

**Pharmacogenetics and the Pharmacy Profession:
A Sociological Exploration**

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Abstract

Pharmacy, particularly in the community setting, has been subject to significant changes over the last three decades. Running concurrently to these changes has been the development of the field of pharmacogenetics, or 'personalised medicine', which is likely to have significant impacts on hospital and community pharmacy practice. Despite this, little sociological research has been undertaken to map the contemporary pharmacy landscape into which pharmacogenetics may be integrated and the effects that pharmacogenetics may have on pharmacy.

Through 38 semi-structured interviews with diverse practitioners, this thesis addresses these gaps in the academic literature by positing a novel sociological model through which contemporary pharmacy practice may be analysed and examining the potential impacts of pharmacogenetics on it.

It is argued that a dual approach to the management of medicines intersects both community and hospital pharmacy. Within this dual medicines management model, codified, organisational interests in medicines management are practised alongside a more negotiated approach which is enacted through what has been called here the 'pharmacy gaze'. The pharmacy gaze characterises the ways in which medicines and the patient bodies to which they are administered are co-constructed by pharmacists through discourses of risk and toxicity.

Pharmacogenetics, it is argued, represents a way in which the pharmacy gaze, and patient bodies within it, may be increasingly molecularised and risk and toxicity increasingly managed at the genetic level within pharmacy practice. Within this, a number of 'pharmacogenetic futures' involving pharmacy testing, patient counselling and practitioner education are presented although these are argued to be highly speculative and to present a number of macro- and micro-level challenges for policy makers and pharmacists. The thesis concludes by making a number of recommendations as to how some of these challenges may be addressed.

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Declaration of Originality

In accordance with the University regulations, I hereby declare that;

1. This thesis has been composed solely by myself
2. It is entirely my own work
3. It has not been submitted in part or whole for any other degree or personal qualification

Based on some of the work within this thesis, the following publications have been submitted for consideration:

Chapter Five

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Signed:

Date:

Chapter One: Introduction

1.1 Introduction

This thesis explores the potential impacts of pharmacogenetics, or ‘personalised’ or ‘stratified’ medicine on pharmacy practice in England. The pharmacy profession plays a key role in the healthcare system but has received relatively little attention within the social sciences. In recent years, pharmacy, particularly in the community setting has experienced significant changes with respect to the support and management of prescribed medicines and its increased clinical role with a move toward independent and supplementary prescribing by pharmacists themselves (Department of Health, 2005a; 2006).

Running concurrently to these changes in pharmacy has been the development of pharmacogenetics (hereafter PGx), which has been identified as one of the most clinically and commercially useful applications of the data and technologies arising from the Human Genome Project (hereafter HGP). PGx is concerned with genetically-determined drug response variability and is premised on the notion of providing the ‘right drug to the right patient at the right dose’ in order to minimise the risk of adverse drug reactions (hereafter ADRs) and maximise therapeutic benefits (Piquette-Miller and Grant, 2007: 311). In doing so, it is argued that PGx has the potential to reduce the time and financial burden of ADRs and improve patients’ experiences of their medications. This paradigm of practice has, then, been identified by the UK government as an important feature of future healthcare delivery in the National Health Service (hereafter NHS) (Department of Health, 2003a).

At present, PGx has made limited impact outside of secondary care where it is most commonly mobilised in medical specialisms with particularly severe and frequent ADRs, namely Oncology. Despite this, putative links between primary care drugs and genetically-determined drug reactions have been identified (Grice *et al.*, 2006) and the Department of Health’s (2003a) White Paper *Our Inheritance, Our Future* highlights the primary care drug Warfarin as an ‘early candidate’ for tailored dosage through PGx (also see Wadelius and Pirmohamed, 2006).

The uptake of PGx technology is likely to create greater demands on pharmacists and reorganise their everyday work around a more genetic approach to medicines and the patient body. However, commentary on the process and effects in integrating PGx into pharmacy is relatively limited. Work which does exist in this area is (generally) highly speculative, not based on empirical research and not analysed from a sociological perspective. As such Ryan *et al.* (2004: 51) suggest that since ‘pharmacy is likely to be at the forefront of the ‘new’ genetics...it would be beneficial to develop an understanding of how we [pharmacy] construct the new genetics and how they in turn construct us’. The paucity of work in this area of pharmacy and the new genetics reflects a wider neglect of the sector of pharmacy in the social sciences, despite pharmacists’, and the medications which they dispense, centrality to the UK healthcare system. This thesis goes some way to addressing this paucity of social science research in this area by examining the integration of PGx into community and hospital pharmacy and the ramifications it may have on everyday practice.

This introductory chapter contextualises the subsequent work within this thesis by giving an overview of the sociological relevance of pharmacy and PGx. Following this, it outlines details of the specific research questions which underpin the fieldwork and analysis which have been undertaken and provides a structural breakdown of each chapter.

1.2 Why Pharmacy?

When compared with other healthcare practices, pharmacy is relatively under-explored in the social sciences even though pharmacists play a key role in healthcare and are central to patients’ experiences of illness.

In 2008, at the time of the most recent pharmacy workforce census, there were 48,749 registered pharmacists in the UK (Seston and Hassell, 2009). Over 90% of these were concentrated in community (71%) and hospital (21.4%) practice settings and it is the integration of PGx in both of these settings which this thesis is concerned with. This is not, of course, to say that pharmacy practice in primary care

(where 7.2% of registered pharmacists practice), academia (where 2.8% of registered pharmacists work) and industry (where 4.1% of registered pharmacists are based) is not sociologically interesting but community and hospital settings are the most relevant here¹.

This diversity of sectors in which registered pharmacists practise attests to the heterogeneity of pharmacy as a profession, which also typifies practice *within* these sectors. As such, there is a significant difference between the modes of employment and organisation of everyday work for community pharmacists employed in large multiples or supermarkets and owner-occupier community pharmacists. In the hospital setting such diversity is also evident with practices across specialist areas varying in terms of the nature of medications, types of patients and involvement with clinical trials. It is, in part, this diversity which makes pharmacy sociologically interesting.

This thesis is concerned with the implementation of PGx into community and hospital pharmacy. It will be shown that there are significant differences between community and hospital practices and, as such, these two domains are treated as two divergent practice structures. Hence, although British community and hospital pharmacists share a common undergraduate education programme, the everyday work of community and hospital pharmacists in the UK is highly divergent. Bhakta (2010) specifically highlights working patterns, patients and medicines as three key areas where community and hospital pharmacy practice diverge. As such, whilst community pharmacists tend to work in relative isolation (Cooper *et al.*, 2009) and focus on chronic conditions and medications, those practising in hospital settings work in a more inter-disciplinary environment which is typified by acutely ill patients and their more complex medication regimes. Moreover, the technologies which are central to the everyday work of pharmacists are also different in community and hospital settings. Given this, the processes and discourses around PGx in these two settings are highly divergent and can only be understood through the prism of these differences.

¹ The total percentage of active pharmacists is greater than 100% as pharmacists may have positions in two different sectors or two different jobs in one sector.

Despite these differences, however, the thesis argues that medications, risk and toxicity, the patient body, medicines management and the ‘pharmacy gaze’ (a novel concept developed in Chapter Six) are objects and discourses which are central to *both* community and hospital pharmacy. As such, the analytical framework of the thesis does not treat community and hospital pharmacy as two *discrete* landscapes but instead assesses the particularities of each through these shared discourses. In doing so, the thesis avoids a simplistic binaried division between practice in community and hospital settings and, instead, highlights the similarities between different pharmacy practices whilst avoiding a homogenisation of the entirety of the pharmacy sector.

The modern structures of both community and hospital pharmacy can be traced to the late twentieth century when the Department of Health began to reorganise the structure of practice in these settings. In the community setting, uncertainty about the future of community pharmacy was born out of the ubiquity of pre-packaged medicines largely displacing the manufacturing and compounding role of pharmacists (Harding and Taylor, 1997). Given this, concerns were voiced that community pharmacists were ‘over trained for what they do and underutilised in what they know’ (Eaton and Webb, 1979: 73). These concerns were addressed through the UK National Pharmacy Association’s 1982 *Ask Your Pharmacist* campaign. This initiative encouraged the public to utilise their local pharmacy and was followed in the 1990s by the implementation of the ‘extended role’. This extended role was grounded in what has become widely known in pharmacy practice research as the *Nuffield Report* (1986) and later expounded in other policy publications (Department of Health and Royal Pharmaceutical Society of Great Britain, 1992; Royal Pharmaceutical Society of Great Britain, 1995). The implementation of the suggestions from these reports culminated with the community pharmacy contract being expanded to include increased clinical work through prescribed medicines management; chronic illness management; common ailments management and the promotion of healthy lifestyles (Harding and Taylor, 1997). This extended role, and the initiatives which existed around it, reconfigured community pharmacists as healthcare practitioners and relocated them outside of the

dispensary, thus discursively positioning them as a 'first port of call' for patients (Anderson, 2001: 23).

In the hospital setting, significant structural changes began to be implemented during the 1970s. Prior to this, during the period in between the establishment of the NHS in 1948 and the publication of the *Noel Hall Report* in 1970, hospital pharmacy was organised at the local level of the individual hospital. As such, there was a relative lack of standardisation in the profession and concerns around poor job prospects and low pay overshadowed attempts, such as agreeing national pay scales, to standardise and expand the sector (Anderson, 2001). In response to these concerns about hospital pharmacy, the Department of Health's *Noel Hall Report* (Hall, 1970) recommended that hospital pharmacy should be organised at the regional level under the management of an Area Pharmaceutical Officer with every 4,000-6,000 hospital beds being served by around eight pharmacists. Additionally, it was suggested that new salary structures for principle pharmacists, staff pharmacists and pharmacy technicians and on-going training reviews would make hospital pharmacy a more appealing career for young people (Levitt, 1976; Stone and Curtis, 2002). By the end of the 1970s, most hospital pharmacists were routinely practising ward pharmacy (i.e. dispensing medications and offering medications counselling on wards rather than in the dispensary), which later became established as clinical pharmacy and during the following decades the profession became increasingly characterised by clinical specialisation in fields such as Oncology or paediatrics (Anderson, 2001).

The role of pharmacists in both sectors has been further expanded since the turn of the twenty first century with the implementation of supplementary prescribing. In 2000, the Department of Health set out a number of principles in its *NHS Plan* in which pharmacist (and nurse) prescribing was identified as leading to improvements in patient care and safety, increased patient choice and access, more effective use of healthcare professionals' time and more flexible working structures throughout the NHS (Department of Health, 2000). Following this, in 2006 pharmacists were permitted to train as independent prescribers which gave them the ability to prescribe any medicine from within the British National Formulary independently of other healthcare professionals (Department of Health, 2006).

In 2008, the Department of Health published a seminal White Paper on the future of pharmacy services in the NHS. Within it, community pharmacists were discursively configured as central practitioners in medications safety and efficacy given their expertise in medicines and their associated ‘stuff’ (see Barber, 2005). Moreover, their proposed increased involvement in health promotion work such as smoking cessation support, Chlamydia screening and teenage pregnancy initiatives positioned community pharmacists as public health practitioners and redefined the community pharmacy space as an accessible ‘community-based healthy living centre’ (Department of Health, 2008: 118) rather than retail spaces in which pharmacists only engage with dispensing work.

More recently, in 2011 a new community pharmacy contract was implemented with community pharmacy’s Advanced Services being extended to include a new medicines service (NMS). This NMS involves community pharmacists counselling patients who have been prescribed a new medication for a long-term condition and has been proposed as a way in which community pharmacists can contribute to improved patient adherence and help patients to have a better experience of their medication regimes. In this way, community pharmacists’ role as advisors, rather than dispensers, is reinforced and supported by health policy.

This is further reinforced by two recent reports around shared-decision making in which pharmacists, in both community and hospital settings, are positioned as central practitioners in medicines decisions making. In the first report, a subgroup of the Royal College of Physicians (2011) argue that collaboration between pharmacists, nurses, prescribers and other healthcare professionals is essential in order to provide the most effective medicines decisions based on diverse and complementary expertise. In the second, Cribb *et al.* (2011) on behalf of the Royal Pharmaceutical Society, argue for the need for collaboration between healthcare professionals (including pharmacists) and patients in decision-making in order to reach the most effective medications regime for individual patients. In both of these reports limited inter-professional communication is identified as a barrier to such collaborative practice and shared decision-making. Nonetheless, the positioning of pharmacists as *the* pharmacology experts in both hospital and community settings

attests to the centrality of pharmacists in the healthcare system and patients' experiences of it.

