice; the formal and informal roles of hospital pharmacists as prescribers; and a practice model I developed for pharmacists to practice as both specialist and generalist prescribers. I also discuss my research into inappropriate prescribing.

The innovative practices in Chapter Four include the introduction of different models of practice to improve patient care and medicines use, with significant focus on a specific initiative - redesigning the discharge medication prescription pathway. Chapter Five highlights other work which I undertook to demonstrate the potential of hospital clinical pharmacy to improve outcomes.

Throughout my professional career I have promoted the development of research capability within hospital pharmacy, to better improve patient care. In the concluding chapter, I draw from other professions to conceptualise a model of integrating professional practice, theory and research. *Pharmacy Praxis* is a philosophy which bears further development, in order to continue the progress of clinical pharmacy.

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CHAPTER ONE: Background and Overview

Everyone has been made for some particular work, and the desire for that

work has been put in every heart

- Rumi (1207-1273)

1.1 Introduction

This context statement describes my research and leadership in the complex healthcare discipline of hospital clinical pharmacy practice in the UK. There are many definitions of clinical pharmacy, an issue which I return to in the description of one of my Public Works. However, my professional opinion, developed over many years of providing and leading clinical pharmacy services, is that the overarching raison d'être of a hospital clinical pharmacy service is 'to optimise the use and safety of medicines at individual patient, population and organisational levels'. Clinical pharmacists work closely with doctors, nurses, therapists and other clinical colleagues to provide individualised care to patients. Optimising the use of medicines includes ensuring safety, efficiency and cost-effectiveness, hence clinical pharmacists also work with hospital managers, finance officers and governance departments to reduce drug costs, and minimise the risks involved with medicines use.

Hospital clinical pharmacy services are led and delivered mainly by pharmacists, working closely with pharmacy technicians. It takes several years of training to become a pharmacist in the UK. One must complete a four-year degree course, to be awarded a Masters' level first degree (MPharm). A twelve-month period of pre-registration training must also be completed, by the end of which the trainee must demonstrate acquisition of pre-determined competencies. The pre-registration training period usually follows the completion of the MPharm course; however, some Universities have intercalated courses. To work and progress as a clinical pharmacist in the UK, it is expected that practitioners undertake further postgraduate certificate, diploma and/or MSc [SA1] studies.

Unlike in the medical profession, undertaking research is not demanded for career progression in clinical pharmacy (Kasivisvanathan, Tantrige, Webster, et al., 2015; Lowrie, Morrison, Lees, et al., 2015). The links between academia and practice are traditionally limited to hospital pharmacy staff providing Universities with undergraduate student lectures, workshops and clinical placements and Universities providing hospital pharmacy departments with postgraduate training courses and assessments. Although experienced clinical pharmacists have a high-level of clinical expertise, and are keen to introduce new models of care, research capability is often underdeveloped. A lack of understanding of how to generate and disseminate robust, reproducible evidence hampers the effective advancement of clinical pharmacy practice.

In this chapter, I first describe my background and development as a clinical pharmacist and researcher, followed by an overview of the Public Works and how these link together.

1.2 My background and development

I have been a clinical pharmacy leader for over 25 years. In that time, I have trained, lectured and debated with other pharmacists, pharmacy professionals and students, developed policies and practice, written academic and professional articles, and presented at conferences; I therefore acknowledge my influence on others within my community of practice. I am currently Group Chief Pharmacist and Clinical Director for Medicines Optimisation at the largest acute NHS Trust in England. My career pathway has broadly followed a traditional chronology, as can be seen in Figure 1.

I first registered as a pharmacist in Nigeria in 1986, having moved there from the UK at a young age. Working as a pharmacy technician was my earliest experience of working in the NHS, and it was before clinical and ward pharmacy were well-developed. I now believe that many of the pharmacists themselves were not clear about their new clinical roles, which is why, despite working in three different pharmacy departments in a 12-month period, I could not form a picture of what the pharmacists did.

Newly returned to the UK, I had to get used to a different culture, set of norms, and healthcare system. My experiences of having to learn and navigate different cultural

references, working practices and values made me more curious about why things are done in certain ways. On reflection, I can see that I have always had an inquiring nature and I have continued to question professional and clinical pharmacy practice throughout my career, always with the aim of making improvements, and enhancing patients' experiences. These personal characteristics have driven my interest in research, wherein I am continually challenging accepted norms, to try and find and create best practices, the evidence behind what we do, and demonstrate improved outcomes. The pharmacy conversion course was for overseas pharmacists, from all over the world. Discussions about the differences between the UK and the various countries where we had grown up also helped me frame my new environment.

My first job was as a junior pharmacist, in Organisation I, part of a team of four, rota'd to be the sole responsible pharmacist out of hours and all weekend, for the whole organisation (three hospitals). We were given very little guidance on how best to carry out our duties and feedback was generally only given when a mistake had been made. I stayed in this post for 12 months, after which I gained a full-time place on an MSc. in Clinical Pharmacy course. There were about 12 of us on the course. Our experiences as pharmacists ranged from 12 months to several years, therefore we also learnt from one another. Although I conducted a research project in part fulfilment of the degree, it was of little help in increasing my research abilities, and it was not until I completed a second Master's degree ten years later, that these noticeably improved.

My additional responsibilities at Organisation III included managing more services and deputising for the Chief Pharmacist. Once more, I set up systems for clinical supervision, feedback and assessment. My interest in measuring and improving service quality also developed at this time. I instituted regular quality audits of our clinic and advisory services. I also continued to encourage and conduct project work. At this point, I was quite proficient in conducting audits and small-scale projects, but my abilities did not extend to understanding how to conduct and write-up publishable studies. I also developed an interest in clinical risk management. I therefore decided to study for a MSc in Clinical Risk Management. This was a two-year, part-time course, which I started in 1999.

1986 to 1987
- I graduate from University in Nigeria and return to the UK
- Work in the NHS as a pharmacy technician

1987 to 1989
- I undertake pharmacy conversion course and pre-registration year to register as a UK pharmacist

1989 to 1992
- I join Org 1 as Resident Pharmacist
- Undertake MSc in Clinical Pharmacy

1992 to 1996
- I Join Org. II as senior pharmacist
- Promoted to Clinical Pharmacy Services Manager, started developing leadership and management skills

1996 to 2000
- I join Org III for more senior role. Embark on MSc in Clinical Risk Management

2000 to 2004
- I Leave the NHS for Organisation IV - non-pharmacist role; used as expert in pharmacy and medicines
- Returned to the NHS in 2004 - Organisation V - Chief Pharmacist role

2004 to 2016
- I join Organisation VI in 2004 - Deputy Director of Pharmacy, Clinical Services
- Develop and build on research interests, improve research skills, published academic and professional papers
- 2012 - I become an independent prescriber
- Embark on doctoral studies

2016 to date
- I leave Org VI and join current Org. VII
- Took up Chief Pharmacist role in 2018
- Continue research activities
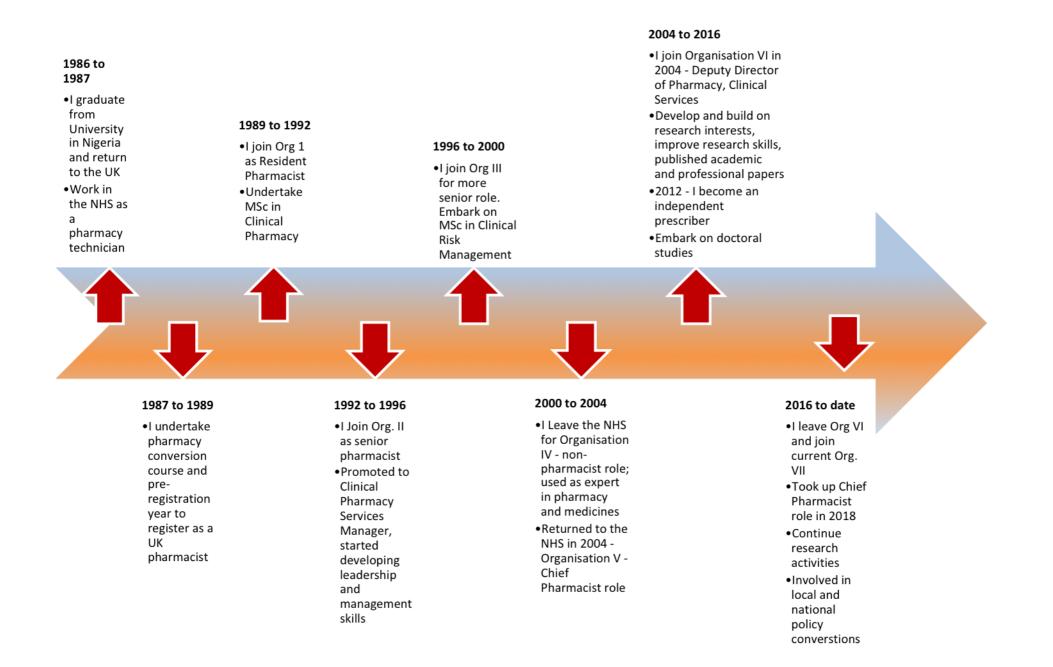- Involved in local and national policy converstions

Figure 1. My career pathway timeline

The clinical risk management course was multiprofessional – I was the only pharmacist, but there were senior doctors, nurses and therapists on the course. Multidisciplinary learning is considered to have many advantages, including greater personal and professional confidence, enhancing reflective practice, and a better ability to share skills and knowledge (Munro, Felton & McIntosh, 2002). I certainly felt these benefits whilst on the course. There was a strong focus on research and writing skills and critical appraisal. The benefits of this degree for my professional life were significant. My first Master's degree was at the beginning of my career and I felt that I learnt a lot but had very little to contribute because of my lack of experience. By the time I undertook this second MSc, however, I had years of practice behind me which enriched my learning experience. I could also contribute to discussions from my perspective as a senior NHS professional.

In 2000, one year into the MSc. course, I left Organisation III, and joined my fourth organisation, a newly formed non-departmental public body, charged with reviewing the quality of healthcare provided by NHS Trusts. I was the first pharmacist in this new, high-profile organisation. It was a good fit for me, as I was working with colleagues, who like myself, had highly developed senses of altruism, integrity, duty and advocacy. We were empowered to articulate our views freely, including criticising the organisation we worked for. My professional profile increased whilst working for this organisation. I was invited to present to groups of pharmacists locally and nationally. I also published articles informing pharmacists about the inspection process and their potential roles within it. Within the organisation, I was used as a subject matter expert when questions arose about medication and prescribing issues within the organisations we were inspecting. Paradoxically, I also felt that I had lost my professional identity. I was therefore pleased to be asked to become a part-time facilitator for the Continuous Professional Development of senior staff in a nearby hospital pharmacy department.

Missing the hospital pharmacy environment, I returned to the NHS, to Organisation V, a teaching hospital, in 2003, first as a Deputy, and later as Acting Joint Chief Pharmacist. I stayed at this hospital for 12 months. In 2004 I was invited to apply for a post as Clinical Pharmacy Services Lead and Deputy Director of Pharmacy at a larger hospital trust (Organisation VI). Being keen to return to my first passion of Clinical Pharmacy, I applied

and was successful. I stayed there for 12 years, during which time I embarked on my Professional Doctorate journey.

I originally joined my current organisation as Deputy Chief Pharmacist, leading the clinical pharmacy service delivered to five hospitals, in a similar role to that of Organisation VI, but on a larger scale. Since April 2018, I have been Chief Pharmacist for Organisation VII. I decide and direct the way the pharmacy service develops, interpreting national and professional guidelines and setting and leading on organisational priorities for medicines use. My position also enables me to have a voice in local and national policy conversations. It is only partly my choice as to whether I take advantage of this, as I am acutely aware of the responsibility I now bear whenever I either publicly express an opinion or choose to remain silent during a public debate.

1.2.1 Learning to Lead

In this section, I describe in more detail, how my personal, professional and clinical leadership framework has developed.

Personal leadership - My strongest recollection of my first few years back in the UK is the huge learning process I went through to adapt to a different culture. Having spent all my adolescent and adult life so far in Nigeria, I did not have the same cultural references as my new colleagues. Additionally, it was very common to find pharmacists from Australia and New Zealand working in the UK, so the differences in language, values and ways of working often became further complicated. On a social level, I had a lot to learn, and in this I was helped by family and friends. Ang et al (2007) discuss the concept of Cultural Intelligence (CQ) - defined as an individual's capability to function and manage effectively in culturally diverse settings. They discuss CQ as a construct of different types of capabilities, related to, but distinct from, abilities such as emotional intelligence and general cognitive ability. Hong (2010) presents a similar model, that of bicultural competence. This suggests that individuals who have internalised two cultural schemas (a cultural schema being a set of knowledge about values, norms, and beliefs for a given culture) are more effective in the workplace generally, as well as in multicultural social environments. This model is pragmatic, albeit simplistic, as it suggests that one can only

be either bicultural or monocultural. There is very little in the literature about how one develops a bicultural identity, however, I can relate to Hong's model and believe that between 1986 and 1990, I subconsciously focussed significant effort into developing my bicultural competence. This partly explains my determination to experience different working environments. If I had not done this, I would not have been able to adapt sufficiently to reach this current stage in my career.

The development of my leadership and management abilities has significant overlap with my professional development. My experiences as a junior pharmacist in Organisation I shaped my thoughts about the role of senior staff in supporting juniors, and the importance of feedback and communication. In my first senior post, in Organisation II, I line-managed one person, but had a service lead role, therefore I had to learn how to lead without managing. I made some mistakes in my enthusiasm for change and improvement. My ability to pick up on non-verbal cues and body language during conversations was under-developed. It took me many years to develop the skill of looking for, and understanding, non-verbalised sub-texts. However, I attended several study days and workshops designed to develop the management and leadership skills of new senior pharmacists. They included practical sessions on how to do particular aspects of the job and training and assessing others. I also participated in network meetings with other clinical pharmacy managers in order to share learning and support joint initiatives. I had unofficial mentors who I could learn from and call upon for help and advice. My first real exposure to management was at Organisation III, where I managed a group of pharmacists. I was always very clear about my expectations regarding professional behaviour and clinical standards (although I had not yet consciously, or subconsciously articulated my personal philosophy), and therefore I felt that my staff regarded me as their clinical lead.

The work of Organisation IV had a high political profile. If we identified problems that had potential impacts on patient care, the political stakes were even higher. I had to very quickly learn how to appreciate the political sensitivities, whilst not constraining my findings. I found this very difficult and sometimes stressful and underwent some significant personal and professional changes. I reflected often during this time, trying to work through my antipathy towards organisational politics. I learnt to accept that the

politics were unavoidable, and thus needed to be understood and applied 'for the greater good'. Formal leadership training during this time was in the form of workshops on team building, self-leadership and self-awareness. As part of one course, participants had to undergo 360-degree (multi-source) feedback. The value of 360 feedback process has been studied and appraised in the literature (London & Beatty, 1993; Alimo-Metcalfe, 1998). It was very valuable to learn how I was perceived by others. I used this to reflect on whether I projected the image to which I aspired.

During my 12 years at Organisation VI, I embedded my leadership skills. I also improved the profile of the clinical pharmacy service. I believe this was enabled by my learning to accept and understand the politics and behaviours required to leverage new developments, funding opportunities, networks, organisational priorities etc.

The size and complexity of Organisation VII, where I currently work, is such that I have had to adapt and develop different models of leadership practices. I have done this by drawing on my varied experiences to date.

Developing and leading clinical practice: When applied to reflective practice, critical incidents can be important learning events, positive or negative, that influence one's professional development. They involve personal experience and transformation of knowledge and meaning (Parker, Webb, & D'Souza, 1995; Branch, 2005). My transition from a junior pharmacist into a clinician in my own right, who embraces the attendant personal and professional responsibilities can be illustrated through the use of selected critical incidents which I summarise below.

The first episode was while I was a pre-registration trainee pharmacist. I neglected to follow up a patient's abnormal blood results with their doctor, believing that it was not my responsibility. My tutor was quite forthright in explaining to me that since I had discovered the problem, it then became my responsibility to ensure it was resolved and it was entirely inappropriate (and dangerous) to assume that someone else would notice and resolve it. I recall being shocked by the realisation that my inaction could have led to a patient being harmed. I had a duty of care to the patient, which remained until I handed over the problem to someone in a better position to take action.

The next high impact episode in my clinical development was the time spent learning from senior doctors and other healthcare professionals, during my time on the MSc. in Clinical Pharmacy and subsequently in my first senior clinical role at Organisation II. As an MSc. student, I attended two or three medical ward rounds a week. These afforded me the opportunity to observe and learn from the practice of senior clinicians – especially how they sifted through all the information about a patient, picking up on the most relevant findings and the use of ward rounds as opportunities for teaching. I also started to understand how and where my expertise, as a clinical pharmacist, fitted within the multidisciplinary team and the unique contribution pharmacists made to patient care.

The MSc. in Clinical Pharmacy had the explicit aim of producing the clinical pharmacy leaders of the future. There was therefore a focus on personal skills to enhance one's ability to influence others. This included sessions on Transactional Analysis, negotiation and persuasion skills as well as how to work alongside senior doctors as equal clinical professionals. Interspersed with this was intensive clinical skills teaching and experience, delivered in such a way to enable us to be able to pass on the learning to others, in line with the objective of teaching us how to develop clinical leadership in others.

For four years subsequently at Organisation II, I attended a weekly Consultant-led ward round, developing and contributing my pharmaceutical knowledge. This experience of having to make decisions and give advice about patient care alongside other clinical professionals significantly influenced the way I aligned my professional role within multidisciplinary clinical teams in the future. During this time, I was also conscious of creating my space within the multiprofessional team and learning how best to influence clinical decisions (Mesler, 1991; Doucette, Nevins, & McDonough, 2005). This was very important in the 1990s, as the position of the physician as final clinical decision-maker was still the established order and the role of clinical pharmacists as care providers was still being debated and negotiated (Mesler, 1989; Hepler & Strand, 1990; Batty & Barber, 1992; Cotter, Barber, & McKee, 1994; Winslade, Strand, Pugsley, et al., 1996; Van Mil, McElnay, De Jong-Van Den Berg, et al., 1999; Raehl & Bond, 2000; LeBlanc & Dasta, 2005). My ideal model of practice would have been 'transdisciplinary' (Ray, 1998), with shared boundaries, problems and knowledge between our professions. I did not achieve

this so early in my professional career, although I would argue that my presence on rounds facilitated interdisciplinary working (Ray, 1998; Curley, McEachern, & Speroff, 2003). Additionally, my regular presence on the rounds increased the overall dialogue regarding medicines by non-pharmacist team members, as well as improved their learning about the use of medicines (Kaboli, Hoth, McClimon, et al., 2006; Makowsky, Schindel, Rosenthal, et al., 2009;). I describe this period of consolidating the experiences from the MSc., as honing my 'craft'. Shepard et al. (1999) in their work on describing expert practice in physical therapy discuss the use of craft knowledge or tacit knowledge in clinical reasoning and decision-making. Carmel (2013) applies the definition of craftsmanship to the practice of medicine, using as an analogy with craftsmanship, that medical doctors also use their hands in their work (they have to physically examine patients). Clinical pharmacists traditionally have little or no need to touch patients. However, I would argue that in my expert opinion, clinical pharmacy is still a craft, in as much as one develops the skills of good patient care by continual practice, learning from others, making mistakes and improvisation. During my time at Organisation II, I also started developing my own concept of Clinical Leadership.

In Organisation III, I was also responsible for facilitating the development of others' clinical practice. I would have trainees accompany and observe me as I tried to model good clinical pharmacy practice. We would also discuss the values and ethics of caring for patients, to encourage them to develop their own vision of the type of pharmacist they would like to be. I believed, and still do, that practitioners need to develop a personal philosophy of practice which they use as an internal guide and aid to decision-making. The principle of having one's own philosophy of practice is common in other disciplines, most notably in education. Shepard and colleagues (1999) explain how the experts they interviewed had developed their own personal frameworks, which are similar, but not identical.

The final examples arose during my time in Organisation VI. While I was studying for my prescribing qualification, my mentor was a senior Consultant, and he invited me to use his weekly hypertension clinic as my area of practice. Although I had spent my clinical career advising doctors on which medicines to use, and correcting prescribing mistakes, it was soon evident to me that being the ultimate decision-maker about prescribing a medicine

for a patient required a totally different attitude. I did not have an internal framework of practice for prescribing, or indeed how to deprescribe (withdraw a medicine), and therefore I was initially at a loss as to how I should make my decisions. I solved this by asking my mentor to think out loud when he made decisions, which I used as a basis to develop my framework. I finally reached a stage where I felt able to critique my mentor's decisions, which I believe marked my progression from novice prescriber to competent (Roberts, Gustavs, & Mack, 2012).