Pharmacy is, then, highly policy relevant and, moreover, sociologically interesting from a number of perspectives especially in regard to its changing profile as a profession. Despite this, there has been comparatively little work in this area by social scientists. Research which has been undertaken has variously focused on patient-pharmacist communication (Nguyen, 2006; Pilnick, 1998; Pilnick, 2003) inter-professional communication (Cooper *et al.*, 2009; Hughes and McCann, 2003); professional identity and status (Birenbaum, 1982; Denzin and Mettlin, 1968; Edmunds and Calnan, 2001); boundary encroachment (Eaton and Webb, 1979; Messler, 1991) and new technologies (Barrett *et al.*, 2011; Petrakaki *et al.*, 2012). Within this work we see a focus on the status of pharmacy, particularly in the community setting, as a 'profession' as opposed to an 'occupation'. Sociological analyses of professional autonomy and the 'role strain' (Harding and Taylor, 1997) generated by community pharmacists' dual role as retailers and healthcare practitioners are especially prominent. As an example, the location of community pharmacy work within retail settings is understood by Harding and Taylor (2000) and Bush *et al.* (2009) in line with Ritzer's (2000) *McDonaldization* framework as a corporatisation of pharmacy leading to a decline in pharmacists' autonomy and a universality of 'McPharmacists'. Moreover, Petrakaki *et al.*'s (2012) study of electronic prescribing systems (EPS) in community pharmacy and Barrett *et al.*'s (2011) study of dispensing robots in hospital pharmacy address the ways in which the implementation of innovations in pharmacy affect this autonomy and professional status. As an example, Petrakaki *et al.* (2012) argue that EPS acts to both de- and re-professionalise community pharmacy through automation simultaneously rendering practice more visible and so open to governmental control, yet providing increased opportunities for engagement in clinical work.

Social science work in the area of pharmacy practice has tended to focus disproportionately on community pharmacy and tends to neglect practice within hospital settings. In doing so, these sociological analyses have tended to treat community and hospital pharmacy as two discrete professional worlds with the former (owing to its, arguably, dubious 'professional' status) being represented as

being of more sociological interest. Given this, very little work has been done to map the entirety of the contemporary pharmacy landscape.

As an attempt to remedy this, this thesis presents a sociological overview of both community and hospital pharmacy practices through an analysis of the discourses and practices which intersect both of these settings. As such, although the differences between the everyday work of practitioners in these sectors are drawn out, the community and hospital are not treated as *discrete* professional worlds. In this way, the thesis offers something of a novel contribution to the sociological study of pharmacy practice. Moreover, in centralising hospital as well as community pharmacy, the thesis helps to address the paucity of social science research in the area of hospital pharmacy practice.

1.3 Why Pharmacogenetics?

Running concurrently to the recent changes in community and hospital pharmacy has been the development of the scientific field of PGx, or ‘personalised’ or ‘stratified’ medicine. This approach to drug development and clinical practice is concerned with genetically-determined drug response variability and is premised on the notion of providing the ‘right drug to the right patient at the right dose’ in order to minimise the risk of adverse drug reactions (hereafter ADRs) and maximise the therapeutic benefits (Piquette-Miller and Grant, 2007: 311). In the 1990s, PGx was regarded as one of the key applications of the genomics data and sequencing technologies emerging from the HGP and was central to global population stratification projects such as the SNP (pronounced ‘snip’) consortium and the International HapMap project (see Hedgecoe, 2004). More recently, the UK Technology Strategy Board announced stratified medicine as a key five year priority area and, in 2011, launched the Stratified Medicine Innovation Platform with the objective to invest £200 million in stratified medicine projects by 2016.

PGx is posited as a way in which drug development processes and prescribing practices could be reorganised around a more stratified approach. In this way, it is argued that the traditional blockbuster drug production model and the trial-

and-error approach to prescribing may be displaced by a more targeted model (Pirmohamed and Lewis, 2004).

In terms of drug development, implementing PGx into clinical trials is understood as a way in which potential drug candidates could be targeted to genomic sub-populations who are most likely to respond well to therapies rather than the population as a whole where the chances for rejection by the UK National Institute for Clinical Excellence (NICE) or the US Food and Drug Administration (FDA) are increased due to ADRs. This stratification of clinical trial participants by likely drug response means that genomic sub-populations with a predisposition to good or poor reactions can be identified. By doing so, trials can exclude those with a propensity for ADRs, which would improve trial bias, improve the safety profile of the drug and, potentially, 'rescue' drugs which have been abandoned at the later stages of a clinical trial due to safety concerns (Martin *et al.*, 2006; Shah, 2006; Webster *et al.*, 2004)

This stratified approach to drug development is imagined to reduce the cost of research and development (hereafter R&D) and the time spent conducting clinical trials. As an example, writing some years ago Tollman *et al.* (2001) argued that the cost of drug development could be reduced by \$140 million and one year could be taken off clinical trial time. This, he argued, is because the binary scenario which traditionally typifies the later stages of clinical trials (i.e. drugs are either shown to be effective, pushed through clinical trials and marketed or shown to be minimally effective and abandoned as unmarketable) is displaced by a more flexible model where effectiveness and ineffectiveness can co-exist through stratified populations. In this way, ineffectiveness does not necessitate abandoning a drug but rather marketing it to a restricted sub-population. More recently, Amir-Aslani and Mangematin (2010) draw on trials of the Diabetes drug Sitagliptin, in which biomarkers for response variation were identified and employed early on, to argue that stratification in clinical trials could reduce the time taken to phase III trials from 3.5 to 2.1 years.

The most commonly cited use of PGx in clinical practice is pre-prescription testing. The following vignette by Pfof *et al.* (2000: 334) demonstrates this use of PGx well;

“In your doctor’s office, sometime in the future, you spit a sample of mouthwash into a vial. The following day, the doctor advises you not to take the drug that he had considered prescribing to treat your condition, because a genetic test for certain single nucleotide polymorphisms (SNPs) predicts that you could suffer a severe adverse reaction to it. By contrast, the same test indicates that you are expected to show an excellent response to a different medication with little chance of side effects, and you are given the appropriate prescription. This is the promise of pharmacogenetics – the optimization of drug therapy”

Martin *et al.* (2006) also identify this use of pre-prescription testing as a means to identify patients at risk of ADRs and those with an increased likelihood to respond well to medications. Through this use of PGx testing, it is argued that medications can be better targeted with the effect of minimising the risk of ADRs and maximising the therapeutic benefits of medications. This not only has the potential to improve patients’ experiences of their medication but is also widely argued to be a way of reducing the financial burden of ADRs (Department of Health, 2003) which are estimated to cost the NHS around £2 billion annually (Compass, 2008) and be responsible for 6.5% of all UK hospital admissions (Pirmohamed *et al.*, 2004).

Pre-prescription testing, then, is argued to potentially offer a cost-effective way to identify the likelihood, and reduce the occurrence, of ADRs and non-responsiveness in patients. Arguably the most common use of PGx pre-prescription testing is for the breast cancer therapy Herceptin where testing tumours’ protein expression identifies the 25-35% of patients whose tumours over-express the human epidermal growth factor receptor 2 (HER2) and will benefit from this medication. Given the ubiquitous use of HER2 testing in breast Oncology, Hedgecoe (2004: 99)

has described Herceptin as ‘the first example of a pharmacogenetic drug in regular clinical use’.

Debates have appeared elsewhere about the cost-effectiveness of pre-prescription testing for numerous medications across a diversity of disease areas (see Chalkidou and Rawlins, 2011; Veenstra *et al.*, 2000). Central to these debates is the cost of providing testing compared with the cost of adopting a ‘trial and error’ model or testing efficacy through monitoring. With the decreasing cost and increasing speed of genotyping technologies, the parameters of these economic analyses are, however, subject to change. In a recent paper, Bowler *et al.* (2011) detail a dynamic chemistry approach to SNP testing where, they argue, identification of allelic variation could be undertaken at a significant time and cost advantage due to the circumvention of the need for complex assays and optimisation work. Hence, the potential for pre-prescription PGx testing to be undertaken for a relatively low cost within primary care clinical encounters is beginning to emerge as a realistic proposition.

PGx, then, is a highly significant area of biomedicine and, as such, has been subject to examination by social scientists. Much of these analyses sit within a wider examination of the social impacts of genetics where sociologists have explored the implications of genetic testing for family (Lehtinen and Kääriäinen, 2005), doctor-patient relationships (Cox and McKellin, 1999) and society as a whole (Tutton, 2009). With respect to PGx specifically, Hedgecoe (2004) presents a comprehensive overview of the social and political implications of, and challenges posed by, PGx in drug discovery and clinical practice. Writing later, he also examined the differential degrees of uptake of PGx across medications and disease areas (Hedgecoe, 2008a). Within this, he argues that the limited integration in some medical specialisms should not be considered as ‘resistance’ but should, instead, be examined more sociologically. He posits, then, a framework of ‘clinical usefulness’ where he argues that PGx technologies are defined as useful or otherwise based on a number of social elements of practice such as clinician’s knowledge; differing interests between clinicians and researchers; clinical contexts; economics; and clinical cultures.

The uptake and integration of PGx has also been dealt with by other social scientists (see Hopkins *et al.*, 2006; Martin *et al.*, 2006; Webster *et al.*, 2004). As an example, as part of a Wellcome Trust grant, Webster *et al.* (2004) identified five ‘innovation options’ for the implementation of PGx into routine drug development and clinical practice. These were (i) using PGx to discover better drugs; (ii) using PGx to improve the safety of new drugs in development; (iii) using PGx to improve the efficacy of new drugs in development; (iv) using PGx to improve the safety of licensed drugs; and (v) using PGx to improve the efficacy of licensed drugs. In a later publication and following a number of other sociological projects on PGx, Martin *et al.* (2006) also identified disease stratification as a sixth potential area in which PGx may be useful. In addition to providing a sociological framework within which to understand PGx, these publications also demonstrate the centrality of sociological perspectives to the scientific work being undertaken in this area. Moreover, writing some years ago Allen Roses (2000: 857) of GlaxoSmithKline highlighted the ‘ongoing ethical debate concerning potential genetic applications and the impact on individuals and families’ as being central to PGx. More recently, Ozdemir (2011: 12) notes that ‘it is not just scientific and technical factors that are important to the uptake of innovative technologies’. Instead, he notes that the social implications of PGx are as central to the integrative landscape as the technology itself. PGx, then, is a highly relevant area for Sociology.

1.4 Why PGx in Pharmacy?

Given the objective of PGx to better target medicines to improve safety and efficacy, the ‘promises’ (Hedgecoe and Martin, 2003) of PGx are well aligned with the discourses of medicines management which are central to pharmacy practice. Hence, both the paradigm of PGx and the practices (community and hospital) of pharmacy are underpinned by the same principles of safety, efficacy and personalisation. Given this, it has been argued elsewhere that PGx represents the ‘next challenge’ for pharmacy practice (Clemerson *et al.*, 2006) and that pharmacists will be at ‘the forefront’ of PGx delivery (Ryan *et al.*, 2004: 51) and will have an ‘essential role’ to play in future genetically-informed prescribing practices (Akhtar, 2002). The integration of PGx into pharmacy settings is likely to reorganise the everyday work of pharmacists around more genetically-defined patient bodies and medications.

Within this, the discourses and practices of risk which are central to medicines management are likely to take on a more molecular approach as the body becomes increasingly defined in such terms.

Despite this, and the sociological importance of pharmacy, limited work has been done looking at the particularities of integrating PGx into pharmacy practice. What work has been done in this area is highly speculative, based on limited empirical evidence and has tended to come from disciplines outside of the social sciences. Given the constantly decreasing cost of genotyping and the shifts in practice which PGx will potentially entail, the present project is timely and relevant both sociologically and in terms of pharmacy and health policy.

1.5 Thesis Overview

Given this lack of empirical sociological work in the area of PGx and pharmacy, this thesis ascertains the perspectives of a variety of practitioners to understand the potential impacts of PGx on pharmacy in England. As such, it asks the following key research question;

- What is the potential impact of pharmacogenetics on the everyday work of pharmacists practising in community and hospital settings?

In addressing this question, three key sub-questions are asked and addressed in the empirical chapters;

- How might the contemporary pharmacy practice landscape be sociologically characterised? (Chapter Six)
- How are new technologies integrated into pharmacy in community and hospital settings and what effects do they have? (Chapter Seven)
- What are the specificities of integrating PGx technologies into community and hospital pharmacy? (Chapter Eight)

The thesis starts with a literature review which expands the ideas and approaches highlighted above in asking *Why Pharmacy?* This chapter (Chapter Two) provides a narrative of the historical development of pharmacy and the sociological debates that this history has generated. In doing this, this literature review chapter traces a shift in sociological approaches to pharmacy from a relatively simplistic ‘Freidsonian’ trait approach to a more dynamic one based around the cultural role of pharmacists.

Following on from this, Chapter Three expounds the ideas above in asking *Why Pharmacogenetics?* In doing so, this chapter describes the technical elements of PGx (i.e. why drug response variations occur), examines its historical development and outlines the sociological work which has been carried out in this area to date. In doing so, this chapter draws together scientific and social scientific literature to provide an overview of the contemporary PGx landscape.

Chapter Four presents an overview of the analytical frameworks which are used throughout the thesis to make sense of the empirical data. Within this, two broad frameworks are discussed as central to the later empirical chapters; Foucault’s (1994) ‘clinical gaze’ as a way of conceptualising professional approaches to the body and May and Finch’s (2009) normalisation process theory (herein NPT) as a tool for understanding the micro-level interactional work undertaken to integrate new innovations into routine practice.

Chapter Five gives details of the methods used to gather the data. This chapter outlines the different practitioner groups which were interviewed, why these groups were targeted for inclusion and the particular challenges generated by conducting qualitative work with these practitioner groups. This chapter also details, and reflects on, the NHS ethics and governance process which was required for the interviews with NHS personnel.

The remainder of the thesis comprises three analytical chapters, each dealing with one of the sub-questions highlighted above. Chapter Six, then, provides a sociological overview of the contemporary landscape of pharmacy in England. It draws on Serra’s (2010) notion of a ‘medical technocracy’ and Rabeharisoa and Bourret’s (Bourret, 2005; Rabeharisoa and Bourret, 2009) notion of a ‘bioclinical

collective' to sociologically characterise the nature of practice and inter-professional relationships in the community and hospital setting. This chapter also offers a model of medicines management which is argued to be characterised by a dual approach to risk and toxicity. Within this, organisational interests in managing medicines are contrasted with medicines management practises which occur in everyday pharmacy work. Here, the novel concept of the 'pharmacy gaze' is developed to characterise the specific approach pharmacy takes to the patient body as a potential site of pharmacological risk.

Chapter Seven uses these frameworks to offer an analysis of technology in pharmacy. This chapter deals with a variety of new technologies in pharmacy (for example, monoclonal antibody drug technologies; robots and electronic prescribing systems) and examines the ways in which these new technologies have the capacity to reorganise everyday work and professional boundaries in pharmacy settings. This chapter, then, demonstrates the ways in which May and Finch's (2009) NPT and the dual medicines management model outlined in Chapter Six can be used to analyse the integration (or lack of integration) of new technological paradigms. This chapter concludes with a figure examining the themes which are important to analysing the integration of technology into pharmacy: the sector into which it is integrated; formalised, bureaucratised medicines management policies; and everyday working practices. This figure is re-visited in Chapter Nine where PGx technologies are positioned within this analytical table.

These frameworks of analysis provided in Chapters Six and Seven are then employed in Chapter Eight where the particularities of integrating PGx into different pharmacy settings are examined. Here, community and hospital pharmacy are treated as two distinct landscapes given the different ways in which PGx is likely to be integrated and the divergent effects that this might have on practice in these two settings. In the hospital setting, the specialist area of Oncology is highlighted as a case study to demonstrate the ways in which PGx may become 'normalised' across disease areas. In the community setting, it is demonstrated that PGx has made limited impact due to the comparatively low severity of ADRs in this setting. Given this, and the lack of standardisation in community practice (as opposed to hospital

practice) a number of ‘macro’ and ‘micro’ challenges of integrating PGx into primary care are identified.

In Chapter Nine, the analytical themes running through the thesis (the medical technocracy and bioclinical collective; the dual medicines management process; and the pharmacy gaze) are drawn together in a discussion of the implications of the thesis for pharmacists working in different sectors. In bringing the thesis together, the figure developed at the end of Chapter Seven is revisited in light of Chapter Eight’s analysis of PGx in pharmacy. As such, the particular issues in the integration of PGx into pharmacy are related to the themes (sector of practice; formalised medicines management policies and everyday practice) which intersect the integration of other technological forms. The thesis concludes by outlining its key implications for future research in the area of PGx and pharmacy and offering a number of recommendations for integrating PGx into pharmacy.

Chapter Two: Pharmacy: A Sociological Approach

2.1 Introduction

Chapter One noted that although pharmacy practice potentially offers a rich arena for sociological analysis, comparatively little work has been carried out in this area. The following chapter presents a review of the sociological literature as context for the subsequent conceptual and empirical analysis. The literature presented here has been identified through two methods. Firstly, ISI Web of Knowledge was used to identify sources where ‘pharmacy’, ‘pharmacy practice’ or ‘sociology of pharmacy’ were keywords or contained within the title of the work. These sources specifically discussing UK pharmacy practice (or those from other contexts, which were deemed highly relevant) were retained and those which dealt with the pharmacy practice landscape in other countries were discarded. These sources were then sorted by date in order to capture the most recent sociological writings in the area of pharmacy practice. Sources dating from before 2000 were only retained if they were deemed to be salient to the analysis being undertaken here.

The second method used to identify literature was a ‘snowballing technique’ (Garrard, 2007). This technique involves using a publication’s reference lists as a resource for identifying other relevant sources, even where the publication used was not. Although academic and medical protocols often express a preference for the first method of literature identification described here, Greenhalgh and Peacock (2005) found that the latter snowballing method is often more efficient at identifying useful and highly relevant references.

Based on these most relevant sources, this chapter is structured around a historical narrative of British pharmacy practice. Within this, sociological analyses are woven into understandings of the various periods of, and changes to, pharmacy practice. The chapter begins with the professional association of pharmacists with grocers through the guild system in the twelfth and thirteenth centuries and follows the development of pharmacy through to the contemporary era of ‘medicines optimisation’. Throughout this chapter there is a substantial focus on the professional

identity and status of pharmacy as this focus characterises much of the sociological literature in this area.

2.2 Pharmacy's History

Prior to the seventeenth century, the ancient principles of Avicenna and Galen dominated the Western approach to medicine and medication². From the European renaissance period onwards, knowledge and technological advances, such as Vesalius' contribution to the understanding of anatomy in the early sixteenth century and the development of the microscope, meant that older medical models, largely based on humourism, lost their influence. Accompanying this was the formal organisation of medicine along the lines of specialist areas of expertise where boundaries of knowledge, and subsequently practice, were drawn (Freidson, 1970). The case of apothecaries and pharmacists is a good example of this.

2.2.1 Apothecaries, Pharmacists and General Practitioners: Drawing Expert Boundaries

The expertise and practice of apothecaries were originally associated with grocers through the guild system that emerged in the twelfth and thirteenth centuries as their everyday work was not understood to be wholly different (see Matthews, 1962: 29-40 for an overview).

As renaissance thinking saw the human body as increasingly complex, the specialisation of apothecaries was formally acknowledged in 1617 by the separation of apothecaries from the grocers' guild by James I (Porter, 1999). The apothecaries' charter stipulated that a seven year apprenticeship followed by an examination was necessary for apothecaries to keep a shop or make or sell any medicines within seven miles of London. Concurrently, by royal decree, only physicians were permitted to provide medical advice (Eaton and Webb, 1979). This formalised separation of the work of apothecaries from grocers, and physicians from other medical practitioners provided physicians with something of a monopoly over advice-giving and drew fairly rigid boundaries around their expertise and practice.

² So great was their influence on pre-enlightenment medicine that they are featured on the coat of arms of the Royal Pharmaceutical Society of Great Britain (RPSGB) (Anderson, 2001).

This medieval guild system, however, was highly localised and proved to be less than robust in light of increasing town populations during the industrial revolution (Parry and Parry, 1976). As such, given the increase in town populations, the development of an urban middle class and increased international migration, the localism on which the rigid boundaries and structures of the guild system depended were blurred. Hence, whilst many physicians crossed the boundaries of their practice and employed assistants to make medicines, similarly apothecaries began offering and charging for medical advice as the workload of physicians increased and an increasingly impoverished population were unable to pay for their expertise (Eaton and Webb, 1979).

In blurring the practice boundaries in this way, nineteenth century apothecaries began to take on more general medical practice and provided the basis of what would later become GP work. As they expanded their practice jurisdictions in this way, their monopoly over making and dispensing medicines began to be challenged by druggists and chemists, who became skilled in using apothecary's technologies and adopted the role of medicines makers and dispensers (Parry and Parry, 1976). In the UK, these druggists became commonly referred to as 'pharmacists' and, in 1815, gained formal recognition and protection for their specialism with the passing of the Apothecaries Act. This Act stated that the work of pharmacists should continue as it had done prior to the passing of the Act with nothing affecting 'the trade of business of a Chemist and Druggist, in the buying, preparing, compounding, dispensing, and vending of Drugs, Medicine and Medicinable Compounds, wholesale or retail' (Matthews, 1962: 115). This Act represents a formal acknowledgement of pharmacists as experts in medicines and their associated 'stuff', which provides the basis for what Barber (2005) calls the 'pharmaceutical gaze'. The Apothecaries Act was followed by the Medical Act of 1858 which separated 'medical professionals' from other medical or healthcare practitioners by establishing a register of all surgeons and GPs (those formerly known as apothecaries). In doing so, these practitioners became united as one 'medical profession' around which professional boundaries were drawn (Eaton and Webb, 1979). Importantly here, pharmacists were not included within these boundaries of the new 'medical profession'.

2.2.2 The Royal Pharmaceutical Society

The encroachment by druggists and chemists on to the apothecary's role of making and dispensing medicines led to the mobilisation of the former to protect their livelihoods against the re-establishment of the latter's making and dispensing privileges. This mobilisation and organisation led to the development of a committee, which was later to become the Royal Pharmaceutical Society of Great Britain (hereafter RPSGB), now the Royal Pharmaceutical Society (herein RPS). This professional society was formed primarily to oppose an 1841 Bill which sought to enforce strict examination and licensing procedures on pharmacists and prevent them offering any medical advice or services (Matthews, 1962). The formation of this committee was, then, centred on a proposed erosion of pharmacists' practice boundaries.

Following the defeat of the Bill, the need for a highly organised group to protect pharmacists and enhance the profession's prestige (to protect it from any future boundary threats) was recognised. At a well-documented meeting on April 15th 1841, in the Crown and Anchor Tavern in The Strand, a motion put forward by Jacob Bell, the son of a London pharmacist, for the formation of such a society was passed and the Pharmaceutical Society of Great Britain (PSGB) was formed (Royal Pharmaceutical Society of Great Britain, no date). The Pharmacy and Poisons Act (1933) subsequently made clear the requirement for all pharmacists and their premises to be registered with the Society (Taylor *et al.*, 2003). Despite being granted its royal charter in 1843, the Pharmaceutical Society did not become the *Royal* Pharmaceutical Society until 1988 when Queen Elizabeth II agreed that the name ought to incorporate the word 'Royal' (*ibid.*). Anderson (2001) notes that following the establishment of the PSGB the status of pharmacy increased and, as such, he argues the practice began to become professionalised. According to Anderson, this increase in status was also linked to a number of other events such as the development of a more formal curriculum and specific schools for pharmacists in London in 1842 and in forty five other towns at the turn of the twentieth century; the legal sanctioning of pharmacy multiples following a Court of Appeal ruling in 1880;

and the increase in the products and services that pharmacists offered to include toiletries and cosmetics and dental services³.

This increase in the professional status of pharmacists can be understood as being related to the specific time in medical history in which it occurred. In the century following the formation of the PSGB the fields of pharmacology and analytical chemistry advanced significantly. These advances led to the discoveries of new and pervasive drug technologies, most notably several antibiotics which were heavily documented in scientific journals between 1877 and 1939 including penicillin in 1929 (Drews, 2000).

These new drugs and the large pharmaceutical companies which were formed to manufacture them shifted the role and identity of pharmacists. As such, pharmacists' everyday work moved away from compounding medicines to dispensing and offering advice on increasingly technical and standardised drug products which were becoming more available to the whole population. What this indicates, then, is that the early history of pharmacy can be understood sociologically by placing technological developments and innovation at the centre of the story.

2.2.3. The Role of Technology in Drawing Expert Boundaries

Within such a sociological analysis John Pickstone's (2000) *Ways of Knowing* framework provides a useful analytical tool through which to examine the shifting role, identity and professional boundaries of pharmacy. This framework links science, medicine and technology (SMT) as mutually dependent on and co-constitutive of the five 'ways of knowing' which have characterised medical practice from the seventeenth century onwards. In other words, Pickstone argues that the ways in which SMT understands and explains the world are central frameworks in shaping the ways in which medicine is practised. He posits the following five ways of knowing;

4. Hermeneutics or 'world readings' refers to the textual rhetoric of medicine which limited physical intervention in favour of an interpretive model of illness. Within

³ Many pharmacists offered dental services in their pharmacies and when the first dental register was taken in 1879, two thirds of the people on the list noted that they also practised pharmacy.

this, nature and its symbolism was prioritised as a way of understanding illness. This way of knowing was linked with religious explanations of illness where disease was understood as a punishment for sin.

5. During the late sixteenth and seventeenth centuries, this hermeneutic approach was displaced by enlightenment rationality when the natural world and the illnesses within it were conceptualised as explainable and manageable rather than supernatural. Pickstone calls this second way of knowing ‘natural history’.
6. Thirdly, ‘analysis’ as a way of knowing refers to the increasing rationalisation of medicine and the endeavours to discover and explain the composition of both the human body and the compounds which are used to treat it. Perhaps the best example of such an analytical endeavour is William Harvey’s discovery of the human circulatory system which replaced previous quasi-Galen theories of human blood (see Schultz, 2002).
7. This analysis led to the fourth way of knowing which Pickstone terms ‘experimentalism’ which involves the trial and error of various forms of innovative devices which formed the basis for medical diagnosis and treatment.
8. The final way of knowing, for Pickstone, is ‘technoscience’ which refers to the contemporary structural form of SMT which is based on laboratory and industrial medicine and utilises a variety of innovative technologies, such as genomics, to understand the body, illness and cures. Links can be seen here with Clarke *et al.*’s (2003) biomedicalisation thesis where the body, and the medicines administered to it, increasingly mobilise innovation through technoscientific technologies and practices.