Prior to 2004, my length of employment in any one organisation had been four years at most. I remained at Organisation VI for 12 years as I was professionally fulfilled and continually found new challenges to address and opportunities to expand upon. For example, one of my past colleagues is now in a national senior leadership role. As part of my professional development, I decided that I wanted to do some work at national level. I therefore forced myself, against my natural inclinations, to contact my friend and asked to meet with him to discuss any projects or opportunities that I might be able to contribute to. This led to me collaborating on a national discussion document about the commissioning of pharmacy services, which led to my being asked to contribute to the development of national Professional Standards for Hospital Pharmacy Services. with the Royal Pharmaceutical Society (RPS, the Professional Body for pharmacists). I have continued my relationship with the RPS ever since, working with them on policy-setting, presenting at workshops and conferences and promoting the work of the Society. I am now a member of the RPS Hospital Expert Advisory Group and a Fellow of the Society, recognised as a leader in my profession.

1.2.2 Growth as a researcher

I have always had an inner drive to conduct research and audit. Much of my focus as a clinical pharmacy researcher and senior practitioner has been in the areas of standards and outcomes of practice, ensuring and measuring the quality of healthcare treatments and interventions, (mainly prescribing and pharmaceutical care) and innovations in clinical pharmacy practice to achieve patient-focused and organisational goals. These are directly associated with the quality use of medicines and pharmacists' roles in ensuring this.

My first attempt to publish work was whilst I was at Organisation III between 1996 and 2000. I had supervised a project, but the pharmacist involved had left the department by the time I decided to attempt the write up. Although I had her full report, I could not reconcile her figures so I could not write the results section. I therefore abandoned the attempt.

The MSc in risk management focussed strongly on research and writing skills. We spent a lot of time critically reviewing published papers, including the writing styles, and presentation of data. I still draw upon this learning. Despite this, I was unable to publish my MSc. dissertation, due to my ignorance of the publication process and how to write for publication.

The first piece of work I successfully submitted for publication was PW3, a small service audit, soon after taking up position in Organisation V (Onatade & Mehta, 2007). This was followed by a project which I supervised. This work was rejected by the first academic journal we approached, but one of the peer reviewers gave us very detailed and helpful feedback, such that we were able to rework it and submit to a professional (non-academic) journal (Mehta & Onatade, 2008). In 2008, I took the bold step of asking a journal if they would be interested in publishing a short series featuring our work on the development of quality indicators. They subsequently commissioned us to write a set of articles, the 'Quality Series', PW11a – c, which I describe fully in Chapter Two. This commission was a critical confidence booster.

I continued to work on identifying and measuring quality metrics, and submitting work to conferences. By now I was aware that my projects should be bigger with more robust methodologies. Through trial and error, I learnt how to improve my methods, but I was hampered by my poor knowledge of applied statistics and lack of time and resources to conduct larger pieces of work. However, my work was accepted at national and international conferences, some of which won awards.

My role as a researcher is not confined to creating personal knowledge or academic publications. I have always believed that I have a responsibility to encourage and support others to undertake research. This is just as important to me as my clinical leadership

role. On joining Organisation VI, I created and chaired a departmental Research and Audit Group, with the stated objectives of providing expertise and resources, improving the quality of the projects carried out within the department and reducing research waste (Glasziou & Chalmers, 2018). As my skills and knowledge as a researcher developed, I was able to put them into practice by working with colleagues and helping them develop their research skills, which in turn led to better research outputs and practice outcomes. Whilst most projects remained small-scale, output increased, quality was demonstrably improved and submissions to, and acceptance by, conferences increased. The pharmacy department benefited from an increased national profile, increased credibility, and an ability to attract high-quality staff.

A turning point in my research career was the development of a strategic partnership between Organisation VI and a local University. I suddenly had access to high-quality expertise and support for research. With the availability of expert help, there was also increased appetite for research within the department. I easily extended a small-scale project I had proposed, to a much larger piece of work. Advanced analytical support was provided by the university. The paper was accepted by the first journal we submitted to. Since the publication of the paper in 2013, I have continued to undertake research, collaborate with others, present and publish peer-reviewed articles, presented as Public Works in this statement. I also get frequent requests to peer review manuscripts, which I accommodate as far as possible, both as a contribution to the research community and also for my own development as a scholar. The upturn in my research skills had an additional benefit of facilitating my transfer from the Doctorate in Professional Studies, to my current programme, DProf. by Public Works, in 2018.

I have developed and 'polished' my skills throughout my career, by continually learning, practising, and reflecting on various approaches and putting the learning back into practice. This cycle of putting knowledge into practice and learning from practice is an example of what I now would describe as 'praxis' (Rolfe, 1993). I return to praxis as a framework for clinical pharmacy practice and research in the final chapter of this Context Statement. My ability to conceptualise praxis was only made possible through the transformation of my ontological and epistemological positions. Clinical pharmacy practice is grounded in a largely positivist-realist stance, which I previously subscribed to

unhesitatingly. I had little understanding that different methods generate different types of knowledge, and that the methodological approach was relevant to one's view of what constitutes reality (Popay, Rogers, & Williams, 1998). As I have developed as a researcher, I have questioned the dominance of the positivist stance in healthcare research. I understand that my ontology and epistemology inform the design and analysis of my research and I find myself debating the primacy of different types of knowledge with colleagues. At the same time, I have sympathy with the view that you do not necessarily have to be a slave to your epistemological stance, as it is a tool to use to formulate your questions and find answers (Soini & Kronqvist, 2011; Winit-Watjana, 2016). My personal viewpoint has moved towards a more constructivist philosophy, wherein I believe that in some situations, understanding may be more useful than scientific explanations (Marsh and Furlong, 2002). PW34 - *Evidence for the outcomes and impact of clinical pharmacy: context of UK hospital pharmacy practice* (Onatade, Appiah, Stephens, et al., 2017), discussed in Chapter Five, exemplifies how this perspective has influenced my view of how researchers should consider conducting research into clinical pharmacy outcomes in the future.

1.3 Motivation

Professional Doctorates are '*attractive to those who view their own personal development and academic ambition as fully integrated with their professional development and have a commitment to furthering the cause of their profession'* (Bourner, Bowden, Laing, et al., 2010). Above, I have so far described how I have modelled these values, rendering a Professional Doctorate the most appropriate next step in my ambition to enhance clinical pharmacy practice. In addition to the intellectual challenge and personal fulfilment, a Professional Doctorate evidences my claim to be a scholarly professional (Wellington & Sikes, 2006; Fenge, 2009) and my authority as an originator of practice (Costley & Lester, 2011), thus establishing my influence within the hospital clinical pharmacy community.

1.4 Overview of the Works

This Context Statement covers work conducted from 2007 to 2017. The 35 Public Works (PWs) consist of 24 conference abstracts and related posters or presentations, 10 refereed publications in professional and academic journals, and one pre-print, a report of a service development.

I have been the lead researcher and/or author for 26 of the PWs; I have conceived and designed the research studies and conducted the majority of the analyses and/or directed the analytical strategies. I have also drafted the manuscripts; in some cases, co-authors contributed to specific sections. A common theme in my work is my commitment to increasing research expertise and capability within the hospital pharmacy community. I have strived to do this by encouraging less-experienced colleagues to initially conduct small audits, present these as conference abstracts, and then encouraging them to join me on larger research projects suitable for peer-reviewed publication. Many of my co-authors are therefore first-time authors.

The PWs presented fall into overlapping themes, all of which are linked to my stated aim of contributing to the advancement of clinical pharmacy practice. The themes may be summarised as

- measuring & improving standards and quality of care
- prescribing, prescribing practices and prescribing safety
- innovative practice within legal and ethical frameworks
- the impact & outcomes of clinical pharmacy

In this context statement, I discuss the PWs thematically, demonstrating how I have developed and led on these in my sphere of practice. By presenting them this way, the impact of the works and the links between them will be more easily observed and the genesis of the published research articles can also be appreciated. Appendix 1 contains a list of the works in chronological order. Figure 2 is a diagrammatic representation of the overlap and interactions between the four themes.

The PWs relating to measuring and improving standards and quality of care demonstrate my role in developing, implementing, measuring and disseminating clinical pharmacy quality and performance indicators. I started my work in this area in 2004, when, as noted

by a number of authors, there were no developed performance indicators for clinical pharmacy services (Calvert, 1999; Fowler & Campbell, 2001; Radley, Millar, & Hamley, 2001; Millar, Sandilya, Tordoff, et al., 2008; Ng & Harrison, 2010). The concept of measuring and assessing what pharmacists do in order to improve our practice was not on the agenda of clinical pharmacy practitioners. In contrast, medical and other clinical professions had been debating quality and safety improvements for many years (Donabedian, 1966; Closs & Tierney, 1993; Grimmer & Dibden, 1993; Maas, Johnson, & Moorhead, 1996; Ingersoll, McIntosh, & Williams, 2000; Griffith, Alexander, & Jelinek, 2002). I therefore adapted and applied concepts from other disciplines, including the wider Quality Improvement field.

The chapter on prescribing, prescribing practices and prescribing safety encompasses the impact of electronic prescribing on pharmacy practice; the formal and informal roles of hospital pharmacists as prescribers; and the practice model I developed for pharmacists to practice as both specialist and generalist prescribers (solving the conundrum of how to describe the clinical practice of most senior hospital clinical pharmacists). I also discuss my work on assessing potentially inappropriate prescribing.

Measuring and improving the quality of prescribing and pharmaceutical care

Efficiency and safety of discharge from hospital

Provision of information to patients

Preventing medication-related problems at transitions of care

Indicators for clinical pharmacy and pharmaceutical care

Non-medical prescribing

Pharmacists and electronic prescribing

Measuring and improving the quality of prescribing and pharmaceutical care

Prescribing, prescribing practices and prescribing safety

Measuring and improving quality and standards of care

Innovative practice within legal and ethical frameworks

The impact & outcomes of clinical pharmacy

Recording, analysing and rating clinical pharmacy contributions

Pharmacist (non-medical) prescribing

Indicators for clinical pharmacy and pharmaceutical care

Measuring and improving the quality of prescribing and pharmaceutical care

Efficiency and safety of discharge from hospital

Provision of information to patients

Pharmacists and electronic prescribing

Pharmacist (non-medical) prescribing

Figure 2. Diagram showing the overlap across themes and Public Works

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The works described under 'innovative practice within legal and ethical frameworks' cover the introduction of different models of practice. I focus on the expansion of pharmacists' roles to make the medication-related aspects of hospital discharge processes safer and more efficient; innovations across the care interface; and the introduction of an in-reach, specialist pharmacist consulting service model.

The final theme, 'The impact and outcomes of clinical pharmacy' is centred on those works with which my primary intention was to demonstrate the benefits of clinical pharmacy activities, especially with regards to the impact on direct patient care and health service priorities. I also highlight the other PWs where this is a secondary theme. In this chapter I also discuss the state of the published literature on the outcomes of clinical pharmacy, the need for a coherent vision and new research approaches. Innovative outcome measures and research methodologies for clinical pharmacy practice are necessary if, as a profession, we would be valued as both clinicians and academic practitioners.

I conclude the context statement by discussing the importance of developing a blueprint to ensure research informs practice and vice-versa. Borrowing from the nursing and educational literature, I propose a new philosophy for clinical pharmacy practice and research.

CHAPTER TWO: Measuring and improving standards and quality of care

The ultimate goal is to manage quality. But you cannot manage it until you have a way to measure it, and you cannot measure it until you can monitor it

- Florence Nightingale (1820 - 1910)

2.1 Introduction

My earliest works are weighted towards the initial development of quality indicators, followed by processes to assess care standards, in order to monitor and improve quality. In this first chapter therefore, I present my work in this area. Section 2.2 provides the background to this topic, and I also discuss how my interest developed. In 2.3, I describe the related Public Works, starting in section 2.3.1 with PW11, the 'Quality Series' of articles I was commissioned to write in 2008 and 2009. In sections 2.3.2 to 2.3.4, I elaborate on the developmental work undertaken to establish the initial indicators and measuring processes. These works included are PW2 - *Frequency of Drug History taking by pharmacists at King's College Hospital* (Virani, Onatade, & Mehta, 2008), PW4 - *Assessing the proportion of patients discharged with medicines issued directly from the ward* (Ling, Mehta, & Onatade, 2008), PW6 - *Quality and quantity of information on medicines given to patients discharged from hospital* (Khudairi, Onatade, & Patel, 2008), PW7 – *The use of missed doses as an indicator for assessing the quality of clinical pharmacy services: a comparison of two audits* (Onatade, Bell, Garcia, et al., 2008), PW8 – *Pilot of a ward discharge medication labelling service* (Brown, Patel, & Onatade, 2008) PW10 - *Identifying criteria for use in assessing the quality of pharmaceutical care* (Onatade & Zuhair, 2010), PW12 – *The selection, modification and reliability testing of a tool for rating the significance of pharmacists' clinical contributions* (Onatade, Mehta, & Shallal, 2010), PW15 *Assessing the quality of pharmaceutical care: a feasibility study* (Onatade, Shah, Alidina, et al., 2011) and PW17 - *Quality of vancomycin prescribing and clinical outcomes in individual patients at a London Teaching Hospital* (Talpaert, Aroyewun, & Onatade, 2011).

PW27 – *The use of Always Events in a survey of inpatients' experiences with their medication and the clinical pharmacy service* (Onatade, Gujral, Phul, et al., 2015)*, although a later work,* is also relevant. PW23, in section 2.3.5 - *Baseline assessment of the confidence, knowledge and skills of pharmacists when providing pharmaceutical care to patients with diabetes* (Bell, Callender, Razouk, et al., 2014), is a different approach to assessing the capacity of a clinical pharmacy service to provide high-quality pharmaceutical care. In section 2.3.6, PW29 – *A quantitative comparison of ward-based clinical pharmacy activities in 7 acute UK hospitals* (Onatade, Miller, & Sanghera, 2016) introduces benchmarking of clinical pharmacy activities between hospitals. Finally, in section 2.3.7, I highlight work undertaken in later years, mainly aimed at addressing the monitoring gaps which still existed in the service after I implemented the quality monitoring system - PW13 (Considine, Onatade, Knighton, et al., 2010), the collections in PW20 (2004 to 2017) and PW30 (2009 and 2017), PW21 (Onatade, Auyeung, Scutt, et al., 2013), PW25 (Knight, Scaria, Lama, et al., 2015) and PW26 (Amadu, Adebimpe, & Onatade, 2015). Other related works are described in later chapters - PW3, PW5, PW19, and PW28 - these were carried out as a means of improving our processes or patient outcomes where issues had been identified.

2.2 Background to standards and quality improvement

I have an inherent interest in clinical risk, quality assessment and quality improvement. I expand on the definition of these terms later on in this chapter. The development and measurement of indicators of the quality of clinical pharmacy performance and pharmaceutical care continues to be a topic requiring much work, although it is now a significant area of enquiry for pharmacy researcher-practitioners (Ng & Harrison, 2010; Bruchet, Loewen, & de Lemos, 2011; Fernandes, Gorman, Slavik, et al., 2015; Marine, Spinewine, Bruno, et al., 2018). There are two strands of quality improvement which are mainly applicable to clinical pharmacy practice - *standards of practice* (indicators, key performance indicators) and *quality of care* (examples of quality indicators are discussed below). High standards of practice should be expected to lead to high quality of care (Pierce, 1990; Chassin, 1996). There were several important sources which informed my thinking and learning in the early stages. Donabedian (1966) describes a framework for

assessing the quality of medical care. His triumvirate of Structure, Process and Outcome is applicable to all healthcare professions, including healthcare leadership.

2.2.1 Quality improvement and indicators in pharmacy practice

In the early 2000s when I began my work in the arena of quality and standards, I was unable to locate information on clinical pharmacy indicators. This was despite the availability of a considerable body of literature in the healthcare research arena, conceptualising and describing processes of quality measurement (Donabedian, 1966; Committee on Quality of Health Care in America, 2001; Rubin, 2001; Wenger & Shekelle, 2001; Arah, Klazinga, Delnoij, et al., 2003; Mainz, 2003a; McGlynn, Kerr, Adams, et al., 2003). There were also debates regarding the nature and utility of quality evaluation and quality indicators in healthcare as a concept (Maxwell, 1984; Closs & Tierney, 1993; Miles, O' Neill, & Polychronis, 1996; Idvall, Rooke, & Hamrin, 1997; Davies & Lampel, 1998). At the same time, other professions and clinician groups were introducing broad, disease-specific (Campbell, Roland, Shekelle, et al., 1999; Hickey, Scott, Denaro, et al., 2004) or practice-based quality measures (Grimmer & Dibden, 1993; Tobin, 1999; Skews, Meehan, Hunt, et al., 2000; Devane, Begley, Clarke, et al., 2007). Although there was little work on pharmacy practice, criteria for prescribing and appropriate use of drugs were being developed and introduced into practice (Hanlon et al. 1992; Beers 1997; Portelli 1999; Campbell et al. 2000; Knight et al. 2001). I called upon this then-prevailing literature in my bid to develop measures of clinical pharmacy service quality indicators.

My interest in quality and risk management led me to embark upon an MSc. in Clinical Risk Management (1999 - 2001). My knowledge of, and interest in risk and quality were significantly enhanced by this course. In addition, in 2000, I joined the first organisation to be charged with reviewing and reporting on the quality of healthcare provided by the NHS, the Commission for Health Improvement (CHI). CHI was responsible for improving healthcare standards through inspections and investigations. My role involved leading and managing Clinical Governance inspections (reviews) of NHS Trusts. Some of the reviews covered pharmacy services, but the role was wide-ranging, and could include any clinical speciality, leadership and management, staff engagement and patient involvement (Commision for Health Improvement, 2001). There was rarely a specific focus on

pharmacy. I was introduced to quality assessment tools and concepts and also worked with colleagues who were equally as passionate about improving care. I brought this passion with me when I returned to the NHS in 2003. In the first pharmacy department I returned to, I introduced Key Performance Indicators (KPIs) into the department, with variable success. I moved to King's College Hospital (KCH) in 2004, as Deputy Director of Pharmacy for Clinical Services. I was responsible for a large clinical pharmacy service, of approximately 60 staff members (and growing), with many different specialties and clinical pharmacy leads for each. I recognised immediately that I needed to have adequate intelligence to monitor, evaluate, manage and improve the quality of the service and demonstrate value for money. This information was lacking. I therefore embarked upon a journey to develop, implement and embed quality and performance indicators for the service.

The holy grail of quality measurement is said by many to be outcomes - the effect of care on health status (Donabedian, 1966; Mainz, 2003b) - as these are what ultimately matter to patients. Important clinical outcomes include mortality/survival, recovery, symptoms, readmission rates, side effects, adverse events, quality of life, client or patient satisfaction (Campbell, Braspenning, Hutchison, et al., 2002; Closs & Tierney, 1993; Mainz, 2003a). When considering non-clinical aspects of quality, outcomes such as costs, expenditure and waiting times to access care are included. Outcomes can be difficult or unfeasible to measure, especially indicators of satisfaction or if the relevant outcome may occur years after the care has been provided. Additionally, a poor outcome may not reflect poor quality of care. It may also happen that a patient will have a good outcome, despite sub-optimal care (Brook, McGlynn, & Shekelle, 2000; Mant, 2001; Rubin, 2001). In PW11a - *Quality indicators are important measurement tools for pharmacy* (Onatade, 2008), I discussed the limitations of outcome indicators in monitoring the quality of clinical pharmacy practice.

Often the primary focus of quality improvement, process measures or indicators, on the other hand, assess 'what was done', i.e. activities or tasks undertaken whilst providing care. These include diagnosing, providing treatment, counselling or advising patients, or activities to minimise or avoid unwanted effects of treatment. To assess structure, one

must study the resources, setting, environment, facilities, staffing, organisation, operations and other attributes under which care is provided (Donabedian, 1966).

All three dimensions are linked in the assessment of quality. To be deemed valid, a process measure must be able to be linked to improvements in outcomes, and a good structural indicator must be demonstrably or theoretically shown to achieve better outcomes or enable improvements in care processes. Therefore, each indicator type cannot be used in isolation and measures must be chosen according to their appropriateness to the area being monitored. An evidence-based approach and intellectual inquiry is thus required when developing quality indicators (Donabedian, 1966; Mainz, 2003b).

A second paradigm for framing quality of healthcare uses the six dimensions of quality as postulated by the Institute of Medicine (IOM) in 2001. These are: *safe, effective, patient-centred, timely, efficient and equitable*. Interestingly, these dimensions are very similar to those first described by Maxwell (1984) - *access, relevance to need, effectiveness, equity, social acceptability, efficiency and economy* - although he is not referenced by IHI. The IHI dimensions were not widely quoted in the literature when I was considering quality indicators; as a result, I did not address them in my developmental work, nor in PW11a. However, the series of articles provide concise explanations of various concepts in quality measurement as they apply to clinical pharmacy practice. As such the series is a useful primer and provides a robust baseline for pharmacy professionals starting out in this field.

2.3 Public Works on measuring and improving standards and quality of care

2.3.1 The 'Quality Series' of articles

When I started my research into quality indicators in the early 2000s, the only relevant UK-based publication that I could find was a paper by Radley et al (2001). The authors developed clinical pharmacy quality indicators at a District General Hospital in Scotland. I drew on their methodology of deriving 'quality statements' and using these to develop indicators. The four quality statements I derived or adapted were:

1. Each patient will have an accurate medication history within two working days of admission

2. There is seamless continuation of prescribed therapy (during inpatient stay) to achieve the desired patient outcome

3. All pharmaceutical care issues have been addressed for each patient

4. Patients will be discharged with all medication already available on the ward with no additional dispensary input

The indicators address the different stages of the inpatient pathway - admission, acute stay and recovery, and discharge (now often called transfer of care). A crucial aspect, which was later considered, is the requirement to ensure a safe transition to the next care setting (e.g. home, intermediate or residential care). This is returned to later in this chapter.

I pitched the idea of the Quality Series (a series of three publications) to the editor of a professional journal (Pharmacy in Practice), as a way of introducing to practitioners, the need for the profession to start talking about assessing the quality of our clinical practice and clinical pharmacy services. PW11a – *Quality Indicators are important measurement tools for Pharmacy* (Onatade, 2008) was the introductory article, discussing concepts of quality improvement and measurement, describing the journey undertaken to develop initial quality indicators for the clinical pharmacy service at King's College Hospital (KCH) and introducing the early indicators. All three articles in the series are publicly available on a research website (**www.researchgate.net**) and currently, an average of 14 readers a week access the full-text of PW11a.

In 2005, we (the team I led) started auditing the proportion of patients from whom a medication history was obtained and documented by a member of pharmacy staff. PW2 (Virani, Onatade, & Mehta, 2008) is an abstract describing early results. We continued monitoring results and improving upon the methodology for several years. In 2007, the National Institute for Health and Clinical Excellence (NICE) and National Patient Safety Agency (NPSA) produced national guidance on medicines reconciliation (the process of obtaining an accurate medication history soon after admission and ensuring that this is reflected in the current prescription, (National Institute for Health and Clinical Excellence &

National Patient Safety Agency, 2007). The release of this guidance meant that all hospital pharmacy departments started to include medicines reconciliation in their regular audit plans. Medicines reconciliation rates are now a key indicator of medication safety in NHS organisations, and are included in the Medication Safety Thermometer[1] (Rostami, Power, Harrison, et al., 2017). The work described in PW11b -*Each patient will have an accurate medication history within two working days of admission* (Mehta & Onatade, 2008b) predates the national guidance and therefore the terms 'obtaining and documenting a medication history' is used in the quality statement rather than 'medicines reconciliation'. However, they largely have the same meaning.

PW11b describes the first quality statement in the series and how the standard was derived and measured. The quality issue addressed was the importance of having an accurate list of all medication a patient is taking when being admitted to hospital. It has long been recognised that incomplete medication histories are common and a significant area of risk if critical treatment is interrupted or medicines are incorrectly prescribed.

The second quality statement is described in PW7 (Onatade, Bell, Garcia et al. 2008) - *Missed doses as an indicator for assessing the quality of clinical pharmacy services.* This was presented as a conference abstract in 2008. Omitting prescribed medication can cause adverse events and delays to recovery. Many pharmacy departments had presented small audits of their omitted dose rate, but other than by Radley et al., (2001) it had not previously been used as an indicator of the quality of a clinical pharmacy service. In PW7, we presented the results of two audits. The first was to establish a baseline rate and set a target. In the second audit, the severity of the consequences of the missed doses was scored by pharmacists, doctors and nurses using Dean and Barber's rating scale (Dean & Barber, 1999). Severity scoring to establish the importance of missed doses had not previously been conducted. Our conclusion from this work was that auditing the rate of all missed doses was of limited usefulness because of the low rate and low clinical severity of the omissions. We recommended the compilation of a list of drugs which should be audited. Subsequently, national guidance (National Patient Safety Agency, 2010; NHS

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[1] The Medication Safety Thermometer is a measurement tool for improvement that focuses on medication reconciliation, allergy status, medication omission, and identifying harm from high risk medicines.

Improvement, 2013) has been developed which uses the rate of omitted 'critical drugs' to assess the safety of medication use within hospitals. PW7 predates this national guidance.

2.3.2 Assessing the quality of pharmaceutical care

Indicators relating to the third quality statement – *All pharmaceutical care issues have been addressed for each patient* - were the most difficult to develop. At King's College Hospital, my colleagues and I adopted the same statement as Radley and colleagues (2001), but not their methodology. Radley et al conducted retrospective peer reviews of pharmaceutical care assessments and plans after discharge, to check if all care issues had been identified and addressed. They found that the external reviewer agreed with 92% of care plans. In a smaller, follow up audit, no additional clinically significant care issues were identified. In my opinion, the term 'clinically significant care issues' was not sufficiently well-defined to be used as a quality indicator, and the method used did not enable objective assessment of the quality of care. Therefore, I searched the literature on assessing quality of care, to develop a more robust methodology. Campbell et al. (2003) describe methods of developing quality indicators, including how to reach consensus. They advocate using systematic methods, and suggest combining evidence, clinical guidelines and professional opinion to gain agreement on appropriate indicators. Beers et al. (1991) used a Delphi methodology to develop explicit criteria for identifying inappropriate medication use. Hearnshaw et al. (2001) also used a modified Delphi method to identify desirable characteristics of review criteria. Rubin et al. (2001) provide excellent step-by-step guidance on explicit process review. I used all these sources to inform my thinking and work in this area.

PW10 (Onatade & Zuhair, 2010) was the first phase of the work to develop a method to assess the quality of pharmaceutical care. I carried out a modified Delphi study in an attempt to identify valid, objective criteria for assessing the quality of care. The focus was on explicit, rather than implicit criteria, and on the quality of care related to medicines use as received by patients, regardless of which healthcare professional provided that care. The premise was that clinical pharmacists should take responsibility for ensuring that medicines-related issues were appropriately addressed, but did not necessarily have to provide the care themselves. Due to the large number of clinical pharmacists willing to

participate (64 volunteers responded to my call for panel members), the Delphi study took longer than expected and necessitated a change to my initially proposed methodology. In order to have a manageable number of participants, I had to create two separate panels. The first panel were sent a preliminary list of suggested criteria from the literature and expert review, with the aim of streamlining the list by rating the criteria as 'important, unimportant or unsure' and/or adding new criteria. The new list was sent to the second panel, and two rounds of scoring took place. The outcome from PW10 was a list of criteria which senior UK clinical pharmacists deemed relevant in assessing the quality of pharmaceutical care.

PW10 was successful in its aim of identifying criteria for use in assessing the quality of pharmaceutical care. However, Campbell et al. (2003) explain that formulating the list indicators is simply the first step in developing measurable, explicit indicators. Feasibility testing, followed by validation, are also key. Hearnshaw et al's (2001) list of desirable characteristics also includes some criteria which can only be tested and finalised through piloting. Therefore, I embarked on further work, some of which is described in PW15 (Onatade, Shah, Alidina, et al., 2011) and PW17 (Talpaert, Aroyewun, & Onatade, 2011). PW15 – *Assessing the quality of pharmaceutical care: a feasibility study* - is the larger piece of work. I chose four criteria from the Delphi list developed in PW10, and together with my co-researchers, developed standards of care for each, using clinical guidelines, clinical evidence from the literature and our clinical expertise. Descriptions of best practice in medical record review and chart abstraction were used as a guide in creating data abstraction forms and to develop a process to retrospectively review patient records (Roth, Sherwood, Murata, et al., 1993; Banks, 1998; Gearing, Mian, Barber, et al., 2006). This study provided us with information on the proportion of patients receiving fully appropriate care, as judged by the receipt of all care elements in the specific criterion measured. Each criterion was deemed feasible to measure, thus achieving our aim. The next step was to combine several criteria and apply to individual patients, so as to obtain an overall assessment of the quality of pharmaceutical care. Whilst this work was carried out the following year, it was never presented publicly.

I presented the results of the Delphi at a national conference in 2009. At the same conference, I presented a parallel piece of work, which also grew out of my quest to

support the assessment of the third quality statement. PW12 (Onatade, Mehta & Shallal, 2010) is *The selection, modification and reliability testing of a tool for rating the significance of pharmacists' clinical contributions.* A significant proportion of pharmacists' care activities involve advising patients and other healthcare practitioners on appropriate medication use, making changes to prescriptions and intervening to prevent medication errors. There are instruments for scoring the significance of adverse medication events and errors. However, there is no agreed, validated tool to measure the clinical significance of pharmacists' contributions to care unless they are error prevention activities. This lack of a standardised tool hampers any real comparisons of pharmacists' clinical abilities or overall service quality and also hampers benchmarking between services. PW12 was an initial effort at addressing this problem. The study generated considerable interest and won the award for best oral presentation at a national conference. I have continued to develop the tool, and have modified it considerably since the first iteration. PW16 (Onatade, Chowdhury, Bell, et al. 2011) is a study I led, focussing on different ways of recording clinical pharmacy contributions to care, using the tool to rate the clinical significance of these contributions. It has been in use in my previous trust (King's College Hospital) since 2008 and colleagues around the country have also used it in their work. PW33 (Mehta & Onatade, 2016) describes ongoing work to validate the tool. PWs 12, 16 and 33 are discussed in greater detail in section 5.2 – demonstrating the impact of clinical pharmacy activities.

2.3.3 Improving the timeliness of discharge from hospital

PW4 (Ling, Mehta, & Onatade, 2008) - *Assessing the proportion of patients discharged with medicines issued directly from the ward,* relates to the role of pharmacists in ensuring timely patient discharge from hospital, with all required medicines (see section 2.3.1 - Quality statement 4 – *patients will be discharged with all medication already available on the ward with no additional dispensary input).* Ensuring safe efficient patient discharge is as topical today as 15 years ago (National Audit Office, 2003), and the pressure to achieve waiting times targets was just as great then, as now. Pharmacy departments are often targeted in the bid to improve 'flow' through the hospital, as the supply of discharge medication is often the final stage in the patient's stay (NHS Improvement, 2017). The indicator described in PW4 and expanded upon later in PW11c – *'Improving the patients'*

discharge experience is an important pharmacy goal' - (Onatade & Mehta, 2009), reflects the role of Pharmacy. If discharge medication requirements can be anticipated, the medicines can be supplied to the ward in advance of a prescription being written, and finalised once the prescription is available, avoiding any last-minute dispensing delays. By a process of measuring, communication, and setting targets, we managed to increase the proportion of discharges fully 'completed on the ward' from 17% to 30% in two years and the proportion of individual medication items already available on the ward from 33% to 58%. This is described in PW11c (Onatade & Mehta, 2009). The overall outcome of this work was to reduce the time taken to discharge a patient by 45 minutes. PW8 (Brown, Patel, & Onatade, 2008) was a service development designed to support the rapid availability of discharge medication by dispensing and labelling medication closer to the patient. Although the pilot study demonstrated improvements in the timely provision of medication, the work was not continued at the time due to operational reasons. Ward-based labelling is however now very popular in many hospitals as a means of facilitating rapid supply of discharge medication. This indicator, or variations, is now widely used within pharmacy to measure service efficiency (Hobson 2015; Robinson et al. 2016; NHS Improvement 2017). In PW29 (Onatade, Miller, & Sanghera, 2016)– *A quantitative comparison of ward-based clinical pharmacy activities in 7 acute UK Hospitals*, myself and co-authors also reported this measure - this is described below in section 2.3.6.

Whilst the fourth quality statement - *patients will be discharged with all medication already available on the ward with no additional dispensary input* - is meant to improve the discharge experience for patients, it ignores other important, outcome-based aspects of discharge, including safe transition and the provision of appropriate information for patients, carers and other healthcare providers. Some of my other works (PW6 and PW27 in section 2.3.4 and PW25, PW26 & PW29 in section 2.3.6) have addressed this, although I did not manage to fully integrate the learning and outcomes from these other studies into a full quality-monitoring framework.

2.3.4 Improving the provision of medication-related information to patients

To address the provision of information to patients, PW6 (Khudairi, Onatade, & Patel, 2008) describes a study assessing information provided to patients discharged from

hospital. We found that most patients reported receiving no information on how to obtain further supplies, side effects, drug interactions or special precautions regarding their medicines. However, the majority rated the quality of information they were provided highly. There were thus inconsistencies between the type of information received by patients and their perception of the quality of such information. However, the aim of developing a feasible outcome indicator for clinical pharmacy services was achieved, albeit one which was at the time, time-consuming to measure. Unfortunately, clinical pharmacy professionals still do not spend enough time speaking to patients whilst they are in hospital, therefore the problem of insufficient information provision still exists (Care Quality Commission 2015; Onatade, Miller, & Sanghera 2016). The work described in PW6 was revisited years later, in PW27 (Onatade, Gujral, Phul, et al. 2015), using the concept of 'Always Events$^{©}$' (the opposite of Never Events) and rapid Plan, Do, Study, Act cycles to improve our performance. At the time, I believed that I had coined the term 'Always Events' but I subsequently found that it had been conceived by the Picker Institute in 2009 and copyrighted (Hayward, Endo, & Rutherford, 2014). NHS England also started a pilot trial of Always Events in 2015 (Picker Institute Europe, 2017). I left KCH soon after presenting PW27, so was unable to progress that initiative. Providing patients with the information required to use their medication safely and supporting them to adhere to their medication regimen remains an area of care requiring significant input from clinical pharmacy staff.

2.3.5 Assessing pharmacists' ability to provide safe care to patients with diabetes

PW23 – *Baseline Assessment of the Confidence, Knowledge and Skills of Pharmacists when providing Pharmaceutical care to patients with Diabetes* (Bell, Callender, Razouk, et al., 2014) is a project which took a different, surprisingly rare (for pharmacy) perspective on ensuring quality of care. In this work, we assessed, by way of a questionnaire, the confidence and competence of pharmacists to provide safe care to patients with diabetes. The work was led by myself and another pharmacist and involved other senior pharmacists with expertise in diabetes, including an educator. As diabetes is not my specialist clinical area, my expert contribution was in the design and conduct of the questionnaire and study, and the data analysis. This project was striking on two accounts – we found a significant lack of knowledge and skills, accompanied by a lack of

confidence, in the areas assessed. Additionally, in our literature search, we could find no comparable work focussing on pharmacists, either in diabetes or other clinical conditions. There are studies assessing the knowledge and skills of pharmacy undergraduate students, yet it appears that our profession sees little need to assess qualified pharmacists' clinical competence. There are recent signs of more work being conducted on this topic, in other clinical specialties. Diamantouros et al. (2017) describe pre- and post-assessment scores after the delivery of a thrombosis management programme to pharmacists. Belachew et al. (2017) tested the competency of pharmacists in using metered dosage inhalers, and reported that only 4.8% of participants had competent techniques. Because of the paucity of pharmacy-specific published research, we drew on literature from the medical and nursing professions. PW23 was written up and submitted for publication, although it was not accepted. The draft manuscript can be seen in PW23b. My co-author was unable to rewrite the paper for submission elsewhere because of other commitments.

2.3.6 Benchmarking clinical pharmacy services

My most recent work on the topic of measuring and improving standards and quality in hospital clinical pharmacy is PW29. This is a study which I coordinated and led. It is the first published study comparing clinical pharmacy services in different hospital trusts in the UK. In the study, we demonstrated several areas of commonality (including minimal patient consultation episodes) but also significant variation. Much of the variation was due to differences in the types and availability of electronic systems and technology, and hospital types, but there was also considerable unexplained variation. The study enables benchmarking of specific clinical pharmacy processes and outcomes. For example, the percentage of discharge prescriptions completed on the ward ranged from 17% to 38%, with a median of 32%, very similar to the figure achieved at KCH in 2008 (Quality statement 4 - *Patients will be discharged with all medication already available on the ward with no additional dispensary input*). Published information (Hobson 2015; NHS Improvement 2017) indicates that depending on the emphasis placed on this activity and resources made available, up to 100% ward completion of discharge prescriptions can be achieved, although this is highly variable. My professional experience from reviewing work carried out by other people, is that the average is in the region of 30%.

Researchers from Belgium have recently published work on the development of a tool for benchmarking clinical pharmacy activities (Marine, Spinewine, Bruno, et al., 2018). The indicators presented are all included in the activities measured by myself and co-authors in PW29, except for documenting adverse drug reaction monitoring, which we did not record as a separate pharmaceutical care activity.

2.3.7 Other related works

PW13 – *A review of a pharmacist discharge prescription writing service in a large teaching hospital* (Considine, Onatade, Knighton, et al., 2010), the reports and presentations for PW20 – '*Redesigning the discharge medication pathway'* (2004 to 2017) and PW30a – *'The incidence and severity of errors in pharmacist-written discharge medication orders'* (Onatade, Sawieres, Veck, et al. 2017) describe work undertaken to improve the efficiency and safety of the discharge process, including evaluations of the impact of this work. PW20 describes the implementation of pharmacists writing discharge medication orders instead of doctors, and PW30a reports on the consequent substantial reduction in discharge medication error rates after implementation of this initiative. PW21 - *Potentially Inappropriate Prescribing in Patients on Admission and Discharge from an Older Peoples' Unit of an Acute UK Hospital* (Onatade, Auyeung, Scutt, et al. 2013) was research which stemmed from my interest in how pharmacists could improve prescribing quality. In PW25 (Knight, Scaria, Lama, et al. 2015) and PW26 (Amadu, Adebimpe, & Onatade, 2015), collaborative work on preventing and resolving medication-related problems which commonly arise during transitions of care is described. These PWs are all closely related and will be discussed in the chapters on prescribing and innovative ways of working.

In summary, this chapter has described my work in quality improvement and the development of quality indicators for clinical pharmacy services. Some of the PWs will be revisited in later chapters, where themes and PWs overlap. In addition, many of the PWs also demonstrate my commitment to increasing the quality and volume of clinical pharmacy practice research outputs, and mentoring and supporting others to improve their research and writing skills. The PWs presented here were led by myself, however, as can be seen by the list of authors, I always worked with others to produce the work. Many

of my co-authors were pharmacy undergraduates, or pre-registration pharmacists, required to undertake projects. I ensured they learnt how to undertake high-quality audit and research work which were then presented at conferences, so they could cite the work in their CVs. I also encouraged one of my colleagues to be first author on PW11b, by guiding her closely and reviewing the article before submission. I was the driving force behind ensuring that PW29 was published, providing leadership, encouragement and motivation to my co-authors, so that we prevailed in the face of many other priorities in our daily jobs.

CHAPTER THREE: Prescribing, prescribing practices and prescribing safety

It is an art of no little importance to administer medicines properly: but it is an art of much greater and more difficult acquisition to know when to suspend or altogether to omit them

- Philippe Pinel (1745-1826)

3.1 Introduction

This chapter will detail my work in the areas of both medical and non-medical prescribing and the links with prescribing safety and appropriateness. I start with electronic prescribing (e-prescribing) and explore how this affects clinical pharmacy practices and workflow, as this is the subject of PW1 – *Experience of electronic prescribing in UK hospitals: a perspective from pharmacy staff* (Mehta & Onatade 2008a), one of my earliest PWs. The full introduction of an electronic prescribing system into my organisation took some years from initiation, therefore subsequent PWs relating to e-prescribing, described in this chapter, were undertaken many years after PW1.

3.2 Electronic prescribing and clinical pharmacy practice

E-prescribing, computerised (physician) order entry (CPOE), electronic prescribing and medicines administration (EPMA) and electronic medicines administration records (eMAR) are all terms used to describe the constituent parts of an entire electronic system. E-prescribing is often defined as "the utilisation of electronic systems to facilitate and enhance the communication of a prescription or medicine order, aiding the choice, administration and supply of a medicine through information and decision support and providing a robust audit trail for the entire medicines use process" (Cornford, Franklin, Savage, et al., 2009, p9). EPMA also facilitates wider improvements in clinical practice: reductions in paperwork and transcriptions; improved audit trails for medication;

performance monitoring and intelligence; reporting on drug use; greater consistency and continuity of care between primary and secondary care settings; and more enhanced communication between hospital departments and pharmacies (JAC Medicines Management, n.d.).