His argument contends there is a connection between these ways of knowing, the medical technologies of the time and the extent to which medicine is understood as a ‘science’, which then impacts upon the professional identity of the actors involved. In a later work, he uses the example of orthopaedics to exemplify his model (Pickstone, 2006).

Orthopaedics, as a specialist branch of medicine, he argues, was reconfigured from an individualised craft which was disseminated through familial ties, to a mainstream medical practice rooted in a technoscience way of knowing. Within this process of change, the nature of the body and prosthesis were analysed (i.e. in understanding the ways in which joints move) and experimented with (i.e. in using different materials to optimise prosthesis). These ways of knowing the body and prosthesis were particularly prominent in the early twentieth century when orthopaedics became central to wider social shifts such as rapid urbanisation (with many workers requiring treatment for broken bones sustained during construction work); the dominance of manufacturing (with many workers requiring accident services for injuries sustained at work); the occurrence of two world wars (with the ‘reconstruction’ of soldiers following injury being a key priority); and the increasing availability of motor cars (with an increase in the number of accidents involving them).

The changes made in the ways of knowing in orthopaedics influenced a change in the status of the field as a ‘science’ and the professional status of the actors working within it. Hence in the early history of orthopaedics, the practice was carried out by individuals who were seen as craftsmen rather than professional medical practitioners and whose specialist status was rooted in the local community. After early periods of analysis and experimentalism, orthopaedic practitioners were configured as specialist medical professionals and their practice relocated to the hospital setting. As such, the professional status of orthopaedic specialists became entwined with their engagement with advanced technologies developed by industrial companies.

Pickstone’s model can also be employed to understand the early history of pharmacy. Within this, pharmacists’ professional association with grocers through the medieval guild system places pharmacy (and grocery) in an unspecialised hermeneutics way of knowing. During the sixteenth century, pharmacy adopted more of an analytical way of knowing as the natural history of plants became widely documented (for example, William Turner’s *Herbal*, published in three volumes between 1551 and 1568 (see Hoeniger and Hoeniger, 1973)). Following this, the medicinal uses of the plants described in these publications began to be explored (for

example, in William Salmon's *The Practice of Curing*, published in 1681) and pharmacy took on a more experimental way of knowing. Within this, the professional status and specialisation of pharmacy was formalised through the granting of the apothecaries guild in 1617. More recently, pharmacy could be understood to have entered into Pickstone's technoscience way of knowing where practice is based on the use of complex, technical devices and medications. Within contemporary pharmacy practice (particularly in community practice), however, elements of an experimentalist way of knowing can still clearly be seen with the predominance of trial-and-error prescribing and dispensing models. This is discussed in more detail in Chapter Eight. For now this chapter turns to an examination of the effects of this early history on the professional identity of pharmacy and the ways in which this has been interpreted in sociological literature.

2.3 The Pharmacy Profession?

Anderson (2001) argues that following the formation of the PSGB, pharmacy became increasingly professionalised. Even so, although undoubtedly the formation of a professional body and the protection from boundary encroachment that it offered influenced the development of a more professional identity for pharmacy, the extent to which pharmacy can legitimately be regarded as a 'profession' is subject to much debate within the sociological literature in this area. Much of this debate centres on Freidsonian 'trait' analyses of pharmacy practice.

Briefly, Freidson's (1970) classical sociology of professions work argues that a profession is a 'special kind of occupation' associated with certain characteristics or traits which make it different from, and superior to, less professionalised occupations. Taylor *et al.* (2003) note that being a profession, rather than an occupation, is not related to the intrinsic superiority of the former's knowledge and is instead a process of convincing what Freidson (1970: 72) calls an 'elite segment of society' that the sector's work is of special value. In STS scholarship, McLaughlin and Webster (1998) refer to this process as the 'professional project' whereby a body of expert knowledge and the professional identity develop concurrently, affecting each other and carving out the jurisdiction over which that given profession will preside. Wright (1979) exemplifies the importance of the professional project to the

successful understanding of an occupational sector as a profession. Comparing the fields of astrology and medicine (both of which espoused unproven theories about illness prior to the renaissance period), he argues that the success of medicine over astrology was due to the superior social positioning of medicine's clients who were able to influence lay public and governmental opinions of, and discourses surrounding, medicine (also see Freidson, 1970: 72-73).

In the case of pharmacy, Freidsonian trait approaches are dominant in understanding the sectors' professional identity. As an example, Taylor *et al.* (2003) adopt such a Freidsonian trait approach in understanding pharmacy as a profession based on a number of features of practice. I discuss this argument here, offering alternative views along the way.

Firstly, according to Freidson, a profession occupies a dominant position in an occupational division of labour and has an autonomous monopoly over the area in which it specialises. Taylor *et al.* (2003) argue that this trait is evidenced in the pharmacy profession as only registered pharmacists are able to join the RPS and only registered pharmacists are permitted to sell Pharmacy Only Medicines. In contrast, writing some years ago, Denzin and Mettlin's (1968) classic paper on pharmacy argues that pharmacists do not have autonomy over the area and products around which their practice is centred as the act of dispensing medications is most commonly done under the orders of a doctor. As such, control over what medications to provide lies with the doctor and not the pharmacist. This is also echoed by the assertion that pharmacists still 'take their lead from physicians' (Harding and Taylor, 2002: 443). Moreover, the following quote from a community pharmacist in Hughes and McCann's (2003: 604) study of inter-professional communication demonstrates the hierarchical organisation of community pharmacy work;

The GP sits with his prescription pad and until he does something with it, we sit with our degrees, impotent, until we get the piece of paper. He is the instigator, the prescriber is the instigator of the whole thing.

Cooper *et al.* (2009) identify this relatively low status of community pharmacy as being manifested in challenges in everyday practice. As such, the community pharmacists that they interviewed highlighted this subordination as contributing to ethically challenging situations in everyday practice where their professional status meant that they felt unable to challenge GPs' prescription decisions despite their being aware of potential toxicity. Additionally, Cooper *et al.* (2009) argue that the structure of primary care fosters a professional identity for community pharmacists as 'islands' and as 'doctors' tools'. Inasmuch, the relative isolation of community pharmacy practice and its mediation through GP's prescribing work are argued to be central to the subordinate professional identity of community pharmacy.

In addition, the increasing number of pharmacists working in large multiple organisations or supermarkets⁴ is understood to limit the extent of community pharmacy's autonomy given the routinisation of work in these settings (McDonald *et al.*, 2010). In these large multiple and supermarket pharmacy environments it is argued that interactions between patients and pharmacists become based around 'asking structured, formulaic questions' rather than those devised autonomously by pharmacists using their pharmacological expertise (Harding and Taylor, 1997: 556). The result of this is the corporatisation of community pharmacy and the emergence a 'breed of *McPharmacists*'⁵ undertaking routinised work within large corporate organisations (Bush *et al.*, 2009: 307 (emphasis in original); Harding and Taylor, 2000).

It has also been argued that pharmacy's autonomy over medications has been further eroded by the increasing deregulation of medicines which has opened up knowledge and control of medications to the lay public (Hibbert *et al.*, 2002). This erosion of pharmacy's monopoly over medications can be understood as part of a wider process of declining medical hegemony where expert medical knowledge administered in clinical settings is being eschewed in favour of information from the internet being consolidated by 'expert patients' (Shaw and Baker, 2004). As an example of this erosion of medical hegemony, Fox *et al.* (2005) examined the way in

⁴ In a 2008 pharmacy workforce census, Sesston and Hassell (2009) found that 54% of community pharmacists were employed in large multiples whilst 12.2% worked in supermarkets.

which people ‘suffering’⁵ from anorexia undermine the monopoly of both GPs and pharmacists by ordering drugs intended to treat obesity from the internet without any clinical intervention. Such questioning and foregoing of medical expertise is most commonly located within sociological analyses of late-modernity.

Secondly, Taylor *et al.* (2003) point to the requirement for pharmacists to complete a four year undergraduate degree, one year’s pre-registration training and a registration examination as evidence of their specialised knowledge and, thus, professional status. This fits with Freidson’s (1970) perspective of professionals where objective proof of expertise through specialist training is central to a professional identity. Despite this extensive education, the extent to which pharmacy counter assistants and doctors share some elements of this specialised knowledge could be understood as undermining these expertise claims.

Thirdly, Freidson identifies the service-orientation and professional trustworthiness as traits which define a profession. The extended role of pharmacy (see below) is argued by Taylor *et al.* (2003) to be evidence of this orientation towards patient services and confirmation of the independent trustworthiness of pharmacists’ knowledge and advice. However, in an earlier publication Harding and Taylor (1997) noted that the expectation of professional altruism and impartial medical advice is challenging for community pharmacists to negotiate as they experience ‘role strain’ due to their somewhat paradoxical roles as both health advisors and retailers. This retail focus is central to the vast majority of sociological analyses of community pharmacy given the importance of retail activities in community pharmacists’ everyday work. In their seminal paper, Denzin and Mettlin (1968) identify retail work as being central to limited professionalisation in community (or ‘retail’ as it was at the time of their paper) pharmacy. More recently, the professional identity of community pharmacists has been argued to be tied into this ‘shopkeeper’ (Masongo, 2005) image which is pervasive amongst both patients and practitioners. Rapport *et al.* (2010) argue that this leads pharmacists to experience an ‘identity crisis’ given their dual role as medications dispensers/sellers

⁵ The application of the term ‘suffering’ to anorexia is problematic as, although the participants in Fox *et al.*’s study acknowledged anorexia as a disease, they took an ‘anti-recovery’ stance, whereby they were keen to maintain their status as ‘pro-anas’ and reluctant to adopt biomedical programmes of rehabilitation.

and healthcare practitioners. They conceptualise this as leading to ‘double alienation’ of community pharmacists and elsewhere Harding and Taylor (1997) have characterised the pressure of providing both clinical and retail services as ‘role strain’ whilst Hibbert *et al.* (2002: 49) note that the re-branding of ‘retail pharmacy’ as ‘community pharmacy’ hints at the professions’ own acknowledgement of ‘a tension between commerce and professionalism’.

Fourthly, Freidson argues that self-regulation is central to professional status. The ability to self-regulate is understood by Freidson to be justified on three grounds; (i) that the level of skill and knowledge within the profession means outsiders are ill-equipped to act as regulators; (ii) that professionals are responsible and do not require constant external regulation; and (iii) that professionals are trustworthy enough to be entrusted to regulate themselves effectively. The existence of internal regulatory bodies, most recently the General Pharmaceutical Council, is argued by Taylor *et al.* (2003) to be evidence of these three characteristics and, thus, the ability to self-regulate.

The case of medicine in the UK provides an interesting insight here. Although medicine is largely self-regulating and therefore fits Freidson’s model of defining a professional well, its ability to self-regulate is not a stable facet of contemporary practice and is subject to change according to political and public discursive and attitudinal shifts. Hence although medicine’s ability to self-regulate has been somewhat limited, it has still retained its professional dominance. Ham and Alberti (2002) note that the establishment of the NHS in 1948 marked the political enshrinement of a ‘compact’ between the public, the government and the medical profession which allowed the medical profession to ensure high clinical and care standards through self-regulation. Although the professional knowledge and competence of medicine was taken for granted within the compact through the prevailing discourse of ‘doctor knows best’, its dominance as a model for public/government/medical relations was not enduring and from the 1960s onwards it began to weaken as a result of increased visibility of patient groups, public identification of poor clinical and care standards and frequent demands for increased budgets by doctors keen on technological innovation. Ham and Alberti argue that over the course of the next thirty years, a number of incremental changes occurred in

the NHS which undermined the public/government/medical compact and decreased the freedom of self-regulation that doctors had previously enjoyed. As such, an increased public voice within the NHS (both at the macro policy-making level and at the one-to-one doctor/patient encounter level) served to shift the relationship between the public, the government and the medical profession to one where the latter was not all-powerful (Ham and Alberti, 2002). In particular the move towards 'new managerialism' within the NHS during the 1980s shifted the balance of power between doctors, the government and the public as doctors were forced to become more accountable for their clinical and care standards, which undermined the self-regulation ability that doctors had had previously. Moreover, the professional skills and expertise of the doctors, which formed much of the rationality behind their ability to self-regulate, were sidelined in the new managerial discourse by an increased focus on effective budgeting, cost reduction, patient satisfaction and turn-around times (Ham and Alberti, 2002; Poole, 2000).