3.2.1 The impact of e-prescribing on clinical pharmacy practice

When I joined King's College Hospital in 2004, plans were already underway to introduce an electronic prescribing system. A shift from having medication prescribed on patients' individual paper drug charts to electronic prescriptions would mean a significant practice change for all healthcare professionals who needed to see medication lists and/or were involved in making medication-related decisions. A primary role of hospital clinical pharmacists is to review inpatients prescribed medication. However, the potential impact of e-prescribing on clinical pharmacy services was unknown and not under discussion. In the early to mid-2000s, most of the published literature on e-prescribing came from the United States. Bates et al. (1999) concluded that CPOE prevented some medication errors. The Institute of Medicine (IoM) in the United States also advocated the use of electronic and digital systems as a means of improving safety and efficiency (Apsden, Wolcott, Bootman, et al., 2007). US healthcare systems and ways of practice are significantly different from those in the UK, therefore the information in these reports and articles are not necessarily transferable. In the UK, Tully (2000) considered the impact of information technology on the performance of clinical pharmacy services. However, this was broad and largely speculative and did not go into any detail about the known impact of electronic prescribing on practice. Therefore, there was a gap in knowledge regarding EPMA in the UK and how clinical pharmacy activities may need to adapt. Given the pending implementation of EPMA in our organisation, my experience of leading the development of hospital clinical pharmacy services and the dearth of prevailing literature, I decided that it was important to understand and predict how we might need to change the way we work, so that we could continue to practice safely and efficiently. The generic literature validates this position. Wears and Berg (2005) provide a succinct overview of the problems associated with the introduction of computer technology into complex work and explain why healthcare would not be immune. The opportunity to undertake this piece of work came when my deputy (and future long-term collaborator) asked me for a suitable service

evaluation project for her postgraduate diploma coursework. I proposed an evaluation of the effect of electronic prescribing on pharmacy practice. Few hospitals had implemented EPMA at this time. In 2002, Summers' survey of UK Chief Pharmacists found that 3.1% of responding trusts (6/191) had full e-prescribing systems in their organisations (Summers, 2002). Uptake continues to be slow. By 2015-16, just 13% of trusts had fully deployed EPMA (Lord Carter of Coles, 2016). Because of the small number of eligible organisations, I suggested using semi-structured interviews as a suitable methodology to elicit information on changes to clinical pharmacy practice. Some of our findings on practice changes emanating from the implementation of EPMA, as reported in PW1, are reflected in others' later research. Ahmed et al. (2016) reported that pharmacists changed their workflow. Burgin et al. (2014) found that pharmacists experienced less patient contact, alterations in their relationships with doctors because of the need to provide informal training and changes in how and what information they recorded. Burgin concludes that pharmacists develop individual working practices in response to changes that electronic systems provide. I revisit these two latter points in the following section, in PW22 (Austin & Onatade, 2013).

3.2.2 Informal prescribing activities of pharmacists in the context of e-prescribing

Implementation of EPMA in my organisation was suspended in 2006 for various reasons, including difficulties with the roll-out and concerns regarding safety. It resumed in 2010 and concluded early in 2012. An immediate decision was made that pharmacists would have full prescribing rights, whether they were qualified prescribers or not. This meant that pharmacists could generate, amend, or cancel a medication order (individual item in a list of prescribed medication) without contacting a doctor. Non-prescribing pharmacists would not write and sign a new or rewritten medication order on a paper chart as this was illegal - drug chart orders are commonly regarded as prescriptions (they are actually instructions to administer a medication) and nurses (or any competent professional) should only administer medication against an order signed by an 'appropriate practitioner' i.e. a qualified prescriber (The Human Medicines Regulations, 2012). With paper drug charts, non-prescribing pharmacists could and did cancel orders, in accordance with trust policy which stated that all cancellations should be signed and dated, with a brief reason

documented. However, order amendment was not allowed. The order would have to be cancelled and completely rewritten. As a valid medication order on a paper chart must have a signature accompanying it, it would be obvious if a pharmacist had inappropriately signed it. Pharmacists were therefore prevented from signing orders on paper drug charts because of the legal and professional ramifications of so doing. They would on occasion, however, write the order and then ask the doctor to sign. With EPMA, however, there was no requirement or facility to sign orders, as access rights to create, amend and/or cancel orders were granted according to one's login, which was set according to professional group. A pharmacist could enter or amend an order under their own cognizance.

When the decision was made to allow all pharmacists to have full prescribing rights, the expectation was that they would understand the limits of their professional responsibilities and practice accordingly. We therefore did not have any policies or protocols denoting the boundaries of this significant change to their responsibilities. Pharmacists could also enter, amend or cancel orders under the responsibility of a named prescriber; however, this latter option was not mandated. As the service lead, I became concerned that pharmacists were apparently often routinely initiating, changing and cancelling medication orders under their own authority whether or not they were authorised prescribers. It was not clear how widespread this was, why they were doing it, what documentation was entered in the patient record, or if the responsible doctor was contacted before changes were made to patients' prescriptions. As there were likely significant medico-legal implications of this practice, it was important that the extent of this was investigated.

PW22 – *Evaluation of the Ordering and Cancelling of Inpatient Prescriptions by Pharmacists using Electronic Prescribing* (Austin & Onatade, 2013) was the result of this investigation. The first author was a pharmacist in the e-prescribing team. She carried out the project to fulfil the requirements of a postgraduate diploma. I designed and supervised the work. The findings showed that pharmacists were generating 7% of all medication orders and cancelling 21%, therefore a significant amount of 'prescribing' activity was being undertaken. Only a small proportion of the new and cancelled orders were reviewed fully in the study, because of time restrictions. The review took the form of inspection of patient records to identify reasons for the pharmacists' actions, and to assess the level of documentation. Documentation was limited. However, the main reasons for

the pharmacists' actions appeared to be to ensure appropriate continuation of medication and to improve safety. This informal practice of pharmacists, ordering and cancelling medication orders, pre-empts authorised pharmacist prescribing.

PW22 was a forerunner to later studies evaluating the extent and type of pharmacist prescribing in hospitals. It is instructive to note the similarities and differences between our findings and those of later research. Baqir et al. (2014) undertook an evaluation of pharmacists' medication prescribing in three hospitals in North East England. The authors included both initiating and stopping medication orders in their definition of prescribing activities. Pharmacists accounted for 12.9% of all prescribing. This is similar to our figure of 10.3% if one applies the same definition. As with our study, the main reason for prescribing was that patients' regular medicine was not prescribed. However, Baqir et al. found that 13% of pharmacists' medication orders were for new therapy, which would be entirely appropriate in the context of authorised prescribing, but less so at KCH where we were investigating the unauthorised and informal 'prescribing' activities of pharmacists. The profile of therapeutic categories prescribed was also different, likely because at KCH new medicines were unlikely to be ordered. More recently, Cross et al (2017) evaluated the introduction of pharmacist prescribing in critical care units in a single UK hospital. Unlike in Baqir et al., these units had implemented e-prescribing. Data were collected over one month. Pharmacist-initiated orders accounted for 10.7% of all medication orders. The results of PW22 and Cross et al., are not directly comparable. Cross et al., were unable to report on the proportion of medication orders discontinued by pharmacists, due to the limitations of their system. In addition, PW22 excludes critical care, as e-prescribing had not been implemented in those areas in 2012. Given the differences between critical care and general inpatient units, it is unsurprising that there are differences in findings between the three studies. As a result of our study, we introduced a policy (presented with PW22 in Volume II) clarifying which types of medication and under what circumstances, non-prescribing pharmacists could amend a patient's medication profile.

3.3 Authorised pharmacist prescribing (non-medical prescribing)

Whilst PW22 describes informal prescribing activities of pharmacists, PW18 – *An Adaptable Scope of Practice Template* (Onatade & Wong, 2012) is a facilitator for qualified,

authorised pharmacist prescribers to undertake a wide range of prescribing activities, both specialist and generalist. Non-medical prescribing is a generic term for prescribing undertaken by healthcare professionals who are not doctors.

Patients are individual, complex, often multi-morbid, and when admitted to hospital, require a wide range of treatment modalities - some specialist, some generalist. Ensuring that a patient's routine medication is ordered on admission, reviewing and changing medication, doses and formulations to suit a patient's changing clinical status, and ensuring that discharge medication is prescribed appropriately when care is transferred to another setting are all important clinical pharmacy activities. The majority of clinical pharmacy activities in hospital are broad-based and non-specialist (Stephens, 2011), therefore there was potential value in using Pharmacist Independent Prescribers (PIPs) to improve clinical care by incorporating prescribing into their daily activities. However, pharmacists in our organisation, as in others, were still focussed on practising as prescribers in defined specialties, therefore they were not using their prescribing rights in their routine day to day general clinical practice. This was evident from my discussions within my department as well as the wider network of clinical pharmacists across the UK. This was an artificial divide between practice as a 'generalist' clinical pharmacist and as a specialist clinician, specifically in the context of prescribing. However, a framework or scope of practice to describe how clinical pharmacists might combine generalist and specialist practice was required. PW18 was my response to this. It was my first public work related to pharmacist prescribing.

For most of my time working at KCH, I was the non-medical prescribing clinical lead for the whole trust. This role involved chairing the Non-Medical Prescribing Group and setting and advising on trust policy regarding non-medical prescribing. Within pharmacy, I also led on developing and monitoring pharmacist prescribing roles. In 2006, pharmacists were legally granted independent prescribing rights. This allowed us to prescribe for any medical condition deemed to be within our competency, in accordance with a scope of practice which would largely be determined by the individual practitioner. (Controlled drugs and unlicensed medicines were initially excluded, by law). Prior to 2006, pharmacists could only prescribe for patients within the confines of a clinical management plan, the details of which needed to be pre-agreed with a supervising medical practitioner,

and the patient (Bissell, Cooper, Guillaume, et al., 2008; Baqir, Miller, & Richardson, 2012). This was called supplementary prescribing and is suitable for managing long-term conditions (e.g. within an outpatient clinic setting) but is unwieldy and inflexible. It is impossible to devise and agree, in a timely fashion, a supplementary prescribing clinical management plan for inpatients whose clinical status is unstable. Before independent prescribing was introduced, we made attempts to devise generic clinical management plans for those inpatients with clinical conditions where treatment often followed a predictable pathway. This was partially successful but excluded any medication requirements which could not be anticipated. Independent prescribing introduced flexibility and autonomy. Timely prescribing and access to medicines is very important when patients are acutely unwell, therefore the freedoms afforded by independent prescribing were welcomed. The separation between specialist and generalist prescribing is not a problem for medical prescribers, as their ability, competence and responsibility to prescribe in many different situations is expected.

PW18 is innovative in that it was the first example of a structure for hospital clinical pharmacists to prescribe in different scenarios, but still individualised for their competency level and specialist skills. The framework was developed through weeks of discussion and testing. My co-author was our lead Surgical Pharmacist, who specialised in Vascular Surgery. As soon as she qualified as an independent prescriber, we identified that her scope of practice (SoP) needed to accommodate both generalist and specialist prescribing. Previously, our PIPs had all been working in clinical areas where their focus was on prescribing specialist or complex medication. There are few specialist or complex medicines in Vascular Surgery, and there was no requirement for the pharmacist to see patients in outpatient clinics. Yet the patient group is diverse, and reviewing and optimising medication use before, during and after hospital admission is just as important as for other groups of patients.

The framework described in PW18 recognises the wide range of different prescribing scenarios that exist, including initiation (either autonomously or after discussion and agreement with clinical colleagues) continuation of prescribing initiated by others, adjusting doses or formulations, and discontinuing medication. There is an optional section in which the practitioner can describe their specialist practice and the setting or settings in

which this will take place. The Personal Prescribing Formulary is where the pharmacist lists those drugs which they are competent to initiate autonomously. This list is individualised to the practitioner, and would be agreed by myself as Clinical Lead, and then the trust Non-Medical Prescribing Group, as the committee with overall responsibility for approving all practitioner Scopes of Practice. Although hospital clinical pharmacists are usually accepted as full members of the clinical teams providing patient care, we cannot be present at all times when treatment is being reviewed or decisions being made.

Poor communication can lead to adverse clinical consequences and lack of documentation of prescribing decisions is well-known to be a problem affecting continuity of care (Apsden, Wolcott, Bootman, et al., 2007; Ljungberg, Lindblad, & Tully, 2009; Franklin, Reynolds, Shebl, et al., 2011; Avery, Barber, Ghaleb, et al., 2012; Ross, Ryan, Duncan, et al., 2013). Therefore, I was careful to insert a mandatory paragraph detailing the requirement for the pharmacist to record their prescribing decisions in the patient record. This framework was very successful in achieving its desired aim of enabling widespread adoption of PIP in our organisation; we rapidly increased the proportion of eligible pharmacists prescribing from under 10% to over 40%. It was adapted for pharmacists in several different specialties, and also used to increase the number of non-specialist pharmacist prescribers. I have shared it with colleagues across the country (see documents under PW18 for testimonial from Royal Stoke Hospital, and an adaptation for Barts Health NHS Trust, where I worked with a colleague to combine the original PW18 framework with an existing template). My own personal Scope of Practice can also be compared with the original, demonstrating how the framework is both specific and adaptable. Nowadays, this model of PIP in hospital is commonplace (Baqir, Crehan, Murray, et al., 2014; Cross, Parker, LawMin, et al., 2017).

Taking PW18 and PW22 together, it is clear that freedoms associated with electronic prescribing and the introduction of pharmacist independent prescribers are separate, but complementary, drivers of the wide-scale implementation of pharmacist prescribing in secondary care. PW18 predates PW22, but the Scope of Practice could not be applied to non-prescribers as this would have meant explicitly agreeing to practices which were legally not within scope for non-prescribing pharmacists. In section 4.2.2, in the next chapter, I introduce another prescribing activity, the practice of pharmacists writing orders

for the supply of discharge medicines. Although this is presented in the context of a practice innovation, the debate about the legal definition of this activity is also described.

3.4 Assessing the appropriateness of prescribing and medication use processes

In this section, I discuss the assessment of potentially inappropriate prescribing, including PW21 - *Potentially Inappropriate Prescribing in Patients on Admission and Discharge from an Older Peoples' Unit of an Acute UK Hospital* (Onatade, Auyeung, Scutt, et al. 2013) in some detail. As well being the first published work to investigate potentially inappropriate medications (PIMs) in an acute UK setting, PW21 marks a significant milestone in my development as a clinical academic and researcher. This piece of work was conducted between 2011 and 2012 and published in 2013. The driver for PW21 was my continuing search for pharmacy-sensitive indicators of care quality, as detailed in Chapter Two. The work was therefore originally devised as a way of identifying alternative methods of assessing the quality of pharmaceutical care delivered via a clinical pharmacy service. As is now clear, much of secondary care pharmacists' work is ensuring safe, effective prescribing, although traditionally this prescribing is carried out by others. I therefore theorised that a marker of the effectiveness and safety of hospital clinical pharmacy practice could be the extent of inappropriate prescribing that is unnoticed, unchallenged and/or unchanged throughout a hospital care episode. The findings of PW10 (Onatade & Zuhair, 2010), supported my theory. PW10, which I discussed in detail in section 2.3.2, was a Delphi study to develop criteria for assessing the quality of pharmaceutical care. Potential indicators identified by the Delphi study included drug dosing, drug choice, the presence of interacting and contraindicated medications and medication side effects suffered by patients. All directly relate to prescribing and the possible appropriateness thereof. It was therefore reasonable to expect that both the process of, and the outcomes from, prescribing could be suitable quality indicators.

Tools for measuring appropriateness of medication use or prescribing have been available in the literature for many years (Luo, Scullin, Mullan, et al., 2012). Beers' Criteria for potentially inappropriate prescribing was first published in 1991 (Beers, Ouslander, Rollingher, et al., 1991), and has been updated several times (Beers, 1997; Fick, Cooper,

Wade, et al., 2003; American Geriatrics Society, 2012, 2015). The Medication Appropriateness Index (MAI), is an implicit tool for assessing a patient's individual medications for appropriateness specific to their circumstances (Hanlon, Schmader, Samsa, et al., 1992). The ACOVE (Assessing Care of Vulnerable Elders) Project, introduced in 2001, contains several indicators covering aspects of appropriate medication use, applicable when evaluating care provided to older people (Wenger & Shekelle, 2001). The Medication Regimen Complexity Index (MRCI), a tool for assessing the complexity of medication regimens, as a proxy for the ease with which patients might be able to manage their medicines and thus have improved outcomes, was published in 2004 (George, Phun, Bailey et al., 2004). I theorised that it should be possible to leverage one or more of these instruments to evaluate how well a clinical pharmacy service influences prescribing appropriateness.

Limitations of the tools have however, been well-described. For example, many of the drugs included in the early versions of Beers' Criteria were not available in the UK, and there is no mention of drug interactions or duplicated therapy as potentially inappropriate. MAI is time-consuming to apply and requires a high degree of clinical knowledge and the MRCI was originally validated only in patients with Chronic Obstructive Pulmonary Disease, thus its applicability could be viewed as limited only to those patients with that specific condition (Shelton, Fritsch, & Scott, 2000; Spinewine, Schmader, Barber, et al., 2007; Luo, Scullin, Mullan, et al., 2012; Kaufmann, Tremp, Hersberger, et al., 2014). Furthermore, there was little or no evidence of the available instruments being used in the UK, either for research or clinically (O'Connor, Gallagher, & O'Mahony, 2012). I was therefore continually searching the literature for a tool or indicators which could practically be used to routinely measure quality of prescribing, and by extension, clinical pharmacists' performance on improving prescribing quality.

The Screening Tool of Older Persons' Prescriptions or STOPP (Gallagher, Ryan, Byrne, et al., 2008; O'Mahony, O'Sullivan, Byrne, et al., 2015) is similar to Beers' Criteria, in that it consists of rules relating to the most common and the most potentially dangerous instances of inappropriate prescribing in older people. STOPP has a counterpart, START (Screening Tool to Alert to Right Treatment) which identifies the omission of medication which an older person might potentially benefit from (Barry, Gallagher, Ryan, et al., 2007).

STOPP/START was developed in Ireland and is thus much more relevant to UK practice than previous tools. It was presented in such a way as to be easy to apply in practice and avoided the stated limitations of the earlier tools (Gallagher, Ryan, Byrne, et al., 2008). There were, however, no published articles on the application of either STOPP or START in a UK hospital, hence there was a gap in the literature.

3.4.1 Research into the appropriateness of prescribing

I had previously published in professional journals and regularly presented abstracts and posters at conferences. I had therefore determined that a necessary next goal for my development as a researcher was to publish in a peer-reviewed journal. From reading the international literature already published on the tools, I felt that I had the research capability and capacity to conduct a retrospective study to determine the prevalence of potentially inappropriate prescribing in older patients in a UK hospital, using the STOPP tool. This led to PW21 (Onatade, Auyeung, Scutt, et al., 2013).

The most important limitations of my previous work, mainly from a quantitative point of view, were small sample sizes, insufficient data and my lack of understanding of how to extend small, yet robust audits or service evaluations, into publishable articles. I addressed each of these issues in turn - I reviewed articles with the same or similar aims, in a systematic manner, noting the types and amounts of data collected, and determined whether similar data would be easily available to me. To ensure sufficient patient numbers, I gave the same project to consecutive students working with me, ensuring they adhered to the same data collection protocols, although they had different objectives and conducted different analyses. In this way, I harnessed existing resources to collect sufficient data, yet ensured the students still had unique projects for their own purposes. Once data collection was complete, I invited everyone who had collected data to contribute to the paper as co-authors, and one person (JF) took up the offer. My role in this work was that of lead investigator. I conceived the project, developed the project plan, directed and quality-assured data collection and conducted most of the data analyses. I also drafted the initial manuscript and directed the revisions not written by myself.

My ability to conceptualise, supervise and conduct novel, publishable research was enhanced considerably with PW21. It had a significant positive impact on my confidence and development as a researcher. The publication of this work also led to invitations to collaborate (for example, PW24 - Bourne, Baqir, & Onatade, 2016) and to be a peer reviewer for academic journals. I have also peer-reviewed a grant application for a research project partly based on this PW.

Impact of PW21 – as of December 2018, the article has been cited 35 times (Google Scholar), which puts it in the 93rd percentile of citations for the journal. It has been downloaded 342 times. It remains the only paper describing potentially inappropriate prescribing in an acute UK healthcare setting; therefore it is the only citable authority available for this information. PW21 is also comprehensively cited in a recent Department of Health policy report on the burden of medication errors in the NHS in England (Elliott, Camacho, Campbell, et al., 2018).

In designing the study, I was able to follow examples of other authors who had published similar work in other settings. Thus, the design and concept were not new. However, I contributed unique perspectives, which I describe here. Firstly, one of the objectives of this work was to determine how often PIMs prescribed on discharge were accompanied by a plan for follow-up. Occasionally, the prescription of a PIM may be unavoidable or justifiable, when considering the harm: benefit ratio. In this case, a prescriber may attempt to minimise the potential risk by requesting future caregivers review the need for the medication. This had not previously been discussed as a consideration in potentially inappropriate prescribing. Ensuring appropriate follow-up after discharge is also a route by which pharmacists can support safe medicines use and is therefore a potential measure. A recent paper assessing PIMs in patients discharged from an Australian hospital (Chang, Kowalski, Sorich, et al., 2017) also investigated this. The authors did not reference my work; therefore, they may have developed the idea independently. However, other researchers (Pandraud-Riguet, Bonnet-Zamponi, Bourcier, et al., 2017) have compared their findings to ours. The second novel concept in PW21 was the creation of the PIM Index, a metric to enable comparison of prescribing appropriateness between studies, by taking the total amount of medications into account. The PIM index has since been used

by other researchers (Hudhra, Beçi, Petrela, et al., 2016; Tanna, Tatla, Winn, et al., 2016; Mucalo, Hadziabdic, Brajkovic, et al., 2017).

3.5 Other prescribing-related works

There are several other PWs related to the themes in this chapter, which I now briefly describe. PW24 – *Pharmacist independent prescribing in secondary care: opportunities and challenges* (Bourne, Baqir, & Onatade, 2016) came about as a direct result of my work in the area of pharmacist prescribing. I was invited to co-author this editorial discussing the state of pharmacist independent prescribing (PIP) in secondary care in the UK, the opportunities still to be exploited, and the challenges to be addressed. For PW24, each co-author had specific sections to lead on, as well as reviewing and commenting on the full paper. I contributed my areas of expertise, mainly around challenges for widespread adoption of PIP and the safety of medical and non-medical prescribing. My knowledge around prescribing errors and safety stemmed from my research on prescribing and quality indicators in general. PW24 has been cited 11 times.

PW3 (Onatade & Mehta, 2007) is a very early work looking at the organisational processes involved in developing Patient Group Directions (PGDs) in an attempt to improve the speed and efficiency with which these important documents were produced. A PGD is *'a written instruction for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment'* (Department of Health, 2000). Although small and published in a niche professional journal, the article has been cited (Williams & Knox, 2010) and is referenced on a Guidelines in Practice website discussing the appropriateness of PGDs (**https://www.guidelinesinpractice.co.uk/are-your-local-patient-group-directions-appropriate-and-legal/305030.article**) – last accessed 1st December 2018. Despite the widespread use of PGDs in healthcare settings, there have been no further articles looking at the issues involved in their development.

PW14 – *Developing the definition of a reportable prescribing error* (Eaton, Cavell, & Onatade, 2010) was a small study to develop a definition of a reportable prescribing error. The lead investigator, GC, was a KCH colleague who asked me to assist because of my

experience of research into prescribing errors and my experience of using consensus methods to gain agreement. The outcomes of this work were later used in a scale for rating the clinical significance of pharmacists' contributions to care, as I later describe in section 5.2.1.

PW17 (Talpaert, Aroyewun, & Onatade, 2011), mentioned previously in section 2.3.2, was an evaluation of the quality of vancomycin prescribing. Vancomycin is a high-risk antibiotic with complex prescribing and monitoring requirements. I supervised this study, in which we attempted to relate the quality of prescribing to patient outcomes (treatment success), but the study did not have enough power to demonstrate a relationship. This typifies the issues regarding challenges in demonstrating the link between processes of care and patient outcomes, as described in Chapters Two and Five.

PW19 - *Improving antimicrobial prescribing using rapid serial audits and feedback* - (Talpaert, Acosta, Fife, et al., 2013) was a highly successful, award-winning, study focussed on specific aspects of antimicrobial prescribing. At the time of carrying out this work, the requirement to improve the quality of antimicrobial prescribing to reduce the risks of hospital-acquired infection and antimicrobial resistance was a priority (Ashiru-Oredope, Sharland, Charani, et al., 2012). By applying quality improvement techniques, we were able to improve on most of the antimicrobial prescribing indicators.

PW28 – *Time to administration of first dose antibiotics and associated outcomes in respiratory sepsis* - (Gujral, Onatade, Mehta, et al., 2015) was a study on which I advised and guided the data analysis. In this work, the length of time to administer antibiotics in respiratory sepsis was investigated. This is an important patient care issue, as reduced mortality is linked to speedier receipt of antibiotics. However, our study did not confirm this relationship.

PW13 (Considine, Onatade, Knighton, et al., 2010), PW20 (a collection of works from 2004 to 2017) and PW30a (Onatade, Sawieres, Veck, et al., 2017) relate to my long-term work focussed on pharmacists taking over the responsibility (from doctors) of writing discharge medication orders, arguably a form of prescribing. I discuss this initiative in detail in section 4.2.

CHAPTER FOUR: Innovative practice within legal and ethical frameworks

Some men look at things the way they are and ask why?

I dream of things that are not and ask why not?

-Robert Kennedy (1925 – 1968)

4.1 Introduction

The PWs showcased within this chapter demonstrate my design and implementation of several practice and service innovations. Most of this chapter will focus on a long-term, wide-scale initiative, a redesign of the discharge medication pathway. There are several interrelated PWs covering this work, some of which I have mentioned in preceding chapters. However, the main works related to this - PW13 – *A review of a pharmacist discharge prescription writing service in a large teaching hospital* (Considine, Onatade, Knighton, et al., 2010), PW20 (a collection describing my work on redesigning the discharge medication pathway, including Onatade, 2015, 2017) and PW30a – *The incidence and severity of errors in pharmacist-written discharge medication orders* - (Onatade, Sawieres, Veck, et al., 2017) - are discussed here. Other practice innovations described in this chapter are PW9 – *A study to assess the safety and time-effectiveness of Pharmacy Technician triage on a gynaecology/surgical ward* - (Onatade, Jogia, & Choudhary, 2010), PW25 – *The extent of, and documented reasons for, discrepancies in post-hospital medicines reconciliation* - (Knight, Scaria, Lama, et al., 2015), PW26– *Post-hospital medicines reconciliation: the impact of providing enhanced information regarding medication changes* - (Amadu, Adebimpe, & Onatade, 2015) and PW32 – *The introduction of a specialist pharmacist in-reach service to improve the pharmaceutical care of patients on psychotropic medication* - (Onatade & Oduniyi, 2016).

4.2 Redesigning the discharge medication pathway

In Chapter Three, 'Prescribing, prescribing practices and prescribing safety', I discuss my work on the prescribing activities of pharmacists, both formal and informal. With PW18 (Onatade & Wong, 2012) in section 3.3 and PW24 (Bourne, Baqir, & Onatade, 2016) in section 3.5, I have highlighted the benefits of pharmacist prescribing to improving patients' access to medicines. In this current section, I discuss my work on a large-scale practice innovation which also significantly improved patients' timely access to discharge medication.

In the NHS, hospitals are responsible for ensuring that before patients are discharged or transferred to another care setting, that they have sufficient medication for a set period of time (usually 2 to 4 weeks). This usually means that the hospital must provide patients with a supply of medication before they leave. The hospital pharmacy department will dispense any required medicines upon receipt of a written and signed (by a doctor) discharge document. The document combines a summary details of patients' course of illness and treatment during their stay, plus a prescription for medication to be supplied. The combined treatment summary and prescription are checked and validated by a pharmacist before dispensing can commence. PWs 30 and 20 describe the quality, safety and efficiency issues associated with this traditional pathway for supplying discharge medication. These include prescribing errors, missing and incorrect documentation and duplication of effort. These have considerable consequences for the hospital and patients, including delays to discharge, patient dissatisfaction and complaints. As the pharmacy service is inextricably linked to the discharge medication supply pathway, these departments are understandably seen as part of the problem.

In 2004, the hospital (KCH) leadership requested that the pharmacy department devise solutions to the issue of discharge medication not being available before patients are ready to leave hospital. I proposed changing the pathway so that the preparation of the discharge prescription was uncoupled from the treatment summary to allow pharmacists to write the discharge medication prescription, instead of doctors. This would streamline the process (as no additional check would be required) and ensure more timely discharge prescriptions. Medication could then be supplied without waiting for the treatment summary to be ready. This was piloted between 2004 and 2005, and was very well-

received, however, it was unsustainable at the time due to low staff numbers. PW20d contains reports from the pilot projects. I reintroduced the service in 2008 and completed roll-out across the hospital in 2012 (Onatade, 2017).

We called the list of pharmacist-written discharge medication orders, 'drug lists' and the service was, and continues to be known as, 'drug listing'. A common term for discharge prescriptions is TTAs (To Take Away), and therefore TTAs written by pharmacists are also known as PTTAs (Pharmacists' TTA). Table 1 contains an explanation of the different terms used. Since 2012, I have presented on the drug listing initiative at numerous local and national meetings and conferences, hosted visitors from hospitals across the UK and introduced or supported the introduction of the service in other hospitals. Examples of presentations are in PW20. While earlier researchers have written about, and evaluated the impact of, pharmacists writing discharge medication prescriptions on a small scale (Cattell, Conroy, & Sheikh, 2001; Chantelois & Suzuki, 2003; Hobson & Sewell, 2003; Rahman, Green, & Armstrong, 2005) this was the first (and remains the only) UK hospital where writing discharge medication prescriptions ('drug listing') is part of clinical pharmacists' routine practice across the whole organisation. The terminology used to describe this activity is important and slightly contentious. Professionally, I have been involved in professional debates as to whether it is prescribing, therefore in the next section, I explain how I use the different terms.

4.2.1 Terminology used in descriptions of the discharge medication pathway

The Royal Pharmaceutical Society's Medicines, Ethics and Practice (MEP) Guide (Royal Pharmaceutical Society, 2017) states that writing discharge medication orders, to enable a supply, is not prescribing, as the supply is made in accordance with an original written order on the inpatient drug chart. The MEP calls the production of this list of discharge medication, 'transcribing', as do other researchers and practitioners (Hobson et al. 2003, 2004; Healthcare Commission 2007). Transcribing is a process *'by which information is transferred to another form or format, by way of a written copy'* (Dictionary.com, 2018). Therefore, where the pharmacist is merely copying orders from the inpatient drug chart to another form in order to enable supply, he/she is transcribing. My personal and professional opinion is that if the list of orders must be finally signed off by a prescriber,

the pharmacist writing it is not legally prescribing. However, to produce an appropriate, clinically safe PTTA without continually involving doctors, certain clinical decisions often have to be made by the pharmacist. Transcribing is therefore not an appropriate description of this activity, when it is carried out as originally intended. I therefore use the terms 'PTTAs', or 'drug listing' neither of which are completely satisfactory but avoid the incorrect descriptors of transcribing or prescribing. Table 1 contains conventional explanations of the different terms. Most terms have been widely used in UK hospital pharmacy practice for decades, therefore the definitions stem from my experience, while others (drug list, PTTA) are terms which I have coined.

Table 1. Explanation of terms used in descriptions of the discharge medication pathway

Term	Explanation
Prescription	A list of medicines prescribed for a patient
Discharge prescription	The list of medicines that a patient should be taking once discharged from hospital, to be dispensed by the hospital pharmacy
TTA (To Take Away)	Another term for the list of medicines that a patient should be taking once discharged from hospital, to be dispensed by the hospital pharmacy
Medication order	An individual item within a list of prescribed medicines
Discharge medication order	An individual item within a discharge prescription
Transcribing	Copying medication orders from one source to another
Drug list	A discharge prescription written by a pharmacist
PTTA (Pharmacist To Take Away)	Another term for a discharge prescription written by a pharmacist

4.2.2 Discharge medication pathway redesign – formative review

The implementation of the pathway redesign took place over a few years. In order to increase their engagement, when rolling out in their areas, I encouraged the clinical pharmacy leads to conduct evaluation projects. PW13 (Considine, Onatade, Knighton, et al., 2010) is a poster abstract assessing the impact and quality of the service in a subset of wards at KCH. This was a formative review. The review and assessment supported further

implementation by highlighting issues to focus on, such as the importance of regular monitoring of performance and quality metrics, the timing of the writing of prescriptions, and pharmacists' error rates. In Chapter One, I discuss my development and use of quality indicators to improve services. The use of metrics was key to the successful implementation and roll-out of the new pathway. (I expand on this in PW20).

Regarding the timing of writing PTTAs, we established that although knowing pre-planned discharge dates are essential, writing the discharge prescriptions too early (more than 24 hours before the estimated discharge date) was inefficient, as medication was often changed just before discharge, and the prescription had to be rewritten and reprocessed. In PW13 the proportion of PTTAs requiring an error correction, as identified by another pharmacist, was 10%. This compares with unpublished data from 2009, in PW30b, showing that 32% of TTAs written by doctors contained an error (Onatade, Sawieres, Veck, et al. 2015). These figures should not be compared with the proportion of medication orders written erroneously. Lewis et al. (2009) state that prescribing errors affect 7% of medication orders (individually prescribed medications), 50% of hospital admissions and 2% of patient days. The EQUIP study (Dornan, Ashcroft, Heathfield, et al., 2009) found that 6.4% of discharge medications were prescribed erroneously, with the rate for doctors ranging from 5.6% to 6.4%. In a similar study, Ashcroft et al. (2015) found that 6.3% of discharge medications prescribed by doctors were erroneous. deClifford et al. (2009) evaluated a pharmacist discharge medication transcription service and compared error rates between pharmacists and doctors. They found that pharmacists decreased the error rate from 9.6% to 1.4%. In PW13, our methodology for defining, identifying and differentiating errors from changes required for clinical reasons was not robust enough to be conclusive about whether our pharmacists made fewer errors than doctors.

4.2.3 Pharmacists' error rates in discharge medication prescriptions (PTTAs)

The specific issue of error rates led to PW30a (Onatade, Sawieres et al., 2017), a comprehensive, retrospective study of the incidence and severity of errors in pharmacist-written discharge medication orders. As mentioned above, when doctors prescribe

discharge medication, pharmacists are expected to check the prescriptions for errors and/or ambiguities and ensure these are resolved before medication is dispensed.

The redesigned pathway did not allow for another pharmacist to check the PTTAs - this was the responsibility of the discharging doctor, who had to write the accompanying clinical summary and check and sign the final version of the PTTA before medication could be handed to the patients. This final PTTA would be filed in the patient record. In addition, it was not economically viable or logistically feasible to always ensure that another pharmacist was available to provide a check, and there was an unsaid presumption that pharmacists would be more accurate than doctors.

The results of PW30a justified the decision not to build in a second pharmacist check to the new pathway. The pharmacist error rate was so low (2% of PTTAs contained an error, 0.2% of pharmacists' orders were erroneous) that it was not possible to reliably describe the potential severity of the errors. The positive results from this study was a significant relief for myself and colleagues. Although there had been no reported clinical incidents from drug listing, there was always an underlying concern that there was no evidence that removing the validation step was safe. This study allayed those concerns.

Even though this clinical activity does not fit the legal definition of prescribing, PW30a is one of few papers showing the early promise of the safety of pharmacists' ordering medication for supply or administration to patients, without consulting a prescriber. Research into physician's prescribing errors is plentiful, from the UK (Dean, Schachter, Vincent, et al., 2002; Dornan, Ashcroft, Heathfield, et al., 2009; Seden, Kirkham, Kennedy, et al., 2013) and other countries (Reckmann, Westbrook, Koh, et al., 2009). The one paper describing pharmacists' error rates that predates PW30a, is Baqir et al. (2014). The authors found a 0.3% error rate in pharmacists' medication orders for hospital inpatients. Cross et al., (2017) evaluated critical care pharmacists' prescribing errors, and found an 0.18% error rate. Our findings are therefore comparable to the prevailing literature. PW30a is the second of my PWs highly referenced in a recent Department of Health report on medication errors in the context of errors occurring during transitions of care (Elliott, Camacho, Campbell, et al., 2018). The other was PW21 (Onatade, Auyeung, Scutt, et al., 2013). In the report, PW30a was discussed.

An unfortunate limitation of PW30a is that it is observational only. One peer reviewer suggested that the findings would have been more robust in the context of a randomised clinical trial. I do not fully agree with this sentiment and provide my reasons for this in some detail in PW34 - *Evidence for the outcomes and impact of clinical pharmacy: context of UK hospital pharmacy practice* - (Onatade, Appiah, Stephens, et al., 2017), in section 5.3.1 in the next chapter. However, to date, there have been no studies directly comparing prescribing pharmacists' errors with those of doctors. I had previously led a project at KCH, to evaluate the error rate in doctors' discharge prescriptions. The unpublished results of this work can be seen in PW30b, a draft manuscript comparing doctors' and pharmacists' errors on discharge prescriptions. I was unable to publish this comparative paper, as the study of doctors' errors was conducted before the organisation implemented electronic prescribing (e-prescribing), whilst the evaluation of pharmacist errors, as seen in PW30a, the published paper, was in the context of a full e-prescribing system.

4.2.4 Discharge medication pathway redesign – evaluation of implementation

In 2017, I undertook an evaluation of the pathway redesign itself, as described in PW20a (Onatade, 2017). PW20a is a preprint paper (posted online, not peer-reviewed). In the paper, I retrospectively applied the Consolidated Framework for Implementation Research (Damschroder, Aron, Keith, et al., 2009) to the implementation and roll-out of the redesigned pathway, discussing the influencing factors and strategies used to ensure success. PW20a is very much a self-assessment, rather than an objective review, therefore it has its limitations. However, by faithfully following the framework and addressing all potential factors, I was able to identify the drivers for success. I also found that I had probably not sufficiently acknowledged the legal and professional considerations of this new practice, in as much as it constituted a significant role extension and possible 'identity change'. PW20a was written five years after full implementation at KCH, and thus these issues had been overcome by the time of this realisation. However, I am now very conscious of the need to address the reluctance of staff to adopt new roles and responsibilities by considering how the new role may affect their views of professional boundaries, values and legal considerations.

4.3 Clinical pharmacy innovations across the interface of care

Errors in discharge prescriptions are not the only medication-related risks faced by patients when leaving hospital. Complete and accurate transfer of medication information to the next caregiver is essential in order to ensure continuity of care (Picton & Wright, 2012). PW25 and PW26 are outputs from a joint quality initiative between KCH and local Clinical Commissioners to improve the information provided to GPs regarding changes made to patients' medication whilst they were in hospital. There is national guidance (Picton & Wright, 2012; Health and Social Care Information Centre & Academy of Medical Royal Colleges, 2013) on the type of information that should be included in discharge documents, including information on medication changes. Despite this, sufficient information is often lacking. This can lead to significant differences between GP and hospital records, and discontinuity of care, where patients are restarted on medicines which had been stopped, or new medication is not continued after discharge. The published literature indicates the scale of this problem (Forster, Murff, Peterson, et al., 2003; Cornish, Knowles, Marchesano, et al., 2005; Tam, Knowles, Cornish, et al., 2005; Kergoat, Latour, Julien, et al., 2010; Grimes, Duggan, Delaney, et al., 2011; Lenert, Sakaguchi, & Weir, 2014; Belda-Rustarazo, Cantero-Hinojosa, Salmeron-García, et al., 2015; Bonaudo, Martorana, Dimonte, et al., 2018).

As described in section 4.2, since 2012, at KCH, pharmacists produced the majority of discharge medication prescriptions (PTTAs). Small audits had demonstrated that medication changes were more likely to be communicated to GPs on PTTAs. PW20d contains an internal report from 2014 showing that when pharmacists wrote discharge prescriptions, approximately 80% had complete information on medication changes. This compares well to the literature. A large-scale audit of 1454 patients discharged from English hospitals found that, for example, only 39% of discharge summaries gave reasons for dose changes (Shah, Hough, & Jani, 2013). Hammad et al (2014) found that rationale for therapy change was detailed in only 49% of summaries. Despite the better quality of information seen in our discharge summaries, the format and the large of amount of information contained in them, did not facilitate easy extraction of the required information by GPs.

In 2014, to improve the quality of information exchange, and thus support post-discharge primary care reconciliation of medication lists, local commissioners agreed to resource a quality initiative to provide enhanced information on medication changes for older patients discharged from hospital. The team, led by myself, and a senior medical Consultant, devised a Clinical Medication Review Letter (CMR), which was sent to a patient's GP as soon as possible after discharge. The CMR contained detailed information on medication changes, as well as the rationale, and recommendations for GP review and/or further actions. A pharmacist was employed to write the CMRs, and pharmacists and doctors from the included wards were trained to document medication changes throughout the patients' stay, to enable accurate completion of the CMR. The format and content of the CMR was tested with GP and CCG pharmacy colleagues, and their requests incorporated.

I evaluated the initiative firstly by investigating the discrepancies between CMRs (i.e. the hospital record) and GP records. The results of this study, PW25 (Knight, Scaria, Lama, et al., 2015), showed that up to 88% of hospital recommendations were reviewed and actioned when appropriate, but that at any one time, only a minority of hospital discharge medication lists and GP medication lists would match.

The second aspect of the evaluation was PW26 - *a study of the impact of CMRs on discrepancies between hospital and GP medication lists* - (Amadu, Adebimpe, & Onatade, 2015). It took place at the second hospital within the trust. Data was analysed for 87 intervention (in receipt of a CMR) and 37 control (usual discharge documentation) patients. The study demonstrated conclusively that the provision of a CMR was associated with a lower number of discrepancies between the two lists. Four weeks after discharge, GP medication lists of 86% of intervention patients matched with hospital records, compared to 60% of patients from control wards (p = 0.006). Patients without CMRs were more likely to have at least one discrepancy (odds ratio = 4.1), and there was a significant difference between the groups regarding the number of discrepancies (12 compared to 35, p = 0.024). Fewer discrepancies should be expected to lead to better continuity of care and patient safety. Farley et al. (2014) found similar benefits from the provision of a discharge plan to primary care physicians. The authors however followed patients for longer than we were able to and found that the benefits of the discharge plan did not persist 90 days after discharge. This is consistent with our findings from PW25, which

showed just 30% of matching lists (between GP and Hospital), despite the fact that a high proportion of hospital recommendations were actively considered and/or actioned.

Although similar problems to those above continue to be described both in the UK and elsewhere (Spinewine, Claeys, Foulon, et al., 2013; Monfort, Curatolo, Begue, et al., 2016; Mills, Weidmann, & Stewart, 2017; Tong, Roman, Mitra, et al., 2017), variations on the initiative described in PW26 appear to be the only currently feasible solutions to improving the quality of communication regarding medication changes on discharge from hospital.

I conceived, designed and supervised both PWs 25 and 26. Their main impact was being able to bring a degree of rigour to the evaluation of the quality initiative, demonstrating its value beyond the achievement of set targets and improved satisfaction of GPs and CCG colleagues. This initiative was so successful that it was extended for a further year, beyond the initial 12 months, and a project to improve the pharmaceutical care of a different group of patients was requested. This is described in PW32 in the next paragraph.