Ham and Alberti (2002) note that more changes occurred within the NHS since New Labour was elected in 1997 than in the preceding forty nine years following the creation of the NHS. Although the Conservative doctrine of new managerialism within the NHS continued to redesign the relationship between the public, the government and doctors, the extent to which the state could restrict medical self-regulation was limited following defensive responses to governmental attempts to invade the traditional medical territory of self-regulation (see Salter, 2004). Salter narrates the period at the beginning of New Labour's period in office when the 'policy window' (2004:122) opened following the Bristol Royal Infirmary and Alder Hey organ retention scandals and the discovery of the serial murders committed by GP Harold Shipman and New Labour's subsequent attempts to limit the self-regulation of medicine. He argues that despite the establishment of numerous regulatory bodies and the issuing of several official documents, the response from the medical profession was negative which, coupled with the government's lack of managerial capacity to overhaul the regulatory model of the NHS, meant that the government were forced to retreat from the medical professions regulatory territory and allow self-regulation to continue. In other words, although medicine is still self-regulated to some extent, its regulation exclusively by medical professionals has been stunted. What this means is that self-regulation and autonomy are not *always*

traits to be associated with professional status as medicine has become less able to self-regulate but has nonetheless retained a professional status.

In addition to Freidson's analysis of professions, Johnson's (1977) idea of 'mystification' in everyday practice can also be considered in regard to pharmacy. Johnson argues that a sense of mystery around the activities and expertise of professionals is a key characteristic of a professional identity. Although many of the activities of pharmacists are fairly invisible (i.e. carried out in community or hospital dispensaries to which the public do not have access), Harding and Taylor (1997) argue that there has been a decline in the mystification of the work of pharmacists due to the advent of large scale drug production in the latter half of the twentieth century. Whilst pharmacists' compounding skills and detailed knowledge of medicines were once exclusive of the lay public, the ubiquity of pre-packaged medicines has largely displaced this compounding role. Moreover, the patient information leaflets (PILs) which are supplied with these pre-packaged medicines codify and black-box pharmacists' expertise in pharmacology for patient consumption; in this way the mystification of pharmacists' pharmacological expertise could be understood as being undermined. On the other hand, Bjerrum and Foged (2003) found that even when companies were manufacturing identical products, their PILs did not provide identical information. This led to an increased need for pharmacists' expertise where the mystified knowledge of pharmacists was configured as increasingly important given the shortcomings of the codified information in PILs.

In short, the above review suggests that pharmacy possesses some of the traits which might define it as a profession but does not possess the degree of autonomy associated with other professional practices, especially medicine. Denzin and Mettlin (1968) characterised pharmacy as a 'quasi-profession' because of this. This characterisation echoes Freidson's notion of 'paraprofessional' practice where he argued that paraprofessional practices mimic many of the activities of professions such as the formation of professional groups; the development of a code of ethics; the creation of a specific curriculum for training novices; and the development of a licensing process. However, he argued that paraprofessionals occupy a lower position in the division of labour and are never fully granted autonomy in their work.

Denzin and Mettlin (1968) suggested that community pharmacy underwent a process of ‘incomplete’ professionalisation during its formation in the nineteenth century because of its failure to create an exclusive knowledge base; its failure to refrain from profit-making and advertising; and, above all, its failure to gain complete control over the objects around which its everyday work is centred (i.e. drugs).

Denzin and Mettlin’s (1968) paper is seminal in pharmacy practice research and somewhat enshrined the ‘trait’ approach as a standard for sociological analyses of pharmacy practice. More recently, Dingwall and Wilson (1995) have offered a critique of Denzin and Mettlin’s (1968) paper challenging this trait approach to understanding professions and professional identities. They argued that adopting a trait approach does little more than allow researchers to point out where occupations and professions demonstrate (or do not demonstrate) professional traits rather than analyse the context in which these traits become culturally significant. Specifically, they argued that Denzin and Mettlin’s assertion that pharmacists failed to gain control over the object around which their practice is based, fails to distinguish between drugs as material objects and drugs as a basis for social action. As such, they proposed that pharmacy practice and its professional identity should be understood sociologically in terms of the cultural role of pharmacists in symbolically transforming chemical compounds into socially meaningful objects of drugs. Harding and Taylor (1997) concur with this more dynamic analysis and argued that pharmacists are socially sanctioned to carry out this cultural role and imbue medications with particular social meaning for the benefit of patients.

Although some sociological analyses have tentatively moved away from a Freidsonian trait approach to pharmacy, the relative status of pharmacy as a profession is still an important analytical framework given the nature and structure of contemporary pharmacy work. Most of these analyses have tended to (and continue to) focus on community pharmacy whereas hospital pharmacy work has tended to be neglected. As such, most of the questions about the professional status of pharmacy are really questions about the professional status of *community* pharmacy. Nonetheless, the following section shows how the late twentieth century changes to the nature of pharmacy work affected those practising in *both* community and

hospital settings. Moreover, the later analytical chapters in this thesis deal with the sociological importance of both community and hospital practice.

2.4. Pharmacy in the Late Twentieth Century: Shifting Professional Boundaries

In the latter half of the twentieth century, pre-packaged medications produced by large pharmaceutical companies removed the need for pharmacists to compound their own medicines. This led to concerns around de-skilling, particularly in community pharmacy where Eaton and Webb (1979: 73) argued that they became ‘over trained for what they do and under-utilised in what they know’. Davey (1983) argued that this could be financially problematic for the NHS with patients using up GP appointments where the expert knowledge of pharmacists’ would be sufficient or, in the case of questions about medications, more appropriate. These concerns were addressed in the National Pharmacy Association’s 1982 *Ask Your Pharmacist* campaign and by a 1986 report by the Nuffield Foundation which suggested an ‘extended’ role for community pharmacists. This extended role expanded the community pharmacy contract to provide extra clinical services through prescribed medicines management; chronic illness management; common ailments management and the promotion of healthy lifestyles (Harding and Taylor, 1997). Much of this was undertaken under the rubric of the Pharmacy in a New Age (PIANA) strategy, which was launched by the Department of Health in 1995. This strategy was, and continues to be, a gradual process of change in community pharmacy within which the boundaries of practice are shifted towards a more clinical focus (Longley, 2006; Parkin, 1999). This extended role, and the initiatives such as PIANA which existed around it, somewhat shifted the professional identity of pharmacists as they became reconfigured as healthcare practitioners (Anderson, 2001). As such, pharmacy shifted from product-based to more clinically focused (Benson *et al.*, 2009; Petrakaki *et al.*, 2012). Moreover, their increased clinical work and one-to-one contact with patients altered the spatiality of community pharmacy practice in relocating pharmacists outside of the dispensary. In doing so, pharmacists became discursively posited as ‘first port of call’ for patients (Anderson, 2001: 23).

More recently, the government published a White Paper in 2008 outlining the ways in which pharmacy's extended role will be shaped in the future. In terms of practice, *Pharmacy in England: Building on Strengths- Delivering the Future* (Department of Health, 2008) advocates that pharmacies and pharmacists ought to concentrate on expanding access to clinical services, supporting healthy living and lifestyles and providing better care for patients managing long-term conditions. Within this, the report recommends that community pharmacies become 'healthy living centres' where the public are able to obtain information about preventative health strategies such as nutrition and exercise, as well as about medications for both acute and chronic conditions. What this suggests is that contemporary policy is instrumental in shifting the professional identity, and practice boundaries, of community pharmacists.

This extension of the role of pharmacists into more clinical practices also affected hospital pharmacists where a report by the RPSGB (1977) suggested that;

There is an important role for pharmacists to play in direct contact with patients on all matters concerning medication. On the patient's admission, pharmacists can take the previous medication history; because of their specialist knowledge they can make an invaluable contribution in the selection of the drug treatment for the patient; they can monitor the progress of the medication, particularly in relation to possible side effects or adverse reactions; and they can counsel a patient on the proper use of drugs and medicines both in the hospital and when they return home

As in community settings, this extension of pharmacy work reconfigures pharmacists as healthcare professionals whose pharmacology expertise and pharmaceutical gaze (Barber, 2005) are of benefit to both the hospital organisation and the patient. In the hospital setting, this extended role was implemented, arguably, more readily than in the community setting given the increasing standardisation in hospital pharmacy and the absence of retail pressures.

In both settings, the expansion of pharmacy's professional role shifted the boundaries of practice and the professional identities of practitioners. Historically, Eaton and Webb (1979) argue, medical professionals have been anxious about paramedical occupations (such as pharmacy) encroaching on their traditional roles and duties and eroding their professional hegemony. As such, the shifting boundaries of the extended role which expanded pharmacy's jurisdictions to include more clinical activities created sociologically interesting questions about potential boundary encroachment by pharmacists. More recently, the shifting of pharmacy's jurisdictions to include supplementary and independent prescribing has also raised these boundary encroachment issues (Avery and Pringle, 2005). These issues can be understood with regards to Gieryn's (1983) boundary work framework.

Briefly, Gieryn (1983) draws on the examples of anatomy and phrenology in the nineteenth century to demonstrate the demarcation of 'science' (anatomy) from 'non-science' (phrenology). He argues that boundary work is the process of groups drawing on their cultural and professional repertoires to define themselves and their expertise for the lay public and its authorities (Freidson's elite segment of society). In doing so, groups which become defined as 'science' are able to maintain their professional status and autonomy and lay legitimate claim to resources. They then secure a privileged position within the 'intellectual ecosystem' which makes them largely immune from government regulation and enables them to enjoy the social status of experts and the advantages associated with it (such as being called upon as a reliable expert witness in a court of law).

The most common sociological analyses of boundary work within medical practices tend to centre of the negotiation of professional boundaries between doctors and nurses within the hospital setting (see Allen, 1997; Wicks, 1998). Much of the focus of these analyses tends to be the official boundaries which are drawn between high-status doctors and low-status nurses and the concurrent expectation that nurses will transcend this boundary for the benefit of both patients and doctors but not expect the official boundaries of their work to be moved into the professional territory of doctors. Additionally, Mizrachi *et al.* (2005) point to the boundary work which perpetually occurs between co-located biomedical and complementary and alternative practitioners. They argue that biomedical practitioners have been able to

draw on their cultural repertoires to discursively construct alternative practitioners as unreliable and unscientific which serves to maintain the hegemony of the biomedical practitioners.

Contrary to concerns about the potential encroachment of pharmacists onto the jurisdiction of medical practitioners, Eaton and Webb's (1979) empirical data suggested that doctors were willing to delegate or relinquish certain tasks to pharmacists as part of their clinical work. Eaton and Webb (1979: 85) argue that a 'negotiated' settlement between medical practitioners and clinical pharmacists was reached whereby pharmacists accept the responsibility of medics in return for permission to practice certain 'medical activities'. In the hospital setting they found that pharmacists most often shifted their boundaries into areas which medics have previously neglected, such as patient counselling or ADR monitoring. In doing so, it is argued that pharmacists take on some of medicine's 'dirty work'.

More recent work by Edmunds and Calnan (2001) also found that these concerns about boundary encroachment as a result of increased clinical work in pharmacy were unfounded in everyday practice. In their empirical study of community pharmacists involved in extended role projects, they found that pharmacists drew relatively rigid boundaries between their role as dispensers and doctors' role as prescribers within the patient care team. As such, pharmacists were keen not to encroach on the work of doctors, particularly in relation to the management of chronic conditions, and discursively configured themselves as a point of guidance for patients rather than a substitute for doctors' advice. Eaton and Webb's (1979) and Edmunds and Calnan's (2001) papers suggest that the boundary work between medical and pharmacy practitioners in both community and hospital setting is somewhat less pressing than that of Gieryn's nineteenth century anatomists and phrenologist.

2.4.1 The Extended Role as a (Re)Professionalisation Project

According to Edmunds and Calnan (2001), the development of an extended role in community (and hospital) pharmacy can be understood as an attempt to (re)professionalise the sector. In the US context, Birenbaum (1982) presents this

(re)professionalising project as an attempt to maintain prominence for pharmacy in the context of increased routinisation and uncertain financing of healthcare and pharmaceuticals. Pharmacists' participation in extended role projects (such as adherence services; ADR monitoring; and chronic illness management) is understood by Edmunds and Calnan as a way for pharmacists to redefine their status as professionals and take full advantage of their training and expertise. Hence, the pharmacists in Edmunds and Calnan's (2001) study understood the extended role as a positive (re)professionalising strategy for community pharmacy. In contrast to this, Harding and Taylor (1997) argued that the extended role as recommended in the 1986 Nuffield Report had, after ten years, ultimately failed to make significant impacts on the professional status of community pharmacy for a number of key reasons outlined below. They argued, instead, that the extended role has actually had a de-professionalising effect on community pharmacy in focusing too heavily on non-medicines related activities.

Firstly, they argued, the extended role does not acknowledge that professional status is based on the exclusivity of expert knowledge and the creation of a chasm and power imbalance between experts on the one hand and the lay public on the other. Here, Johnson's (1977) notion of 'mystification' again becomes central. Harding and Taylor argued that the extended role is flawed in that it does not capitalise on this chasm and instead concentrates on promoting services which are centred around technological devices (i.e. testing devices) which routinise work and undermine pharmacists' claims to expertise (see Ritzer and Walczak, 1988). Moreover, they argued, the extended role necessitates pharmacists offering advice on non-medicine related issues, such as smoking cessation, which undermines their rightful claims to expert status in the field of medicines.