4.4 Improving the pharmaceutical care of patients with severe mental illness

The follow-on quality initiative, PW32, was requested by primary care commissioners and GPs because of the success of the work described in PW26. For this initiative, I was given a much looser steer, merely being requested to devise a programme to support primary care colleagues to improve the quality of care of patients with severe mental illness (SMI). An ongoing issue with looking after these patients is that they often do not engage well with primary care services, although they have an elevated risk of premature mortality and poor physical health (NHS Mental Health Task force, 2016). Patients are also often taking psychotropic medications which require frequent monitoring and review. Patients with SMI are treated in specialist mental health hospitals, and only admitted to acute hospitals when they have serious illnesses requiring physical health treatment.

In accordance with government and Royal College guidance for all acute hospitals (Department of Health, 2011; Joint Commissioning Panel for Mental Health, 2012; Royal College of Psychiatrists, 2013), KCH had a Psychiatric Liaison Team (PLT), consisting of

doctors and specialist nurses. Clinicians could refer patients with SMI to the PLT for advice on management and treatment. Preventative monitoring and review did not come under the remit of the PLT at KCH.

When patients are admitted to hospital for an acute illness, the opportunity is there to assess other aspects of their health, including cardiovascular status, weight, smoking status and blood sugar levels. Medication reviews can also be conducted. The outcomes of these reviews can then be communicated to GPs and Community Care colleagues, thus improving continuity of care. Unfortunately, acute hospital trusts do not usually possess pharmacy staff with expertise in psychiatric medications as this capability now sits in the psychiatric hospitals where patients are usually seen.

My response was to partner with our local mental health trust, South London and the Maudsley NHS Foundation trust. A specialist pharmacist was seconded from the pharmacy department to work at KCH for the period of the project. Her remit was to carry out medication reviews for patients on psychotropic medications, improve their physical health monitoring, and communicate outcomes and recommendations to GPs. The innovation which I put in place was that this was an 'in-reach' service, where the specialist pharmacist actively sought patients who needed her input, rather than waiting for referrals. As the PLT only saw patients referred to them, they missed a considerable number of patients who would benefit from specialist input. In-reach services are well described within mental health and prison services (McKenna, Skipworth, Tapsell, et al., 2015) but are not the norm in acute trusts.

PW32 was also notable for the innovative use of electronic prescribing and medicines administration (EPMA) and electronic patient records (EPR) systems. A daily report of patients prescribed specific psychotropic drugs was produced from the system, and used to identify potential patients for review. The specialist pharmacist then reviewed relevant patient information from EPR. Where she deemed that her intervention was necessary, she would visit the ward and speak to the ward pharmacist and/or the doctor. In the past, to identify patients requiring input, a pharmacist would have had to pull a report from the pharmacy system of patients who had been dispensed the specific drugs (assuming it had

the functionality), then visit each ward, reviewing patient paper records. EPMA and EPR greatly improved the efficiency of this endeavour. PW32b is a report written for the mid-point evaluation of this project, demonstrating the clinical benefits. The project won a national Patient Safety Award and I also presented it at the American Society of Health System Pharmacists MidYear Clinical Conference (Onatade, 2016). The model of an expert clinical practitioner working across organisations to provide specialist input to the care of patients is common within the medical or nursing professions, but is largely unknown within pharmacy. However, cross-organisational collaboration is now actively encouraged to reduce variations in care (Lord Carter of Coles, 2016), therefore this model can easily be adapted for other specialties. Other benefits of having a specialist pharmacist on site included training the inhouse pharmacists, and developing prescribing guidelines and checklists for the clinical management of this vulnerable group of patients.

4.5 Pharmacy technician triage of inpatients

PW9 (Onatade, Jogia, & Choudhary, 2010) is a relatively early practice innovation. A senior pharmacy technician[2] (author SJ) and a junior pharmacist (author IC) working together on a gynaecology ward, had introduced a practice of having the pharmacy technician 'triage' or prioritise patients for the pharmacist. The aim was that every day, the pharmacy technician would identify the patients who required input from the pharmacist. The pharmacy technician would see the remaining patients, who would not see the pharmacist. This would release the pharmacist's time to concentrate on those patients who needed her expertise. I believed that this was an interesting initiative, and one which should be encouraged, as it is not essential that a pharmacist sees every patient every day. However, they had not agreed any criteria or protocols to guide the triage process, which was concerning. To perform their roles on the wards (mainly drug history taking, medication ordering, patient education), pharmacy technicians do not traditionally possess or require, clinical training. This new role appeared to put SJ in the position of making decisions about patients' care, which she was not trained for. This had legal and ethical implications. I therefore decided to evaluate the safety and feasibility of the practice. As

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[2] A pharmacy technician is a qualified professional, working under the supervision of a pharmacist, to prepare and supply medicines for patient, or participate in other areas of pharmacy services. Pharmacy technicians are registered with the General Pharmaceutical Council.

well as designing the study, I was the external assessor, or control pharmacist. After IC and SJ had concluded their work on the ward, I assessed each patient, identified any care issues and compared my notes with SJ's and IC's actual activities and checked whether the same issues had been noted by either of them. In hindsight, this could have been a prototype 'case study' (Crowe, Cresswell, Robertson, et al., 2011), involving the two 'subjects', with myself as observer. However, I chose to use an experimental design.

Although the results of this study showed that triaging by a pharmacy technician was time-neutral and largely safe (one potentially harmful care issue was missed – the prescription of a non-steroidal anti-inflammatory drug to a patient over the age of 75, with no clear indication), the practice was not continued. SJ was a specialist senior pharmacy technician, a higher grade than IC, and several years more experienced. Therefore, SJ's time was more valuable. SJ's experience was a key factor in the success of the initiative, however, and it was clear that a less experienced or less senior pharmacy technician would not be able to successfully triage patients. This is an obvious model for organisations with a shortage of pharmacists to consider, although to date it has not been adopted. As recently as 2013, the Society of Hospital Pharmacists of Australia published a list of activities both suitable and unsuitable for pharmacy technicians to perform, as part of supporting clinical pharmacy services (Society of Hospital Pharmacists of Australia, 2013). There is no mention of identifying patients most in need of clinical pharmacy input. Additionally, activities commonly undertaken by hospital pharmacy technicians in the UK, such as providing medication education, obtaining medication histories from patients and speaking to GPs, are deemed not suitable.

4.6 Ethics as a practitioner-researcher

I view the notion of ethics as a scholarly practitioner as broadly encompassing two main facets. The first is typified by ethical challenges which may occur during a study. Most of the research studies I have conducted are service evaluations or audits, therefore ethics approvals have not been necessary, in accordance with both my own institutions' and NHS Health Research Authority guidance (NHS Health Research Authority). However, much of my work has involved assessing the quality of healthcare services provided, therefore, I have to anticipate that may I discover poor quality or inappropriate care and decide *a priori* what action should be taken. Examples include PW25, where I made the decision that should we happen upon errors in the information held by GPs, that all efforts would be made to contact the patient and ensure they had received the correct medication. A few instances of this did in fact occur. With PW30, all potential errors discovered by my co-researchers were reviewed by a senior pharmacist both for confirmation and also to decide if any action needed to be taken either to prevent harm or because the error was a reportable incident. The second aspect is discussed comprehensively by Groundwater-Smith et al (2007) and speaks to what I would call personal research values, considering what is important to me as a researcher. For example, I must be able to justify my work to my community; upholding the principles of collaborative working, transparency and avoidance of research waste is critical, as is ensuring that changes to practice are appropriately evidence-informed. These ethical values are therefore part of my philosophy of practice (which includes research) and have become clearer and more conscious as my research skills have matured, much in the way that I describe the progression of my ontology in Section 1.2.2. This ethical framework also drives my enthusiasm for working with and supporting others to conduct research, as I describe in the next section.

4.7 Encouraging innovation through research mentoring

I have supported and encouraged the development of research skills of less-experienced colleagues, as shown by the collaborative working in the works described in this chapter, and throughout this context statement. PW13 (section 4.2.2) was conducted with a pharmacy undergraduate student, two clinical pharmacists who championed the introduction of drug listing and myself. PW30a (section 4.2.3) has the largest author list of all my works - most of the data collection was undertaken by pre-registration pharmacists,

supervised by their tutors. Participating in a large, collaborative, research project was a new and rare opportunity for early-career pharmacists. As well as designing the study, I provided direction, oversight and overall supervision. I conducted the data analysis, wrote all the drafts of the manuscript, and made sure each person contributed enough to qualify as a co-author. PWs 25 and 26 (section 4.3) were both carried out with undergraduate students and the pharmacists who were part of the project. The pharmacists supervised the students, and I again provided oversight. In PW32 (section 4.4), the pharmacist, although clinically experienced and relatively senior, had never undertaken a research project. All the data was collected by her, and I worked closely with her to ensure appropriate analysis and presentation of results. PW9, described in section 4.5 above, was undertaken with a pharmacy technician and a junior pharmacist. PW20a (section 4.2.4) is the only recent piece of work where I am the sole author. I invited several colleagues who supported the roll-out of drug listing in their clinical areas to co-author, but none took up the offer.

This chapter has described my most significant works in innovating in the field of hospital clinical pharmacy practice. I have also attempted to describe the impacts and outcomes of the various projects and publications. Demonstrating true sustained impacts of clinical practice innovations is difficult because of the inherent complexity of the interventions and the length of time required for follow-up. In Chapter Five, I discuss this issue in more detail, alongside the PWs with which I have tried to contribute to the evidence for clinical pharmacy.

CHAPTER FIVE: The impact and outcomes of clinical pharmacy

An experiment is never a failure solely because it fails to achieve predicted results. An experiment is a failure only when it also fails adequately to test the hypothesis in question, when the data it produces don't prove anything one way or another.

- Robert M. Pirsig, Zen and the Art of Motorcycle Maintenance:

An Inquiry into Values (1974)

5.1 Introduction

Many of the Public Works discussed in earlier chapters of this Context Statement have demonstrated or restated positive outcomes from clinical pharmacy interventions or activities. However, this was not normally the primary intention for carrying out those activities or studies. In this chapter, I will mainly focus on those works not previously discussed, which I have carried out primarily to highlight the potential of hospital clinical pharmacy to impact patient-level and/or health service outcomes. A short discussion showing the links with other works will conclude the chapter.

5.2 Demonstrating the impact of clinical pharmacy activities

PWs 12 (Onatade, Mehta, & Shallal, 2010), 16 (Onatade, Chowdhury, Bell, et al., 2011) and 33 (Mehta & Onatade, 2016) show the progression of a significant research interest of mine, that is, how to make best use of the rich data from documented clinical pharmacy (CP) contributions to care. A CP contribution can be described as a professional activity that directly results in, or is intended to result in, a change to patient management or therapy. The action taken could be a recommendation for change, be directed towards improving the quality use and/or administration of medicines, or medication-taking

behaviour (Alderman, 1997; Alderman & Farmer, 2001). The aim is to optimise a patient's care, minimise adverse effects and/or improve their health outcomes from their medicines use (Alderman, 1997). The term 'clinical pharmacy intervention' is also widely used to describe these activities. However, I prefer the term 'contributions to care' as this captures the sentiment that clinical pharmacy staff also make positive, proactive contributions to patient care, rather than simply intervening (reactive) when we notice an error or suboptimal care.

Descriptive studies evaluating the scope, volume and value of clinical pharmacy contributions are myriad. Early research came from North America and the UK (Vlasses, Lucarotti, Miller, et al., 1977; Hatoum, Catizone, Hutchinson, et al., 1986; Folli, Poole, Benitz, et al., 1987; Haslett, Kay, & Weissfellner, 1990; Torchinsky & Landry, 1991; Batty & Barber, 1992; Batty & Beech, 1994; Mutnick, Sterba, & Peroutka, 1997; Boardman & Fitzpatrick, 2001; Dodd, 2003) as well as Australia (Alderman, 1997; McLennan, Dooley, & Brien, 1999; Alderman & Farmer, 2001; Dooley, Allen, Doecke, et al., 2004).

With the global development of clinical pharmacy, studies from other countries along the same themes can now be found (Allenet, Bedouch, Rose, et al., 2006; Bremberg, Hising, Nylén, et al., 2006; Bedouch, Charpiat, Conort, et al., 2008; Bosma, Jansman, Franken, et al., 2008; Langebrake & Hilgarth, 2010; Langebrake, Ihbe-Heffinger, Leichenberg, et al., 2015; Peterson & Gustafsson, 2017; Yasunaga, Tasaka, Murakami, et al., 2017) as well as studies in focussed clinical areas and patient groups (Bremberg, Hising, Nylén, et al., 2006; Sanghera, Chan, Khaki, et al., 2006; Abdel-Qader, Harper, Cantrill, et al., 2010; Bourne & Dorward, 2011; Shen, Sun, Zhou, et al., 2011; Ibrahim & El-sharif, 2012; Ramadaniati, Lee, & Hughes, 2014; O'Dwyer, Mestrovic, & Henman, 2015; Tjon, Chen, Pe, et al., 2017; Peterson & Gustafsson, 2017; Rudall, McKenzie, Landa, et al., 2017).

In the UK, many hospital pharmacy departments have programmes of routinely or periodically documenting clinical contributions to care (East and South East England Specialist Pharmacy Services, 2015). Outputs of these programmes are generally shared internally only, with the aim of demonstrating the value of clinical pharmacy services. Comparisons with other hospitals are rare and unpublished. Despite the long history of documenting and reviewing CP contributions to care, there is no consensus on a core data

set, categorisation system, or tools for assessing the clinical or other benefits of individual contributions. This makes it difficult to make valid comparisons between pharmacy services or to aggregate data from different hospitals to produce generalisable evidence. A few multi-site studies have been carried out in the UK, but results are combined for presentation, and not compared between organisations (Braithwaite, 2015; Rudall, McKenzie, Landa, et al., 2017).

5.2.1 Evaluating the significance of clinical pharmacy contributions to care

In 2005, while at KCH, I implemented periodic (initially annual) documentation of clinical pharmacy contributions, as part of my work on developing clinical pharmacy quality metrics. Evaluating the clinical significance of the documented contributions was key to using the contributions as quality indicators, however there were no validated instruments available for this. PW12 was carried out in an attempt to identify a suitable methodology for attaching a clinical significance or clinical benefit to each contribution. Our (myself and my collaborator, RM) initial literature review confirmed that while most publications used one of a few popular methods, various adaptations were in use and none had been validated for this specific purpose. PW12 thus describes early efforts to produce a reliable tool for rating the significance of clinical pharmacy contributions to care.

The instrument we derived was based on a comprehensive, popular, previously published rating system (Hatoum, Hutchinson, Witte, et al., 1988) and therefore had face validity. Hence we concentrated on assessing the inter-rater reliability. The pragmatic reason for wanting a tool with high inter-rater reliability was that pharmacy staff self-reported their contributions, and also assigned the clinical significance. The clinical ratings which staff applied to similar contributions was not consistent between individuals, because of the subjective nature of the assessment (staff are asked to decide on the most likely outcome if the contribution had not occurred). To mitigate this, I implemented a process whereby senior clinical pharmacists validated initial significance ratings and made adjustments where they disagreed with the original rating. This was very resource-intensive, hence the need to have a tool which standardised the significance rating process. For the measure of reliability in PW12, I used Cohen's (1960) weighted Kappa statistic for chance-corrected agreement. An *a priori* kappa of 0.6 (upper bound for moderate agreement - Landis &

Koch, 1977) was agreed as the minimum acceptable standard. PW12 was an oral (platform) presentation and won the award for best oral presentation at the conference.

Our results only showed upper bound fair agreement between raters (mean kappa 0.46). We continued to use the tool in-house and shared it with colleagues across the UK (Miller, 2015; Goh, Dave, & Le Morgan, 2016; Hamilton, Hackney, Kearney, et al., 2018), although I decided that it was not ready for academic dissemination. A minimum acceptable kappa of 0.6 was possibly quite severe, as other researchers have presented work showing much lower agreement indices. Bosma and colleagues (2008) measured the agreement between a hospital pharmacist and an internal medicine specialist on the severity and value of pharmacists' clinical interventions. The instrument used was Overhage and Lukes (1999). They found a kappa of 0.3 for severity and 0.2 for value of service. A kappa of 0.2 is regarded as 'slight' agreement (Landis & Koch, 1977). Lee et al. (2006), adapted the same tool and used this to determine the value of recommendations made by consultant pharmacists in hospice settings. Two pharmacists and a physician rated the pharmacists' interventions. Kappa for severity was 0.4, and for value of recommendations, 0.3.

Deciding on the appropriate statistical test for the study was a challenge, as authors disagreed. The process of searching the literature increased my knowledge of tests of agreement and their inherent limitations. I had good occasion to use my knowledge of tests of agreement when attempting to publish PW30a (Onatade, Sawieres, Veck, et al., 2017). Replying to a peer reviewer's challenge about why I had only reported the percentage agreement between the pharmacist and doctor (regarding the severity of detected errors), I addressed the comment by citing the 'Kappa paradox' whereby a high level of agreement can result in a paradoxically low Kappa coefficient (Feinstein & Kramer, 1980).

Over the years, I made minor amendments to the tool in line with feedback from colleagues. I conducted inter-rater reliability studies (not presented), without any significant improvements in the kappa statistic. I undertook a major update in 2014/15, when I realised that the best way to ensure sufficient reliability was to provide more guidance, in the form of 'rules' (recommending severity levels to assign to different types of contributions). I worked with RM to develop the statements describing the rules. We

used this updated tool in-house and also shared it with colleagues across the UK. Rather than repeating the inter-rater reliability studies, I decided that full validation of the instrument was necessary. In 2016, I named the tool IMPACCTS (InstruMent for rating PhArmacy Clinical Contributions To care Significance), convened a research group and conducted PW33 (Mehta & Onatade, 2016), a large multi-site content validation study. PW33 is the first of a series of validation studies which I am carrying out with my research group. It has been highly successful so far, and the tool has been updated in line with the results. The updated tool is not yet in use and will not be shared with colleagues until all validation is complete. For this work, I have consulted statisticians and increased my knowledge of how to conduct validation studies, in order to ensure the research is as robust as possible. Subsequent validation and reliability studies have been conducted and more are planned.

Continuing the theme of recording clinical pharmacy contributions to care, PW16 looked at two different methods for collecting data to evaluate the utility of both. When pharmacy departments undertake periodic, point-prevalence (as opposed to continuous) recording, the standard process is for staff to document all clinical contributions made within a specified time period (usually 1 day to 4 weeks), regardless of the patients' stage of admission. In this study, I chose to ask staff to only document contributions made for patients newly admitted during an index week, and to continue to record their clinical input to those patients for a further week, or until the patient was discharged, whichever occurred sooner. The data collected was compared to those from previous years, where the standard process was used. As discussed in the abstract, the second method provided information not normally available. This information provided important insights into service variations and confirmed that greater levels of input were required within the first 36 hours of admission, and that this need subsequently tailed off. I hypothesised that contribution rates may increase at discharge (i.e. contribution rates peak both at admission and discharge), however as dates of discharge were not documented, I was unable to prove or disprove this. The outcome from this study was a decision to combine useful elements from both methods. We started documenting dates of admission for all patients, but also to collect data more regularly i.e. one day every two months, rather than for 1 week annually. This latter change was also an attempt to reduce the significant

staff resource needed to prepare, collect and analyse data once a year, and to minimise reporting fatigue.

The information from this exercise was essential to provide myself, as Service Lead, with regular data on our clinical pharmacy activities. I also developed a regular report of these activities, assigning them a monetary value (costs avoided - the costing model used is discussed in more detail further in this section, with PW31 (Onatade & Quaye, 2016)). I ensured that these were sent to senior managers and clinicians within the trust. The purpose of this was to inform our stakeholders about the continued quality and financial benefits that our clinical contributions were providing. See Appendix II for an example of a report.

The current rating tool for assessing clinical pharmacy contributions to care is shown in Appendix II, and it is the version in use both at KCH and my current organisation (Barts Health NHS Trust). Some of the rules are highlighted in red, to indicate which contributions should be reported on the trust-wide incident reporting system. This was the product of work carried out with a colleague (GC), with whom I collaborated on PW14 (Eaton, Cavell, & Onatade, 2010). My colleague wanted to increase the number of adverse medication incidents reported by pharmacists. As our contributions reports were a rich source of data for this, we took the agreed list of scenarios produced in PW14, mapped these to the corresponding contribution types in the rating tool, and highlighted them in red. Further work is required to follow this up, or evaluate if the change achieved the aim of increasing the number of reported incidents.