Secondly, the extended role fails to take into account the relatively limited autonomy of community pharmacists employed in large multiples, which contrasts with Freidon's (1970) understanding of professional identity. Moreover, part of the extended role involves the provision of medicines advice services for patients which is based around a set of protocols. This protocol standardisation, Harding and Taylor (1997: 556) argued, removes the ability for pharmacists to use their professional judgement, curtails the scope for pharmacy-patient relationships (see Worley *et al.*,

2007) and reduces their interactions to ‘nothing more than asking structured, formulaic questions’.

Thirdly, the 1982 *Ask Your Pharmacist* campaign regarded community pharmacists as a first port of call for patients who did not want to ‘waste’ doctors’ time (Harding and Taylor, 1994). The necessity of pharmacists being available all of the time without appointments or gatekeepers undermines a fundamental principle of a professional identity, which is the organisation of time by the professional. Harding and Taylor (1997: 556) contended that patients’ ability to make immediate demands on pharmacists’ time serves to ‘demystify and devalue’ the skills and judgements of pharmacists.

Finally, as mentioned, a key social role of pharmacy is the symbolic transformation of inert chemicals into socially meaningful objects of medications. Harding and Taylor (1997) argued that the jurisdictional reconfiguration following the implementation of the extended role has meant the delegation of many dispensing activities to pharmacy counter assistants in order for pharmacists to undertake more clinical activities. There is potential, then, for the dispensing process to be undertaken without the input of a professional. This removes the opportunity for pharmacists to enact the process of imbuing medications with social and cultural meanings which sociological analyses have identified as being central to community pharmacy’s professional identity.

More recently, in a study of EPS in community pharmacy, Petrakaki *et al.* (2012) centralise technological innovation in the professionalisation question which fits into a wider sociological focus on the role of technologies in shaping professional work, identity and jurisdictions. Petrakaki *et al.* (2012) argue that the integration of EPS into community pharmacy changes pharmacists’ everyday activities in the areas of nature of work; professional values; professional roles; jurisdictions; boundaries; and power. For example, they demonstrate the ways in which increased automation as a result of EPS may reconfigure the nature of work by altering the materiality, temporality and manual aspects of pharmacy activities. As such, EPS may eliminate paper in community pharmacy work; allow pharmacists to pre-dispense prescriptions (also see Motulsky, 2008); and remove the need for pharmacists to manually

population patients' demographic information. The consequences of the changes in these areas of everyday practice are not linear or deterministic and instead, they argue, open up the possibility of simultaneous de- and re-professionalisation of community pharmacy. Inasmuch, they argue that de-professionalisation may occur in four key ways; (i) by shifting the temporal and spatial aspects of community pharmacy work; (ii) by eroding inter-professional trust through a depersonalisation of communication with other healthcare practitioners; (iii) by rendering community pharmacy more visible and opening up opportunities for governmental control; and (iv) by expanding pharmacy's professional boundaries to other occupational groups with different professional values- in doing this professional identities become blurred and, they argue, being a professional 'could mean anything and therefore nothing'. Running concurrently to this, they identify three key ways in which EPS may re-professionalise community pharmacy; (i) by freeing pharmacists from mundane tasks to allow them to undertake more challenging clinical activities; (ii) by expanding community pharmacy's jurisdictions and allowing them to exercise more discretion and professional judgement; and (iii) by expanding professional boundaries and allowing pharmacists to become more integrated in the 'NHS family'.

This final point is also echoed by Barrett *et al.* (2011) in their study of the integration of robots into hospital pharmacy settings. They note that pharmacy robots reorganise professional relationships and boundaries throughout the hospital structure. In doing so, pharmacy assistants' everyday work became increasingly focused on the maintenance of the robots (i.e. fixing technical problems and restocking) whilst pharmacists were freed from mundane dispensing tasks and able to undertake more clinical work away from the dispensary. This reconfiguration of pharmacists' work and jurisdictions, Barrett *et al.* (2011), argue, allowed pharmacists to become further integrated into medical teams and increased their 'institutional legitimacy'. This can be understood in line with Petrakaki *et al.*'s (2012) analysis as a re-professionalising consequence of technology in everyday work.

So far this chapter has examined the historical context of pharmacy in the UK from its association with grocers in the medieval guild system to the increase in clinical pharmacy during the latter half of the twentieth century. In order to

contextualise the later sociological analyses in this thesis, the chapter now turns to an overview of contemporary pharmacy practice primarily drawing on the most recent (2008) RPS *Pharmacy Workforce Census*.

2.5 Contemporary Pharmacy Practice

2.5.1 Demographic Data

At the time of the 2008 RPS workforce census, there were 48,749 registered pharmacists in Great Britain (England, Scotland and Wales). Of those actively employed⁶, 71% worked in community pharmacy, making it the most common source of employment for British pharmacists. Within community pharmacy there is a degree of heterogeneity in employment patterns with pharmacists working in independent (30.2%), small chain (11.8%), medium chain (12.9%), large multiples (54%) and supermarket (12.2%) pharmacies. Moreover, pharmacists often work in multiple locations (hence these percentages totalling more than 100). The nature of work in these different community pharmacy settings can be highly divergent with large multiples, generally, restricting the autonomy of pharmacy employees given the focus on profit-generation.

The 2008 census highlighted that 21.4% of British pharmacists were employed in hospital settings making it the second largest sector of employment. Hospital practice is characterised by a banding system based on expertise, experience and responsibility and specialisation in specific disease areas or pharmacy practices. Hence, where community pharmacists are fairly generalist practitioners, hospital pharmacists practise in a specific area of medicine (such as Oncology or Cardiology) and/or a specific practice (such as aseptic manufacturing). Table 1 shows the breakdown of employment patterns in contemporary UK pharmacy.

⁶ Actively employed refers to pharmacists actively practising their profession in a pharmaceutical setting of some description and is different from simply being registered as member of the RPS, which *all* qualified pharmacists (practising or not) are required to do.

Sector	Percentage of active pharmacists
Community	71.0
Hospital	21.4
Primary Care	7.2
Industry	4.1
Academia	2.8
Other	3.8

Table 1: Proportion of actively employed pharmacists working in each sector. Taken from Seston and Hassell. (2009: 20).

This table shows that smaller proportions of active pharmacists are employed in primary care, industry and academia. Primary care pharmacy is a relatively modern phenomenon and so relatively neglected in the academic literature. Primary care pharmacists are, generally, co-located in GP surgeries and work more collaboratively with GPs and practice nurses than those practising as ‘islands’ (Cooper *et al.*, 2009) in other community settings (see Silcock *et al.*, 2004). Pharmacists working in industrial settings are generally employed by large pharmaceutical companies as part of their drug manufacturing processes. Their role within these companies removes them from the dispensing tasks which are central to other pharmacy practises. Similarly, those working in academia are also removed from dispensing activities and are more focused on research and educating trainees (Taylor *et al.*, 2003). However, as the table shows, pharmacists working in all sectors are entitled to have more than one pharmacy job. As such, whilst working in industry or academia as a primary role might preclude pharmacists from dispensing activities, they may undertake dispensing work in a secondary community, hospital or primary care role.

Taylor *et al.* (2002) note that given its historical trajectory, the profession of pharmacy is often associated with middle-aged white men. Contrary to this, however, the RPS members list contains 27,746 women, which constitutes 56.9% of the total population of registered UK pharmacists. This number represents an increase of 5.4% from the 51.5% that women constituted in 2001 (Hassell *et al.*, 2002). Moreover, in the hospital setting, women pharmacists outnumber men by 3 to 1.

This relatively high proportion of women in the pharmacy profession is arguably related to the belief that community pharmacy is a flexible area in which qualified female pharmacists are able to combine family commitments with their desire to continue working within their chosen profession (see Symonds, 1998). This ‘feminisation’ of the pharmacy workforce may have consequences for pharmacy’s professional project. Adams (2005) notes that professions which become feminised find attaining, or maintaining, a high professional status difficult. To demonstrate, Adams (2005) draws on clerical work which suffered a decline in its status as the proportion of women working in the sector increased during the early part of the twentieth century and Sampsel (2008) points to the perpetual relatively low-status of nursing which tends to be dominated by women. Moreover, Gidman and Hassell (2005) note that although the increase in the proportion of female pharmacists reflects a wider achievement vis-à-vis women’s employment, the position of women within pharmacy needs to be analysed more fully within feminist frameworks to understand why women are underrepresented as senior managers and owners in the community sector and overrepresented in lower grade occupations with the hospital sector.

In addition, although pharmacy still continues to be dominated by practitioners from a ‘white British’ ethnic background (59.7%), there has been an increase in the number of pharmacists from non-white ethnic backgrounds. Hassell *et al.* (1998) note that in 1991 practitioners from ethnic minorities constituted 23% of the total number of pharmacists in the UK, compared to 30% in 2008. These demographic characteristics around gender and ethnicity raise interesting sociological questions.

2.5.2 Paying for Pharmacy

Hospital pharmacists are employed, and therefore paid, by the NHS Trust which governs the hospital in which they practice. As mentioned, hospital pharmacists are paid based on a nationally standardised salary framework where inexperienced pharmacists begin on a lower salary tier and move up as they become more experienced in their specialist area.

In the community setting, the funding for pharmacy is less standardised. Community pharmacists' salaries are paid by the private companies within which they are employed with large multiples generally offering higher salaries. Pharmacies are then contracted by the NHS to provide Essential, Advanced and Enhanced services within the terms of the nationally standardised community pharmacy contract. Within this, 'Essential services' refers to services which must be provided by all pharmacies such as dispensing, repeat dispensing and medications disposal. 'Advanced services', such as Medicines Use Reviews (MURs) and New Medicines Services (NMS), can be provided by all pharmacies once practitioners have been accredited to carry out such work. 'Enhanced services' are commissioned by the Primary Care Trust (PCT- as was at the time of writing) within whose jurisdiction the pharmacy falls. These Enhanced services include activities such as needle exchange programmes and Chlamydia screening. Pharmacies are remunerated a nationally standardised amount (set by the Pharmaceutical Services Negotiating Committee) for each service that they carry out (i.e. each prescription they dispense or MUR they complete). In this way, community pharmacies earn around 90-95% of their income from this NHS work.

It should be noted here that this overview of funding in pharmacy was correct as of July 2012. With the current focus on disbanding PCTs and implementing GP commissioning, the future structure of pharmacy funding in the community setting is not yet clear.

2.5.3 Professional Collaboration in Pharmacy

Contemporary pharmacy practice is characterised by something of a disjuncture between work in community and hospital settings (see Bhakta, 2010; Bond, 2001). Until the 1960s, the work of community and hospital pharmacists was relatively similar in that both were primarily focused on compounding and dispensing medications. Following the increased availability of pre-packaged medicines, work activities in these two sectors moved away from compounding and the work of hospital pharmacists began to become more integrated into wider clinical team working (Taylor *et al.*, 2003). This was particularly the case given the specialisation model in hospital pharmacy. The result of this was the evolution of 'ward pharmacy'

where pharmacists mobilised their pharmacological expertise to become increasingly involved in prescription decision making which was thought to be beneficial for both the hospital organisation and the patient (Brookes *et al.*, 2000). As such, pharmacists in the hospital setting are fairly well integrated into clinical care teams.

In the community setting, as noted above, Cooper *et al.* (2009) identified pharmacists as practising as ‘islands’ given the lack of collaboration or inter-professional communication which they experience. Moreover, the collaboration between pharmacists working in different settings is minimal. In the 1990s the RPSGB recommended that hospital pharmacists provided elderly patients with medication checklists upon their discharge to be given to community pharmacists who would then take over responsibility for that patient’s medicines management. This, it was proposed, could increase and formalise the communications between these two sectors of practice and minimise the risk of discrepancies and adherence issues (Bond, 2001). Although these discharge checklists were shown to reduce problems as proposed, they also proved to be expensive and labour-intensive and so were not rolled out on a large scale. Hence, communication and collaboration between pharmacists working in different sectors remains minimal.

2.5.4 From Medicines Management to Medicines Optimisation

As mentioned, medications are the key components around which pharmacy practice and Barber’s (2005) pharmaceutical gaze are centred. The management of the safety and efficacy of these medicines, then, underpins the practices of pharmacy in both community and hospital settings. Stowasser *et al.* (2004) identify nine steps in what they term the ‘medicines management pathway’ in the hospital setting. In each of these steps, the mobilisation of the expertise of the pharmacist is clear;

- (i) deciding to treat and prescribe; once a clinician has ascertained that treatment is necessary, the bioclinical collective team negotiate the most appropriate and cost-effective route to take.
- (ii) recording medicines order; once a medication has been decided on, this decisions needs to be carefully and accurately recorded.
- (iii) reviewing medicines order; the medicine is then reviewed for issues such as funding challenges, drug-drug interactions and ease of compliance.

- (iv) issuing medicine; once a medication is verified as being safe and appropriate, it is manufactured or issued from the producer (this may have already been undertaken and be in storage)
- (v) providing medicines information; the producer should also provide sufficient information on how to take/prepare the medicine and its potential toxicity.
- (vi) distributing and storing medicine; once issued, a medication is delivered to the care space (e.g. wards) and stored appropriately.
- (vii) administering medicine; this involves assessing when and how a medication should be administered (e.g. pain relief medication)
- (viii) monitoring for response; on-going monitoring of patients also includes monitoring for ill effects from medications.
- (ix) transferring verified information; information about the steps above needs to be communicated effectively with other health care professionals (typically via the patient medical record) to affect future medications decisions.

In 1990 Hepler and Strand proposed the notion of ‘pharmaceutical care’ as a more patient-centred approach to medicines management which would increasingly work towards a ‘greater social good’ (Hepler and Strand, 1990: 533). As such, through pharmaceutical care, pharmacy practice moved on from just involving dispensing the correct medicines to a focus on the minimisation of ADRs and the improvement of patients’ experiences of their medications.

More recently, medicines management has discursively evolved further to the notion of ‘medicines optimisation’. This term first appeared in the Department of Health (2010) report *Equity and Excellence*. Within this, it is noted that pharmacists ‘working with doctors and other health professionals, have an important and expanding role in optimising the use of medicines and in supporting better health’ (Department of Health, 2010: 26). In a short article responding to this report, Martin Stephens (one of the National Clinical Directors for Pharmacy at the time) reported that medicines optimisation reconfigures the medicines management and pharmaceutical care agenda of pharmacy in three key ways. Firstly, he argues that it places a new emphasis on patient-centred care; secondly it focuses heavily on

patient outcomes; and thirdly it discursively engages multiple practitioners. This final point is of particular interest in the case of community pharmacy which has traditionally been characterised by isolated working practices (Stephens, 2011). Additionally, Cutler (2011) argues that medicines optimisation provides a key opportunity for pharmacists to demonstrate their skills in patient-centred practice and to work more closely with other healthcare practitioners. At present, medicines optimisation is in its infancy and little academic work has been done in the area with no social science commentary currently in existence. However, this approach has been translated into NHS policy where medicines optimisation forms a distinct work stream in the NHS Quality, Innovation, Prevention and Productivity (QIPP) framework which is focused on making savings within the NHS whilst simultaneously maintaining or improving quality. Future sociological commentaries on this discursive shift to medicines optimisation will be of interest.

2.6 Conclusion

In sum, this chapter has provided a historical narrative of British pharmacy from the medieval period to the contemporary focus on medicines optimisation. It has shown that notions of professional identity and status (primarily centring on questions of autonomy) are central to previous sociological work in this area and that technologies can play an important role in reconfiguring this professional identity through shifting ‘ways of knowing’ (Pickstone, 2000) and professional boundaries (Barrett *et al.*, 2011; Petrakaki *et al.*, 2012). This sociological work, however, is limited in a number of areas. Firstly, it does not properly take into account the sociality of the patient body to which medications are administered. The patient in sociological analyses of pharmacy practice seems to exist as an implicit biological object to which medications are administered and within which they perform their action. This is despite Ryan *et al.*’s (2004: 51) assertion that given pharmacy’s focus on adherence, the body ‘must be fertile ground for [sociological] exploration’ and, elsewhere, the body being highlighted as being of great sociological importance (see Chapter Four)

Secondly, very few sociological analyses of pharmacy focus on both community *and* hospital practice. Instead, community and hospital pharmacy are

often treated as discrete analytical milieus or the latter setting is neglected entirely. It would seem useful, then, for an analysis of pharmacy which examines the themes and practices which are common to both community and hospital given their shared focus on medications.

Thirdly, sociological analyses of community pharmacy highlight the lack of autonomy afforded to practitioners working in large multiple organisations. Perhaps because of the more general lack of focus on hospital practice, there is a lack of research on the relationship between everyday hospital pharmacy practices and the organisations in which practitioners are employed. As such, an examination of the ways in which organisational structures shape everyday work in hospital pharmacy seems necessary.

Fourthly, the work of Barrett *et al.* (2011) and Petrakaki *et al.* (2012) give interesting insights into the potential effects of technologies in the reorganisation of pharmacy work, the reconfiguration of professional boundaries and the consequences for pharmacy's professional identity. There is limited work, however, on the ways in which genetic technologies, as technologies with a particular set of ethical, educational and practice concerns, may affect pharmacy practice.

Given the discussion above, the following research questions have been identified from the existing literature presented here.

- How is the patient body configured in pharmacy practice?
- How do the structures of pharmacy in community and hospital settings shape pharmacists' everyday work activities?
- What themes and practices are common to both community and hospital pharmacy practice?
- How might the integration of (pharmaco)genetic technologies affect pharmacy practice?

Findings from the empirical data feed into the examination of these questions in the later analytical chapters. In order to contextualise this final question, the thesis now turns to an overview of PGx and the sociological literature associated with it.

Chapter Three: Pharmacogenetics: A Sociological Approach

3.1. Introduction

Chapter Two traced the development of contemporary pharmacy from the medieval period to the more clinical role of modern pharmacy. This chapter argues that although some recent social science work has examined the impacts of robotic and EPS technologies in pharmacy practice (Barrett *et al.*, 2011; Petrakaki *et al.*, 2012), the specific issues involved in the integration of PGx into hospital and community pharmacy settings have been neglected. To contextualise this analysis this chapter presents an overview of previous sociological analyses of PGx.

Before this, the chapter provides a descriptive overview of the technical elements of PGx (i.e. why drug response variation occurs) and its recent development within biomedical research. In doing so, PGx is located within a wider genomics framework which characterises many of the approaches in contemporary biomedical research.

The chapter then moves on to examine the public and private stakeholder interest in PGx and the promises which have been constructed in these areas. These are related to the sociological literature through the field of the ‘sociology of expectations’. The sociological literature in the area of PGx is also central to the chapter’s analysis of the integration of PGx into practice and the ethical and social implications which that presents.

3.2. Understanding ADRs

ADRs are argued to account for 6.5% of all hospital admissions (Pirmohamed *et al.*, 2004) and are identified by the left-wing pressure group Compass (2008) as costing the NHS £2 billion annually. Elsewhere, Lazarou (1998) identifies ADRs as the fourth leading cause of death in the USA. As such, the need to understand the factors which influence drug response variation is a ‘critical issue’ (Beard and Lee, 2005: 2).

There are a number of physiological, environmental, individual and genetic factors which can cause variation in drug metabolism such as liver, lung or kidney function; alcohol intake; smoking; age; sex; body fat and genetic polymorphisms (Gibson and Skett, 2001). Within this, there are two categories of ADRs; type A reactions are common, can occur in any individual and can be controlled through dosage adjustment (Severino and Zompo, 2004) whilst type B reactions (also known as ‘idiosyncratic’ reactions) are uncommon and strongly related to genetic variation (Utrecht, 2007).

These type B drug reactions occur as a result of chemical or structural genetic polymorphisms, the most common form of which are single nucleotide polymorphisms (SNPs- pronounced ‘snips’) which account for 80% of all known genetic changes (Jain, 2009). SNPs are allelic variations at the site of one base pair which affect the encoding function of the gene, which affects the protein which is expressed and, thus, can result in a phenotypic variation (Jain, 2009). As well as SNPs, insertions and deletions (INDELS) of DNA and copy number variation (CNV) are also responsible for type B ADRs. Briefly, INDELS are the insertions or deletions of segments of DNA which, when occurring on encoding genes, can result in a ‘frameshift’ meaning different proteins and, subsequently, different phenotypes are expressed. Jain (2009) notes that if one understands the human genome as an instruction book, SNPs are the equivalent of altering single letters whilst INDELS are analogous to inserting or deleting whole sentences or paragraphs. Finally, CNV refers to a deviation from the normal human diploid (two copies of each gene) genome potentially resulting in INDELS or duplications of DNA. This can then cause over- or under-expression of protein which, in terms of drug response, is phenotypically manifested as either non-responsiveness due to abnormally quick metabolism or an ADR due to inadequate metabolic activity (Jain, 2009).

Studies of genetically-determined drug response variability tend to focus on chemical SNP variations rather than structural INDELS or CNV. Jain (2009) notes that this focus on SNPs tends to overlook the importance of structural variations, which Korbel *et al.* (2007) suggest may be responsible for most human genetic variation. Nevertheless, what is demonstrated by this genomic understanding of ADRs is that molecular variability is central to the ADR story.

3.2.1. Terminology

Pharmacogenetics, then, is centred on mobilising the data emerging from these molecular understandings of ADRs and using it in order to manufacture safe and effective drugs and making safe and effective prescription decisions. Within this, there is an ontological distinction between *pharmacogenetics* and *pharmacogenomics* where the former is widely understood to refer to single genetic changes whilst the latter focuses on protein expression in a whole genome. However, there have been, and continue to be, debates within the scientific community about the definitions of these two terms (see European Agency for the Evaluation of Medicinal Products, 2002).

Table 2 shows Jain's (2009) characterisation of the differences between pharmacogenetics and pharmacogenomics vis-a-vis a number of scientific and clinical features (also see Lindpaintner, 2003). Here Jain (2009) demonstrates the focus of pharmacogenetics as individual gene variability and pharmacogenomics as whole genome protein expression. As such, the techniques employed in pharmacogenetics are most commonly associated with clinical practice whilst pharmacogenomic techniques are more commonly associated with drug discovery processes.

Feature	Pharmacogenetics	Pharmacogenomics
Focus of studies	Patient variability	Drug variability
Scope of studies	Study of sequence variations in genes relevant to drug response	Study of the entire genome
Methods of studies	SNPs and expression profiles	Gene expression profiling
Relation to drugs	One drug, many patient genomes	One patient genome, many drugs
Examination of drug effects	Study of one drug <i>in vivo</i> in sample of patients with inherited gene variants	Study of differential effects of several compounds on genome <i>in vivo</i> or <i>in vitro</i>
Prediction of drug efficacy	Moderate	High
Prediction of drug toxicity	High	Moderate
Application relevant to 'personalised medicine'	Patient or disease-specific healthcare	Drug discovery and development or drug selection

Table 2: Differences between pharmacogenetics and pharmacogenomics. Taken from Jain (Jain, 2009: 70).

It is noted elsewhere that the terms pharmacogenetics and pharmacogenomics can be interchangeable since they are both concerned with the same broad area of research (Pirmohamed, 2001; Wieczorek and Tsongalis, 2001). This interchangeability has led to the conflation of these two terms under the umbrella heading ‘PGx’, which is defined as ‘collectively ...the science and technologies associated with dividing patients or populations into groups on the basis of their biological response to drug treatment using a genetic test’ (Hopkins *et al.*, 2006: 403). This has also been called ‘the new pharmacogenetics’ (Pfoest *et al.*, 2000) and ‘pharmacogenetics-pharmacogenomics’ (Wang, 2010).

Alongside these somewhat technical terms, Liggett (2001) notes that less formal terms have also been applied to this paradigm of research and practice. Hence, terms such as ‘personalised medicine’, ‘stratified medicine’ and ‘tailor-made treatments’ have become synonyms for pharmacogenetics/genomics in more popular literature. Hedgecoe (2004) notes that whilst such definitions can be useful for conveying the core approach of this area, they can create a disparity between patients’ and practitioners’ operationalisation of ‘personalisation’; whilst practitioners may understand it relative to existing blockbuster models, patients may understand it as a wholly tailored drug programme. Hedgecoe and Martin (2003: 515) also note that the ascription of a name to a scientific discipline is not an arbitrary or accidental process and argues that ‘the names we use to label particular disciplines have a role in structuring them, and this in turn affects the uptake of particular technologies’. Pharmacogenetics and pharmacogenomics are examples of this, where pharmacogenomics first appeared in the scientific literature in 1997 and utilised the interest and hype surrounding the more general field of genomics which existed at this time. As such pharmacogenomics was discursively posited as a ‘natural or evolutionary development’ of pharmacogenetics due to its utility of contemporary genomic techniques (Vesell, 2000: 119)

For the purposes of this thesis, pharmacogenetics and pharmacogenomics are conflated under the heading ‘PGx’ given that many of the nuances between the two are not likely to be significantly relevant in the context of everyday pharmacy practice. Hence, whilst most pharmacists’ interaction with PGx is likely to involve *pharmacogenetic* technologies and data, *pharmacogenomic* principles are also likely

to be present, not least because the most commonly used PGx test (HER2 testing) is pharmacogenomic in nature. However, most pharmacists' interaction with PGx technologies is likely to be in the form of black-boxed testing devices and/or binaried output data where the scientific methods (i.e. whether these results are arrived at through protein or gene tests) underpinning them are not visible or necessarily relevant for organising PGx work activities. Where the distinction between pharmacogenetics and pharmacogenomics is relevant, however, this is made clear.

3.3 A Brief History of Personalised Medicine

According to Jain (2009: 5), the adoption of PGx into mainstream medicine represents an 'evolution and not a revolution' as personalisation has always been central to medical practice. As such, the clinical practices arising from PGx represent the next phase of the personalised medicine story rather than a completely novel ideology or approach.