Progressing the theme of using documented care contributions to assess the value of clinical pharmacy activities, PW31 – 'Economic value of pharmacy-led medicines reconciliation at admission to hospital: an observational, UK-based study' was published as an academic article. The paper links my previous work on pharmacy-led medicines reconciliation (MR - of which drug-history taking is the initial step), documentation of clinical activities and the monetary value of these clinical activities. In 2007, NICE and NPSA produced guidance for the NHS, recommending that MR should be led by pharmacists (National Institute for Health and Clinical Excellence & National Patient Safety Agency, 2007). NICE had commissioned a simulation modelling report from the Sheffield

School of Health and Related Research (ScHARR) which analysed the costs and benefits of different modalities for carrying out medicines reconciliation and concluded that pharmacist-led MR was the most cost-effective intervention (Campbell, Karnon, Czoski-Murray, et al., 2007; Karnon, McIntosh, Dean, et al., 2007).

The ScHARR economic evaluation was the first UK-based study which gave a financial value to preventable adverse drug events, pADEs (i.e. errors). Previous available information came from North American studies (Bates, Spell, Cullen, et al., 1997), and adapted for use in the UK (Smith, 2004) in the absence of any other data. Although the ScHARR economic model was carried out to purely assess the costs of pADEs caused by lack of medication reconciliation, pharmacy researchers (including myself, see example report in Appendix II) also applied the costing figures to all ADEs prevented by clinical pharmacy contributions, to depict the financial benefits of these activities. However, no researchers had as yet conducted an economic evaluation of medicines reconciliation using the ScHARR model. PW31 is the outcome of a piece of work I conducted with a colleague (SQ), an experienced pharmacy technician, who I invited to work with me. I conceived and designed the study, analysed the data and provided overall direction. SQ supervised data collection, including moderating the consensus panel and conducted some data analysis. Although this was not a full economic evaluation, I followed Consolidated Health Economic Evaluation Reporting Standards (Husereau, Drummond, Petrou, et al., 2013) in the study design, including calculating costs incurred to offset against the costs avoided (benefits), sensitivity analyses and revaluing the ScHARR costings to the present day. We used retrospective data from our periodic recording of clinical contributions to care (PW16) and I also applied and updated my knowledge of the use of expert panels from the literature searches I conducted for PW10 (Onatade & Zuhair, 2010).

PW31 filled several gaps in the evidence base. The study affirmed the average time required to conduct MR in an individual patient. This was in line with previously reported data (Dodds, 2014). Importantly, we demonstrated the substantial, real-world, financial benefit of pharmacy-led medicines reconciliation, by avoiding adverse drug events. In addition, no previous work had shown that there were scenarios where MR might not be financially beneficial, thus encouraging practitioners and managers to review their MR processes and staff deployment to ensure maximum cost-effectiveness.

5.3 Outcomes of clinical pharmacy

5.3.1 Evidence for the outcomes and impact of clinical pharmacy

This chapter has highlighted the work I have done to demonstrate the benefits of hospital clinical pharmacy. As a practitioner, I am aware of the benefits I bring to individual patient care, and as a service lead, I have commissioned and led projects to demonstrate these benefits on a wider scale - clinically, organisationally and financially. However, from an academic perspective, I am aware that there is still much more work to be done. PW34 - *Evidence for the outcomes and impact of clinical pharmacy: context of UK hospital pharmacy practice* (Onatade, Appiah, Stephens, et al., 2017) explores this issue. This paper is a comprehensive narrative review, co-authored with my doctoral supervisors, on the scarcity of published robust evidence on the impact and outcomes of clinical pharmacy. The paper draws on the international literature, although the focus is on UK hospital pharmacy practice.

It is clear that clinical pharmacy (wherever practised) fits the conventional definition of a complex intervention in that it has several interacting components, standardisation of the design and delivery of interventions is difficult, interventions are sensitive to the local context and thus must be highly flexible and adaptable, and linking activities to outcomes is complex and often not possible (Craig, Dieppe, Macintyre, et al., 2008). Clinical pharmacy in the UK is also in a constant state of rapid development and evolution because of the nature of the demands on the health-system, and the multiple ways in which medicines are involved. These characteristics mean that there is no single coherent vision for clinical pharmacy and several acceptable ways to define the practice of clinical pharmacy, its purpose and constituent parts. In PW34, we postulate that this is a key reason for pharmacy researchers' inability to consistently demonstrate the impact of clinical pharmacy activities. Another reason is likely to be that clinical pharmacy interventions do not impact on conventional health outcome measures, although investigators persist in using them. They are therefore likely measuring for insensitive outcomes and using research methodologies which are unlikely to capture other outcomes.

Some researchers, notably from Europe, have attempted to protocolise the provision of clinical pharmacy services to inpatients, by describing and/or implementing elements of a structured approach (Hellström, Bondesson, Höglund, et al., 2011; Graabaek & Kjeldsen, 2013; Rotta, Salgado, Felix, et al., 2015; Ravn-Nielsen, Duckert, Lund, et al., 2018). Whilst this is laudable, patient care cannot truly be systematised to such a degree that factors such as local context and the abilities of the caregivers have no influence. Studies describing implementation of these structured interventions have also not managed to consistently demonstrate an impact on outcomes, although they have shown improvements in other measures, such as reductions in inappropriate prescribing and resolution of drug-related problems.

We conclude the review by calling for new research approaches to enable better understanding of the economic, clinical and humanistic outcomes from hospital clinical pharmacy activities. This would include considering patient-centred qualitative studies instead of the empiricism of quantitative research and robust cost-consequence analyses to overcome the criticisms of the more popular, but less flexible, economic evaluation methods.

5.3.2 Other outcome-related works

In PW34, myself and co-authors advocated cost-consequence analyses (CCAs) as more appropriate economic evaluations of clinical pharmacy interventions, rather than cost-benefit or cost-effectiveness studies. PW35 – *Costs and consequences analysis of a clinical pharmacy service to a surgical ward* (Onatade, Chou, Johnston, et al., 2017) was carried out as proof of concept of the use of a cost-consequence study to demonstrate the value of a clinical pharmacy service. I was the supervisor for an MSc student from overseas (AC), and this was her final project. The absence of similar studies in the literature to learn from caused difficulties in deciding on an appropriate design and methodology. Although small-scale, the results showed significant economic, clinical and staff-related benefits from providing a clinical pharmacy service to wards, although it was not possible to obtain patient feedback. As the project was largely observational and interview-based, but with quantitative elements, I also fulfilled another aim of PW34, that of conducting a mixed-methods study.

PWs 4, 6, 8 (Chapter One), 13 (Chapter Four), 14, 30 (Chapter Three) and 20, 25, 26 (Chapter Four) demonstrate conclusively the added benefits possible when pharmacy staff get more involved in the medication aspects of patient discharge and transfer of care. In PW5 – *Adherence to, and pharmacists' views of, antimicrobial switch and stop policies.* (Patel, Onatade, & Davies, 2008), PW17 – *Quality of vancomycin prescribing and clinical outcomes in individual patients at a London Teaching Hospital* (Talpaert, Aroyewun, & Onatade, 2011) and PW19 – *Improving antimicrobial prescribing using rapid serial audits and feedback* (Talpaert, Acosta, Fife, et al., 2013), I looked at pharmacists' roles in improving the use of antimicrobials and associated stewardship, with PW19 demonstrating the value of collaboration with medical staff to ensure regular feedback on prescribing practices. PWs 11, 15 and 27 (Chapter One), describe how by measuring and monitoring appropriate quality and performance indices, it is possible to make improvements to processes which are important for clinical care and operational effectiveness. PWs 20 and 22 also describe how pharmacists with prescribing rights can improve patients' timely access to the medicines they need, albeit with a caveat regarding ensuring our practice remains within professional and legal boundaries. PW32 (Onatade & Oduniyi, 2016) is an example of how clinical care can be enhanced by ensuring appropriate specialist pharmacist expertise is available and proactively utilised.

CHAPTER SIX: Discussion and Conclusion - a way forward for clinical pharmacy practice and research

Philosophers have only interpreted the world in various ways, the point is to change it

- Karl Marx (1818 – 1883)

6.1 Introduction

The presented PWs showcase my varied professional and scholarly outputs and contributions to clinical pharmacy practice in the UK. I have thematically grouped the PWs, although they overlap and link to build a wide-ranging picture of my role in advancing hospital clinical pharmacy practice and research in the UK. The profession of clinical pharmacy in the UK does not yet have standards of practice, in contrast to Australia and North America. The Society of Australian Hospital Pharmacy has fifteen clinical pharmacy services standards (George, Leversha, Archer et al., 2013), and the American College of Clinical Pharmacy has eight standards (American College of Clinical Pharmacy, 2014). The Public Works presented here, are paralleled in these countries' standards, as shown in Figures 3 and 4, demonstrating the comprehensiveness of the presented PWs. It can be seen that I have put most emphasis on clinical review, processes of care and improving quality of care and services. However, there are other less tangible inputs, which are more difficult to publish or present. These include modelling good clinical practice and supporting others to develop their own models, promoting clinical leadership, professional responsibility, and by extension, professionalism.

Theories of professionalism in pharmacy practice are underdeveloped. However, Arnold (2002), highlights the following concepts as common to ideas of medical professionalism - *reliability, responsibility, honesty and integrity, maturity, respect for others, critique, altruism, interpersonal skills, absence of impairment, respect for others, professional responsibility, self-improvement and adaptability, relationships with patients and families,*

relationships with members of the health care team, honour, integrity, ethical and moral standards; accountability, excellence, duty, advocacy. I believe that these apply to all healthcare professionals, a view which is reinforced by the American Society of Health-system Pharmacists Statement on Professionalism (American Society of Health-System Pharmacists, 2008) which includes all of the above, as well as explicitly mentioning the characteristics of creativity and innovation. However, Brown and Ferrill (2009) and Wynia et al (2014) argue that lists of characteristics are not sufficient to fully capture the essence and complexity of the behaviours and processes that embody professionalism. Preparedness to self-monitor, critically reflect on one's practice and thus continually improve have also been advocated as principles of professionalism (Lachman & Pawlina, 2006; Wilkinson, Wade, & Knock, 2009). Reflective practice should lead to self-improvement and maintenance of professional competence (Mann, Gordon, & MacLeod, 2009).

I believe that the areas that I have focussed on in my practice are appropriate, considering the apparent future of pharmacy and health services in general (Lord Carter of Coles, 2016). Clinical pharmacy practice is now a well-established healthcare discipline in developed countries. There are growing demands for clinical pharmacists to provide increasingly complex and sophisticated models of care. I suggest however, that in order for practice to advance further, we need to ensure our professionalism also matures at a similar pace. This could be facilitated by additional focus on the theoretical, reflective and research aspects of practice, which should be explicitly incorporated into clinical pharmacy practice, extending the ideas put forward in PW34 (Onatade, Appiah, Stephens, et al., 2017). In section 6.2, using concepts from other disciplines, I advance a theory-based view of the future for clinical pharmacy practice and associated research.

Australian Standards of Practice for Clinical Pharmacy Services	Related Public Works
• 1. **Medication reconciliation** • 2. **Assessment of current medication management** • 3. **Clinical review**, therapeutic drug monitoring and adverse drug reaction management • 4. Medication management plan • 5. **Providing medicines information** • 6. **Facilitating continuity of medication management on transition between care settings** • 7. **Participating in interdisciplinary care planning** • 8. **Prioritising clinical pharmacy services** • 9. **Staffing levels and structure for the provision of clinical pharmacy services** • 10. **Training and education** • 11. **Participating in research** • 12. **Pharmacy assistants and technicians supporting clinical pharmacy services** • 13. **Documenting clinical activities** • 14. **Improving the quality of clinical pharmacy services** • 15. **Clinical competencies**	• 1. PWs 2,11, 31 • 2. PWs 10,11,12, 15,17 • 3. PWs 9, 10, 11, 15, 16, 21, 23, 28, 30, 32,33 • 5. PWs 6, 11, 15, 25, 26, 27, 32 • 6. PWs 13, 20, 25, 26 • 7. PWs 9, 13, 18, 19, 20 • 8. PWs 11, 27 • 9. PWs 9, 29, 32 • 10. PWs 19, 23 • 11. PW 34. Overarching - covered by all PWs • 12. PW 9 • 13. PWs 12, 16, 22, 33 • 14. PWs 2,4, 8, 10, 11, 12, 15, 21, 27, 32 • 15. PW23

Figure 3. Relationship between Society of Australian Hospital Pharmacy Standards of Practice for Clinical Pharmacy Services and the Public Works

Qualifications	Process of care	Documentation	Collaborative, Team-Based Practice and Privileging
•No PWs	•PWs 4, 6, 7, 8, 9, 10, 11, 13, 15, 17, 18, 19, 20, 22, 25, 26, 27, 28, 30, 32	•PWs 12, 16, 22, 23, 25, 26, 33	•PWs 9, 13, 18, 20, 22, 24

Professional Development and Maintenance of Competence	Professionalism and Ethics	Research and Scholarship	Other Responsibilities e.g. educators, clinical /mentors, administrators, managers, policy developers
•PW 23	•PWs 9, 22	•PW 34. Overarching - covered by all PWs	•PWs 1, 3, 31, 35

Figure 4. Relationship between American College of Clinical Standards of Practice for Clinical Pharmacists and the Public Works

6.2 Pharmacy practice-based research – a way forward

As discussed in the previous chapter, the strong positivist roots of pharmacy, and the emphasis on the production of empirical evidence are major reasons why qualitative/mixed methods research has not become a mainstream scholarly approach within the profession. Poor engagement with the social sciences and sociological theories is another reason (Bissell, Traulsen, & Haugbolle, 2001; Jesson, 2006). This is despite the importance of understanding the sociological and behavioural aspects of healthcare and the use of medicines (Tonna & Edwards, 2012; Rathbone & Jamie, 2016; Winit-Watjana, 2016). Another plausible reason is the lack of a pharmacy practice-specific conceptual framework. A consequence of this absence and the dearth of theory to underpin our practice is (arguably) reduced *knowledge production* in pharmacy practice research.

The need for pharmacy practice researchers to broaden their field of expertise has long been recognised. Gray (1999) describes the requirement for pharmacy researchers to engage in *mode 2* - knowledge production involving simultaneous research and development. Norgaard et al. (2000) and Bissell et al. (2004) explicitly decry the lack of engagement with theory and postulate that doing so would enrich and strengthen research. Jesson (2006) states that although researchers have adopted some social science techniques, such as interviews and focus groups, the philosophical and epistemological basis of these methodologies have been neglected. Most recently, Winit-Watjana (2016) argues the necessity for a pharmacy research philosophy. This involves designing a study by selecting a methodology based on the theory and research philosophy appropriate to the questions being asked. This is in contrast to the prevailing approach within pharmacy (including my own), which is to go straight from research question to methods, with no consideration of the theoretical basis of the hypotheses. Whilst the various paradigms are well-described by Winit-Watjana, and the argument for a research philosophy is well-made, the author stops short of suggesting a suitable model.

Drawing on the premise that critical reflection has a significant role to play in improving practice and thus is also key to developing and maintaining professionalism and professional responsibility (Mamede & Schmidt, 2004; Lachman & Pawlina, 2006; Brown & Ferrill, 2009), in the following paragraphs, I introduce the concept of *pharmacy praxis* as a model to integrate theory, research, and professional practice. In preceding chapters, I

have described how I have attempted to support and encourage less-experienced colleagues to participate in research. This is important as researchers (Cvijovic, Boon, Jaeger, et al., 2010; Lowrie, Morrison, Lees, et al., 2015) have found that pharmacists often feel that research is separate from practice, and that there is a distinct lack of motivation to undertake or prioritise research, frequently because of the low value attributed to it. Although praxis is well-described in the nursing and educational literature, the term is not found in texts about pharmacy practice or pharmacy research. Norgaard et al. (2000) touch on the benefits of theory-based research, but do not explicitly mention praxis in relation to this. Other researchers have used it synonymously with action research (De Oliveira, Alves, & Ramalho-de-Oliveira, 2017), although this is not strictly correct. Classic action research is 'learning by doing' - systematic fact-finding within a situation; a group of workers or practitioners identify a problem, put a plan into action to resolve the problem, and then evaluate the outcomes to assess how successful their efforts were. Praxis, on the other hand, is personal to the practitioner, as theory and research combine with everyday practice and these continually inform and influence each other. Theorising and reflexive thinking are inherent in praxis, as these impact or change practice. Praxis allows one to carry out research, contribute to academic knowledge and use the research to practically inform professional practice (Rolfe, 1993; Fahy, 1996; Penney & Warelow, 1999). In addition, it enables control over practice, thought to be a fundamental element of a profession (Chenitz & Swanson, 1984). Although there are many uses and applications of the term praxis, overall it can be viewed as a way of closing the gap between theory and practice, within which reflection is key (Rolfe, 1993; Zuber-Skerritt, 2001).

6.2.1 Conceptualising pharmacy praxis

Consciously adopting the principles of praxis as a framework for clinical pharmacy practice and the provision of pharmaceutical care will lead to a different type of research. Pharmacy praxis will enable practitioners to break free of traditional research boundaries and the criticisms of current outcome studies. A new conceptual framework of what constitutes acceptable practice research can be constructed, allowing closer alignment to the social sciences. Drawing from Rolfe (1993, 1998), I propose a process of using experiential practice to develop theory and knowledge and influence research. This will

then influence future practice and will support the evaluation of clinical pharmacy interventions in the context of their fluidity, variability and adaptability to individual patients - and therefore not easily amenable to being defined, standardised or quantitatively measured. In this model, research will be framed as part of practice, which may be less daunting. Additionally, applying theory and research findings to practice will continue the virtuous circle of praxis. Rolfe (1993) introduced nursing praxis primarily to close the gap between theory and practice although he later expands on the importance of practitioner-led research to generate knowledge and theory (Rolfe, 1998). I conceptualise pharmacy praxis as a model to bring theory, practice and practitioner-research closer together, also underpinned by reflection. This is similar to Veloza-Gomez's view of the research-practice-theory relationship for nursing (Veloza-Gomez, 2016). Pharmacy praxis allows for a new way of valuing and framing clinical research.

Figure 5 is a representation of a model of pharmacy praxis. Importantly, although a conceptual framework, pharmacy praxis must be adopted consciously by practitioners, as it must be reflective, informed and committed, in order to influence actions and decisions. A potential area for future work would be the implementation of both 'theory-based/ theory-guided practice' and 'practice theory/ practice-based theory'. The former term relates to the integration of theory into practice, requiring first the knowledge, understanding and adoption of theory followed by the development of corresponding practices (Bolander Laksov, 2018). I define practice-based theory as 'the development of theory from practice and the experiences of practitioners'. I believe, in line with other researchers (Chenitz & Swanson, 1984; Martens, 2011), that this should primarily be undertaken by practitioners (albeit those happy to also be described as theorists), through for example, observing and analysing issues and processes within practice and formulating theories to understand them. Conducting both lines of inquiry will facilitate the development of pharmacy praxis.

Figure 5. Pharmacy Praxis. A model for integrating professional and clinical practice, research and theory

6.3 Conclusion

To conclude, I have described, through the medium of my Public Works, my professional, research and academic practice, across my roles as a clinical pharmacy practitioner, researcher and senior hospital pharmacy manager and leader. I have discussed the Public Works as mainly belonging to four strong themes, *measuring & improving standards and quality of care, prescribing, prescribing practices and prescribing safety, innovative practice within legal and ethical frameworks and the impact & outcomes of clinical pharmacy;* which have been my main research interests for many years. By incorporating a chronological element, I have also shown how by building on the strengths and weaknesses of my early works, I developed more complex and sophisticated approaches as my expertise and skills grew. I have also demonstrated the interdependencies between the themes and shown that the PWs overlap and link. Within the many definitions of clinical pharmacy and pharmaceutical care, the central themes of patient safety, clinical effectiveness and quality use of medicines are clear and recurring.

The future of hospital clinical pharmacy is bright, but embedding academic research and reflexivity into our everyday practice is imperative if we are to continue to advance our professional activities and achieve full potential. An important outcome of my doctoral studies has been the development of a new philosophy of practice, facilitated by my exploration of research in other disciplines.

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Full list of Public Works in chronological order

PW	Title of Public Work	Type of work	Years covered	Additional information
1	Mehta R., Onatade R. (2008). Experience of electronic prescribing in UK hospitals: a perspective from pharmacy staff. Pharmaceutical Journal; 281(7511):79-82	Publication - Professional Journal	2005 - 2008	
2	Virani N., Onatade R., Mehta R. (2008). Frequency of Drug History taking by pharmacists at King's College Hospital. Pharmacy World & Science; 30 (4), p408-p409	Conference abstract	2006	
3	Onatade R., Mehta R. (2007). Tracking the PGD development process. Pharmacy Management; 23 (3): 21–24	Publication - Professional Journal	2007	
4	Ling C, Mehta R, Onatade R. (2008). Assessing the proportion of patients discharged with TTA medicines issued directly from the ward. Pharmacy World & Science; 30 (5), p632-p633	Conference abstract	2007	

PW	Title of Public Work	Type of work	Years covered	Additional information
5	Patel S, Onatade R, Davies JG. (2008). Adherence to, and pharmacists' views of, antimicrobial switch and stop policies. Pharmacy World & Science; 30 (6), p1051-p1052	Conference abstract and undergraduate dissertation	2007	
6	Khudairi N, Onatade R, Patel N. (2008). Quality and quantity of information on medicines given to patients discharged from hospital. Pharmacy World & Science; 30 (6), p1050-p1051	Conference abstract and undergraduate dissertation	2007	
7	Onatade R., Bell C., Garcia M., Mehta R. (2008). The use of missed doses as an indicator for assessing the quality of clinical pharmacy services: a comparison of two audits. Pharmacy World & Science; 30 (6), p1049-p1050	Conference abstract	2007	
8	Brown A., Patel N., Onatade R. (2008). Pilot of a ward discharge medication labelling service. Pharmacy World & Science; 30 (6), p1061-p1062	Conference abstract	2007	

PW	Title of Public Work	Type of work	Years covered	Additional information
9	Onatade R., Jogia S., Choudhary I (2010). A study to assess the safety and time effectiveness of Pharmacy Technician triage on a gynaecology/surgical ward. Clinical Pharmacist; February 2010, Supplement 1, pS27	Conference abstract	2008	
10	Onatade R., Zuhair A. (2010). Identifying criteria for use in assessing the quality of pharmaceutical care: a modified Delphi study. Clinical Pharmacist; February 2010, Supplement 1, pS10	Conference abstract and undergraduate dissertation	2008	Oral communication

PW	Title of Public Work	Type of work	Years covered	Additional information
11 a - c	Quality series a. Onatade R. Quality Indicators are important measurement tools for pharmacy. Pharmacy in Practice; May 2008, 18(4):141-143 b. Mehta R., Onatade R. Auditing medication history-taking can help demonstrate improved pharmacy services. Pharmacy in Practice; September 2008, 18(6):209-213 c. Onatade R. and Mehta R. Improving the patients' discharge experience is an important pharmacy goal. Pharmacy in Practice; January 2009, 19(1):11-13	Publication - Professional Journal	2008 - 2009	
12	Onatade R., Mehta R., Shallal O. (2010). The selection, modification and reliability testing of a tool to rate the clinical significance of pharmacists' clinical contributions. Clinical Pharmacist; February 2010 Supplement 1 pS3-4	Conference abstract and undergraduate dissertation	2009	Best Oral Communication award winner

PW	Title of Public Work	Type of work	Years covered	Additional information
13	Considine A, Onatade R, Knighton S, Leung K (2010). A review of a pharmacist discharge prescription writing service in a large teaching hospital. Clinical Pharmacist; February 2010 Supplement 1 pS15-16	Conference abstract	2009	
14	Eaton C., Cavell G., Onatade R. (2010). Developing a definition of a reportable prescribing error. Clinical Pharmacist; February 2010 Supplement 1 pS25	Conference abstract and undergraduate dissertation	2009	
15	Onatade R., Shah R., Alidina F., Alimi-Odiora A., Goble E., Mitchell M (2011). Assessing the quality of pharmaceutical care: a feasibility study. Clinical Pharmacist; April 2011 S2 pS11	Conference Abstract	2009	Oral communication
16	Onatade, R., Chowdhury R., Bell C., Mehta R. A comparison of two methods for recording and analysing clinical pharmacy contributions (2011). Clinical Pharmacist April 2011 S2 pS13	Conference abstract and undergraduate dissertation	2009	Oral communication

PW	Title of Public Work	Type of work	Years covered	Additional information
17	Talpaert M., Aroyewun M., Onatade R. (2011) Quality of vancomycin prescribing and clinical outcomes in individual patients at a London Teaching Hospital. Clinical Pharmacist; April 2011 S2 pS32	Conference abstract	2010	
18	Adaptable "scope of practice" template for hospital pharmacist prescribers. R Onatade, A Wong. The Pharmaceutical Journal; 2012; 288:720	Publication - Professional Journal	2012	
19	Talpaert M, Acosta N, Fife A, Onatade R. (2012). Improving Antimicrobial Prescribing Using Rapid Serial Audits and Feedback. Clinical Pharmacist; Jan/Feb 2013 S1 pS2-S3	Conference Abstract	2012	2012 Novartis Antimicrobial Management Award winner

PW	Title of Public Work	Type of work	Years covered	Additional information
20 **a-d**	Redesigning the discharge medication pathway a) Onatade R. (2017). Using the Consolidated Framework for Implementation Research to Evaluate a New Discharge Medication Prescription Pathway. Preprints; 2017050061 (doi:10.20944/preprints201705.0061.v1) b) Presentations (2014 – 2017) c) Testimonials (2015 – 2016) d) Reports of drug listing implementation (2004 – 2017)	a) Pre-print Publication	2005 - 2016	
21	Onatade, R., Auyeung, V., Scutt, G., & Fernando, J. (2013). Potentially inappropriate prescribing in patients on admission and discharge from an older peoples' unit of an acute UK hospital. Drugs & Aging; 30(9), 729-737	Academic Publication	2012 - 2013	
22	Austin V, Onatade R. (2013). Evaluation of the Ordering and Cancelling of Inpatient Prescriptions by Pharmacists using Electronic Prescribing. Abstract presented at United Kingdom Residential Symposium November 2013.	Conference Abstract	2013	

PW	Title of Public Work	Type of work	Years covered	Additional information
23	a. Bell C., Callender N., Razouk R., Yerbury P., Shah R., Onatade R. (2014). Baseline Assessment of the Confidence, Knowledge and Skills of Pharmacists when providing pharmaceutical care to patients with Diabetes. Paper presented at United Kingdom Association for Clinical Pharmacy Residential Symposium November 2014. b. Bell C., Onatade R., Shah R., Yerbury, P. An assessment of hospital pharmacists' confidence, knowledge and skills in providing care to patients with diabetes.	Conference Abstract Unpublished manuscript	2013	Oral communication
24	Bourne RS., Baqir W. & Onatade R. Pharmacist independent prescribing in secondary care: opportunities and challenges. Int J Clin Pharm (2016); 38:1. https://doi.org/10.1007/s11096-015-0226-9	Academic Publication	2015	

PW	Title of Public Work	Type of work	Years covered	Additional information
25	Knight E., Scaria A., Lama S., Stevenson J., & Onatade R. The extent of, and documented reasons for, discrepancies in post-hospital medicines reconciliation. Abstract presented at United Kingdom Clinical Pharmacy Association Residential Symposium November 2015.	Conference abstract and undergraduate dissertation	2015	
26	Amadu R., Adebimpe F., Onatade R. Post-hospital medicines reconciliation: The impact of providing enhanced information regarding medication changes. Paper presented at United Kingdom Clinical Pharmacy Association Residential Symposium November 2015.	Conference abstract and undergraduate dissertation	2015	Oral communication

PW	Title of Public Work	Type of work	Years covered	Additional information
27 **a-b**	a. Onatade R, Gujral S, Phul N, Pamanathan K, Torku A, Sawieres S, Oputu T. (2015). The use of Always Events in a survey of inpatients' experiences with their medication and the clinical pharmacy service. Abstract presented at Guild of Healthcare Pharmacists and United Kingdom Clinical Pharmacy Association 11th Joint National Conference. May 2015 b. 'Always Events' as a method of surveying and improving in-patients' experiences with their medicines and pharmacy. In Measuring and improving patients' experience of care. Report of a summit for pharmacy teams. Royal Pharmaceutical Society 2015. **https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Professional%20standards/Professional%20standards%20for%20Hospital%20pharmacy/patient-experience-report.pdf?ver=2016-10-27-125729-413**	a. Conference abstract and poster b. Report	2015	Poster commendation

PW	Title of Public Work	Type of work	Years covered	Additional information
28	Gujral S., Onatade R., Mehta R., Hinton J., & Maharaj R. Time to administration of first dose antibiotics and associated outcomes in respiratory sepsis. Abstract presented at United Kingdom Clinical Pharmacy Association Residential Symposium November 2015.	Conference abstract	2015	Shortlisted for best poster
29	Onatade, R., Miller, G., & Sanghera, I. (2016). A quantitative comparison of ward-based clinical pharmacy activities in 7 acute UK hospitals. Int J Clin Pharm; 38(6), 1407-1415.	Academic Publication	2013 - 2016	

PW	Title of Public Work	Type of work	Years covered	Additional information
30 a-b	a. Onatade, R., Sawieres, S., Veck, A., Smith, L., Gore, S., & Al-Azeib, S. (2017). The incidence and severity of errors in pharmacist-written discharge medication orders. Int J Clin Pharm; 39 (4) 722-728. b. Onatade, R., Sawieres, S., Veck, A., Smith, L., Gore, S., & Al-Azeib, S. A comparison of errors in pharmacists' and doctors' discharge medication orders.	a. Academic Publication and Award winner b. Unpublished draft manuscript	2013 – 2017 2009	2014 Pharmacy Management Best Medicines Optimisation in Secondary Care Award winner (Description and evaluation of the quality of pharmacist written discharge medication lists. Raliat Onatade, Sumiah Al-Azeib, Shivani Gore, Sara Sawieres, Lindsay Smith, Alexandra Veck)

PW	Title of Public Work	Type of work	Years covered	Additional information
31	Onatade R., Quaye S. (2016). Economic value of pharmacy-led medicines reconciliation at admission to hospital: An observational, UK-based study. Eur J Hosp Pharm published first online. **https://ejhp.bmj.com/content/early/2016/12/09/ejhpharm-2016-001071?versioned=true**	Academic Publication	2014 - 2016	

PW	Title of Public Work	Type of work	Years covered	Additional information
32 a-c	Improving the pharmaceutical care of patients with severe mental illness a. Onatade R., Oduniyi O. Improving the pharmaceutical care of patients on psychotropic medication admitted to an acute hospital – the impact of a proactive 'inreach' specialist psychiatric pharmacist service. Presented at United Kingdom Clinical Pharmacy Association Residential Symposium November 2016. b. Conference presentation and professional coverage c. Internal reports and associated documents	a. Conference abstract and Award Winner	2015 - 2016	2016 UKCPA Pfizer Patient Safety Award winner
33	Mehta R., Onatade R. (2016). On behalf of the IMPACCTS group. Content validity of a tool for rating the significance of pharmacists' clinical contributions. Abstract presented at November 2016	Conference abstract and undergraduate dissertation	2016	Shortlisted for best poster

PW	Title of Public Work	Type of work	Years covered	Additional information
34	Onatade, R., Appiah, S., Stephens, M., & Garelick, H. (2017). Evidence for the outcomes and impact of clinical pharmacy: context of UK hospital pharmacy practice. Eur J Hosp Pharm, ejhpharm-2017.	Academic Publication	2017	
35	Onatade R., Chou A., Johnston A., Smith F., Stephens M. (2017). Costs and consequences analysis of a clinical pharmacy service to a surgical ward. Abstract presented at United Kingdom Clinical Pharmacy Association Residential Symposium November 2017.	Conference abstract and postgraduate dissertation	2017	

Confirmations and declarations of authorship

I confirm that the statements below accurately represent Raliat Onatade's contribution to the stated works.

Signed…………………….....……………. Date……………..……………

Reena Mehta

Critical Care Clinical Pharmacy Team Leader

King's College Hospital NHS Foundation Trust

Title of work	Raliat Onatade's contribution
1. Experience of electronic prescribing in UK hospitals: a perspective from pharmacy staff.	Conceptualisation, methodology design, review of first draft, joint writing and editing of second draft. Overall supervision.
2. Frequency of Drug History taking by pharmacists at King's College Hospital.	Conceptualisation, methodology and analysis design, review and editing of draft and final project. Joint supervision.
3. Tracking the PGD development process.	Conceptualisation, joint design of methodology, joint data collection, initial and final draft of paper.
7. The use of missed doses as an indicator for assessing the quality of clinical pharmacy services: a comparison of two audits.	Joint conceptualisation, joint methodology design, joint direction of analysis and presentation of initial results. Joint supervision and direction. Wrote abstract.
11. Quality series	Conceptualisation of article series. Wrote, directed and supervised the writing of articles.
12. The selection, modification and reliability testing of a tool to rate the clinical significance of pharmacists' clinical contributions.	Study conceptualisation, methodology design, jointly directed initial analysis and drafting of report, undertook final analyses and presentation of initial results. Joint supervision. Wrote abstract.
16. A comparison of two methods for recording and analysing clinical pharmacy contributions.	Conceptualisation, supervised methodology design, joint supervision of data collection and data analysis, commented on and critically reviewed final report. Wrote abstract. Overall supervision.
28. Time to administration of first dose antibiotics and associated outcomes in respiratory sepsis.	Jointly advised on methodology, data collection and data analysis. Critical review and comment on draft and final abstracts.
33. Content validity of a tool for rating the significance of pharmacists' clinical contributions	Conceptualisation of study. Joint methodology design, joint direction of data collection and data analysis. Jointly contributed to presentation of results. Jointly drafted abstract. Overall direction and supervision.

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Subject: Re: Small favour please

Date: Monday, 21 May 2018 at 12:47:29 British Summer Time

From: Richard Bourne

To: Onatade, Raliat

Dear Raliat,

Of course. Best of luck with the Doctorate.
I agree that this is an accurate representation of Raliat Onatade's contribution to this work.
Best wishes,
Richard

Dr Richard S Bourne MSc PhD FFRPS FRPharmS

Consultant Pharmacist - Critical Care

Critical Care Department, Northern General Hospital, Herries Road, Sheffield S5 7AU

Tel: 0114 2269686/ 2713036 Pager: 07623602695 Fax: 0114 2269669

On 20 May 2018 at 13:45, Onatade, Raliat <Raliat.Onatade@bartshealth.nhs.uk> wrote:

Dear Richard

I hope you are well. I am finalising my submission for a Doctorate in Public Works, and I have included our paper, below, as one of the works in my submission. For each work where I am not sole author, I have to provide a statement of authorship. Would you mind reading the below, and seeing if you are happy with it. If not, please feel free to let me know and/or suggest changes. All I need is an email from you with a statement along the lines of " I agree that this is an accurate representation of Raliat Onatade's contribution to this work".

I hope this is OK, thanks for your help.

R Bourne, W Baqir, R Onatade. Pharmacist independent prescribing in secondary care:
opportunities and challenges.

RO's contribution - Wrote sections of manuscript. Commented on, and critically reviewed full manuscript

Raliat Onatade MSc., IPresc., MRPharmS
Acting Chief Pharmacist

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Mobile: 07703 469467
raliat.onatade@bartshealth.nhs.uk

Declarations of authorship for other work

Number and title of Public Work	Contribution
1. Experience of electronic prescribing in UK hospitals: a perspective from pharmacy staff.	See separate confirmation from R Mehta
2. Frequency of Drug History taking by pharmacists at King's College Hospital.	See separate confirmation from R Mehta
3. Tracking the PGD development process.	See separate confirmation from R Mehta
4. Assessing the proportion of patients discharged with TTA medicines issued directly from the ward.	Conceptualisation, methodology design, directed analysis, review and editing of draft and final project. Joint supervision.
5. Adherence to, and pharmacists' views of, antimicrobial switch and stop policies.	Conceptualisation, joint methodology design, joint direction of analysis and presentation of initial results. Wrote abstract. Joint supervision.
6. Quality and quantity of information on medicines given to patients discharged from hospital.	Conceptualisation, joint methodology design, joint direction of analysis and presentation of initial results. Joint supervision. Review and editing of draft and final abstract.
7. The use of missed doses as an indicator for assessing the quality of clinical pharmacy services: a comparison of two audits.	Joint conceptualisation, joint methodology design, joint direction of analysis and presentation of initial results. Joint supervision. Wrote abstract.
8. Pilot of a ward discharge medication labelling service.	Conceptualisation, joint methodology design, directed analysis and presentation of initial results. Supervision. Acquisition of equipment. Review and editing of draft and final abstract.
9. A study to assess the safety and time effectiveness of Pharmacy Technician triage on a gynaecology/surgical ward.	Conceptualisation, methodology and analysis design, directed analysis and presentation of initial results. Supervision. Wrote abstract.

Number and title of Public Work	Contribution
10. Identifying criteria for use in assessing the quality of pharmaceutical care: a modified Delphi study.	Conceptualisation, methodology design, directed initial analysis, undertook final analyses, Overall supervision. Wrote abstract.
11. Quality series a. Quality Indicators are important measurement tools for pharmacy. b. Auditing medication history-taking can help demonstrate improved pharmacy services. c. Improving the patients' discharge experience is an important pharmacy goal.	See separate confirmation from R Mehta
12. The selection, modification and reliability testing of a tool to rate the clinical significance of pharmacists' clinical contributions.	See separate confirmation from R Mehta
13. A review of a pharmacist discharge prescription writing service in a large teaching hospital.	Contributed to concept, methodology design, analysis. Reviewed and provided critical commentary on abstract. Joint supervision.
14. Developing a definition of a reportable prescribing error.	Contributed to methodology design. Reviewed and provided critical commentary on abstract. Joint supervision.
15. Assessing the quality of pharmaceutical care: a feasibility study.	Conceptualisation, joint methodology, documentation and analysis design, joint review and editing of draft and final abstract. Joint supervision.

Number and title of Public Work	Contribution
16. A comparison of two methods for recording and analysing clinical pharmacy contributions.	See separate confirmation from R Mehta
17. Quality of vancomycin prescribing and clinical outcomes in individual patients at a London Teaching Hospital.	Joint design of methodology and analysis. Overall supervision.
18. Adaptable "scope of practice" template for hospital pharmacist prescribers.	Conceptualisation of template presented in paper. Joint development of final template. Drafted initial and final manuscript.
19. Improving Antimicrobial Prescribing Using Rapid Serial Audits and Feedback.	Joint conceptualisation of study and methodology, directed data collection and initial analysis. Analysis of final results. Wrote abstract. Overall supervision of pharmacy elements.
20. Using the Consolidated Framework for Implementation Research to Evaluate a New Discharge Medication Prescription Pathway	Sole investigator and author
21. Potentially Inappropriate Prescribing in Patients on Admission and Discharge from an Older Peoples' Unit of an Acute UK Hospital.	Conceptualisation of study. Design of methodology. Supervised and participated in data collection. Majority of data analysis. Drafted major sections of initial manuscript and jointly edited final manuscript. Overall supervision.
22. Evaluation of the Ordering and Cancelling of Inpatient Prescriptions by Pharmacists using Electronic Prescribing.	Joint conceptualisation of study. Directed methodology and data analysis. Review and comment on draft and final abstracts. Overall supervision

Number and title of Public Work	Contribution
23. Baseline Assessment of the Confidence, Knowledge and Skills of Pharmacists when providing Pharmaceutical care to patients with Diabetes.	Joint conceptualisation, joint methodology design, joint direction of analysis and presentation of results. Review and comment on draft and final abstracts. Joint supervision.
24. Pharmacist independent prescribing in secondary care: opportunities and challenges.	See separate statement from R Bourne
25. The extent of, and documented reasons for, discrepancies in post-hospital medicines reconciliation.	Joint conceptualisation, joint methodology design, joint direction of analysis and presentation of results. Review and comment on draft and final abstracts. Joint supervision.
26. Posthospital medicines reconciliation: The impact of providing enhanced information regarding medication changes.	Conceptualisation, methodology design, direction of initial analyses. Conducted final analyses. Critical review and comment on draft and final abstracts. Overall supervision.
27. The use of Always Events in a survey of inpatients' experiences with their medication and the clinical pharmacy service. 'Always Events' as a method of surveying and improving in- patients' experiences with their medicines and pharmacy.	Conceptualisation, methodology design, joint supervision of data collection, directed analysis. Wrote abstract and report. Overall supervision.
28. Time to administration of first dose antibiotics and associated outcomes in	See separate confirmation from R Mehta

Number and title of Public Work	Contribution
respiratory sepsis.	
29. A quantitative comparison of ward based clinical pharmacy activities in 7 acute UK Hospitals.	Conceptualisation, joint methodology design, directed data collection on two sites, conducted majority of data analysis. Jointly contributed to presentation of results. Led and jointly drafted initial and final manuscript. Joint supervision.
30. The incidence and severity of errors in pharmacist-written discharge medication orders.	Conceptualisation of study. Design of methodology. Overall supervision and direction for data collection. Data analysis. Drafted initial and final manuscripts. Overall supervision.
31. Economic value of pharmacy-led medicines reconciliation at admission to hospital: An observational, UK-based study	Conceptualisation of study. Design of methodology. Overall supervision and direction for data collection. Data analysis. Drafted initial and final manuscripts. Overall supervision.
32. Improving the pharmaceutical care of patients on psychotropic medication admitted to an acute hospital – the impact of a proactive 'inreach' specialist psychiatric pharmacist service. Raliat Onatade and Oluwakemi Oduniyi.	Conceptualisation of study. Design of methodology. Directed and advised on data collection. Joint data analysis. Drafted initial and final abstract. Overall supervision.
33. Content validity of a tool for rating the significance of pharmacists' clinical contributions	See separate confirmation from R Mehta
34. Clinical pharmacy in UK hospitals: evidence for its outcomes and impact	Conceptualisation of paper. Drafted initial and final manuscript.

Number and title of Public Work	Contribution
35. Costs and consequences analysis of a clinical pharmacy service to a surgical ward	Joint conceptualisation of study. Joint methodology design, overall direction of data collection and data analysis. Jointly contributed to presentation of results. Drafted abstract. Overall supervision.