Perhaps the earliest known example of personalised medicine principles is Pythagoras' observation in 510BC that some individuals developed a fatal reaction to ingesting fava beans. More recently, nineteenth century Korean Sasang Constitutional Medicine (SCM) divided the human population into four discreet categories based on individuals' physiological, psychological and physical characteristics which are thought to result in herbal medicine response variation (Kim *et al.*, 2009; Shim *et al.*, 2008). Drawing upon these characteristics, practitioners in this sphere of medicine are able to diagnose the constitution of each patient and offer them a personalised therapy regime. In this vein, SCM can be understood as a form of Pickstone's (2000) 'natural history' medical practice where patients' constitution is explained and managed in natural, rather than *supernatural* terms. More recently, this personalised natural history approach has been somewhat legitimised by 'technoscience' discourses of genetics where the four categories of patients identified in SCM have been shown to have a genetic basis (Kim *et al.*, 2009).

Tutton (2012) also provides a useful overview of the history of personalised

medicine. He argues that personalised care and therapy can be seen throughout the history of western medical practice where a conflict between ‘universalism and specificity’ can be seen throughout recent medical history. This is not to say that ‘personalised medicine’ per se has *always* existed in medical practice but rather that different historical forms of personalisation have been enacted throughout nineteenth and twentieth century medicine (Tutton, 2012). He traces the trajectory of personalised western medical practice since the mid-19th century at which time new emerging field of scientific research, most relevantly therapeutics, shifted the focus of medical practice away from what Jewson (1976) calls ‘bedside medicine’ to ‘laboratory medicine’. Within this way of seeing and practising, bodies, diseases and therapeutics became less individualised and more focused on quantifiable universality.

This approach, however, was contested from within the medical profession throughout the nineteenth and twentieth centuries where the conflict between the ‘universalism’ of laboratory medicine and the ‘specificity’ of medical practice routines developed. Tutton (2012) argues that whilst nineteenth century British doctors discursively positioned the practice of personalised medicine as a set of skills- or ‘art’- which no-one else could claim to possess, twentieth century researchers drew attention to the individual psychological and socio-economic factors affecting patients’ health. More recently, laboratory science itself has begun investigating personalisation and individuality through the field of pharmacogenetics.

The foundations for what one might call the *scientific* discipline of PGx were discursively laid down by the English physician Sir Archibald Garrod in 1931 when he observed that inherent individual differences were medically significant and should be taken into account during treatment decisions (Kalow, 2006). Following this, the discreet field of PGx emerged during the 1950s as an experimental science focusing on inherited differences in human reactions to drugs (Council for International Organisations of Medical Sciences, 2005). The majority of the empirical groundwork in the field was done in the early 1950s using succinylcholine (a short-term muscle relaxant), isoniazid (an anti-TB medication) and primaquine (an anti-malarial medication) (Weber, 2008). The results from these, and other,

experiments were drawn together in arguably the most seminal and influential paper in the discipline, Arno Motulsky's (1957) *Drug Reactions, Enzymes and Biochemical Genetics*. In this paper, Motulsky (1957: 170) argued that the differential reactions found in these studies demonstrated that 'hereditary gene-controlled enzymatic factors determine why, with identical exposure, certain individuals become 'sick', whereas others are not affected'. Two years after the publication of this seminal work, the term 'pharmacogenetics' was coined by Friedrich Vogel to describe this burgeoning field of research and in the following decade the importance of genetics in drug metabolism variation was demonstrated through numerous twin studies (Vesell and Page, 1968a; Vesell and Page, 1968b).

Although the interest in PGx gained and sustained a great deal of interest in the decades following the foundation of the discipline in the 1950s, the field expanded at a relatively slow pace with drug-gene relationships being extrapolated as researchers came across them rather than there being an active search for such relationships (Hedgecoe, 2004). In the 1980s, however, the 'molecular turn' in biological science meant that molecular testing was becoming more widespread in laboratories and scientists working within PGx were able to identify polymorphic nucleotides within the genes which encode enzymes which were known to be responsible for drug response variance (Weber, 2008). The molecular turn in PGx more specifically can be traced to 1988 when Frank Gonzalez and colleagues at the National Cancer Institute in the USA successfully cloned the complementary DNA (cDNA) of the CYP2D6 gene, which forms part of the P450 cytochrome system of enzymes. This was a significant breakthrough in the field of PGx as the enzymes of cytochrome P450 are responsible for clearing over half of all clinically used drugs, with the genes CYP2D6 and CYP2C19 being responsible for the metabolism of most of these (Gonzalez *et al.*, 1988; Meyer, 2004). Hence, changes on these genes have subsequently been shown to affect drug reactions and metabolic ability.

Findings from Gonzalez's study and the development of a number of new technologies, such as recombinant DNA and polymerase chain reaction (PCR) opened up the field of PGx to 'the new genetics' which was sparked by the 1953 discovery of the double helix structure of DNA and concerned with providing genetic explanations for various traits, diseases, behaviours and idiosyncrasies

(Conrad and Gabe, 1999). Latterly, in the 1990s, the HGP provided a tool with which scientists could deepen their understanding of genetically-influenced human diversity and located PGx within the biomedical field of genomics (Clarke *et al.*, 2003).

Following the successful completion of the first draft of the HGP's findings, PGx was seen as 'the next great challenge' (Liggett, 2001: 285) for the application of the technologies and information generated from the Project. Building on the somewhat diverse, although ultimately successful, partnership between public and private approaches to the HGP, the SNP Consortium was founded as a collaborative effort between eleven private companies⁷ and the medical charity the Wellcome Trust to locate, detail and make publicly available, 3,000,000 SNPs in the human genome over a two year period (Holden, 2002; Thorisson and Stein, 2003). When the project reached its conclusion in 2001, it had far exceeded this expectation and successfully located and published details of 1.4 million SNPs, which helped to mobilise industrial interest in PGx research (see Hedgecoe, 2004). Following this in 2002, the International HapMap Project was launched as a means of detailing the most common haplotypes (a set of related SNPs which are important in drug response variability) in the global human population. More recently, in 2011 the UK Technology Strategy Board announced stratified medicine as a key five year priority area and launched the Stratified Medicine Innovation Platform with the objective to invest £200 million in stratified medicine projects by 2016.

The principles of personalisation, then, can be traced from an early 'natural history' way of knowing to their centralisation within contemporary technoscientific biomedicine approaches to the body, disease and wellbeing. The disjuncture between personalisation discourses in traditional medicine and more contemporary biomedicine is, arguably, a reflection of the multiplicity of interests which are currently served in the latter. In other words, personalised approaches in traditional medical practice existed primarily for the benefit of patient vis-a-vis maximising efficacy and reducing ADRs. Contemporary approaches to personalisation, however,

⁷ The companies involved in the SNP are: Amersham Biosciences, AstraZeneca, Aventis, Bayer AG, Bristol-Meyers Squibb Company, F. Hoffmann-LeRoche, GlaxoSmithKline, IBM, Motorola, Novartis, Pfizer and Searle (Hedgecoe, 2004: 11).

co-construct the interests of a number of groups of actors- public healthcare institutions, private drug development companies and patients. This chapter now turns to an examination of the ‘promises’ (Hedgecoe and Martin, 2003) which PGx holds for these different groups of actors.

3.4 Public and Private PGx Promises

In the wake of the HGP, technical developments in molecular science were accompanied by an ideological shift towards constructing disease and treatment in genomic terms (Bell, 1998). This technical and ideological shift aroused the interest of private industry (both large pharmaceutical companies and small biotechnology firms) in PGx as it combined the promise of innovative genomic technologies with a focus on drug development activities (Hedgecoe and Martin, 2003). Hedgecoe and Martin (2003) note that a number of ‘visions’ for the future of PGx were then articulated in the scientific and clinical research literature. Of particular note are two visions which focus on (i) drug metabolism and the genetic basis for ADRs and (ii) the associations between markers for drug response and genes involved in the development of specific pathologies. These visions co-construct both public and private interests with a focus on reducing the cost of ADRs for public healthcare institutions whilst decreasing the potential for litigation and reducing the costs of drug production for private drug development companies.

Prior to the genomics turn, pharmaceutical companies demonstrated a ubiquitous ‘one-size-fits-all’ attitude to medicine and drug reactions, and opted for a blockbuster⁸ business model in which new molecules were tested in large clinical trials and aggressively marketed as revolutionary new therapies (Liggett, 2001). Traditionally there has been reluctance within the pharmaceutical industry to acknowledge the extent of drug response variation and so reluctance to fully participate in the PGx field. However, the gradual increase in the pharmaceutical industry’s interest in PGx and the successful ‘shot-gun’ marriage of public and private approaches in the HGP (Hedgecoe, 2004: 11) led to a burgeoning of public/private collaborative research whereby publically-funded university groups were, and are, able to benefit from industry’s large amount of capital, retention of

⁸ Blockbuster drugs are drugs which generate more than \$1 billion annually (Cutler, 2007)

contact with patients and readily-accessible supply of clinical trial data (McCarthy, 2001).

In a recent review of the status of the pharmaceutical industry (so-called ‘Big Pharma’) the accountancy firm PriceWaterhouseCoopers (2009) assert that the traditional ‘profit alone’ business model of the pharmaceutical industry, whereby blockbuster drugs are developed quickly and marketed extensively in order to generate profit solely for the company which owns the relevant molecules, is not a viable model for the future of the pharmaceutical industry. Instead, they argue that Big Pharma need to adopt a ‘profit together’ business model by joining forces with academic institutions, hospitals and health service companies to meet the changing needs of patients who are less willing to accept the traditional blockbuster model and are increasingly conscious of the cost-benefit ratio of therapies.

The proposed collaboration between the pharmaceutical industry and other sectors is presented by PriceWaterhouseCoopers (2009: 2) as a ‘do or die’ requirement. The report proposes a ‘federated’ business model for the future of pharmaceutical companies, within which key actors at various stages of drug development and clinical work form networks which collaboratively work towards the mutual goal of effective patient care. The PriceWaterhouseCoopers report constructs this personalisation of medicine as a phenomenon centred on the personalisation of *patient experience* as well as the personalisation of therapy and thus locates PGx within a wider paradigmatic shift towards personalised medical care which cuts across both private and public healthcare sectors and institutions. In other words, although PGx is concerned with the personalisation of medicinal products, personalised approaches are also increasingly central to general clinical practice through what is commonly labelled ‘patient-centred care’. This approach focuses on the personalisation of clinical encounters and interventions based on patients’ values, needs and preferences; in this way, there is a move away from a homogenisation of patient bodies within a ‘one size fits all model’ of clinical care (see Michie *et al.*, 2003). Hence, the personalisation of medications through PGx can be located within a wider discursive shift towards personalisation and patient-centeredness within the healthcare sector. This can, perhaps, be understood more sociologically as sitting within a postmodern framework of patient understandings

whereby the ‘truths’ of medical expertise are questioned and deconstructed (see Fox, 1999).

3.4.1 Public Sector PGx Promises

This shift towards personalisation of care is identified by Coulter (2002) as being beneficial for both the NHS and patients in terms of better patient adherence to medications and a reduction in ADRs. These promises of personalised care resonate with the visions generated for PGx within the NHS wherein PGx is imagined as a way to improve the safety and efficacy of medications through the identification of patients at risk of ADRs and those who are likely to respond well to therapy regimes. Here Martin *et al.*'s (2006) fourth and fifth innovation options are particularly relevant. Briefly, Martin *et al.* (2006) and, earlier, Webster *et al.* (2004) analysed data from a number of private sector companies to ascertain the commercial and clinical development of PGx. From this they identified six ‘innovation options,’ based around the discovery of better drugs; improving the safety and efficacy of drugs in development; and improving the safety and efficacy of licensed drugs. For the NHS, their identification of PGx as a tool for identifying patients at risk of ADRs and those who are likely to be good responders are of central importance.

Firstly, identifying patients who are at risk of ADRs is, arguably, the most commonly cited application of PGx in clinical practice. The personalisation promises behind it appeal to stakeholders who are interested in reducing the financial burden of ADRs and the application of PGx in this way has previously been identified as a key way in which the NHS could reduce costs (Department of Health, 2003). Results from studies of ADRs as they relate to hospital admission or medical treatment should be treated with some caution as less serious ADRs, such as constipation, tend to be overlooked and under-reported in medical records (Pirmohamed *et al.*, 2004). Nonetheless, it has been widely noted that ADRs place a large financial and labour burden on the NHS with the left wing pressure group reporting that ADRs cost the NHS £2 billion annually (Compass, 2008). Elsewhere, Lazarou (1998) has given a ‘mantra-like’ (Hedgecoe, 2004: 14) figure of ADRs being the fourth leading cause of death in the USA after heart disease, cancer and strokes. In the UK, based on admission data for seven UK hospitals, Smith *et al.* (1996) found that 68.7 per 1,000

hospital admissions were caused by ADRs whilst Pirmohamed *et al.* (2004) found that 6.5% of admissions to the two Merseyside hospitals in their study were ADR-related. More recently, Davies *et al.* (2009) found that 2,000 NHS hospital beds are being utilised by ADR patients at any one time. This, they argue, equates to a £171 million cost for ADRs which occur during patients' stays in hospital and at a cost of £466 million for ADR-related admissions. Taken together, this places a financial burden of over £637 million annually on the NHS, which is the equivalent of £5,000 per hospital annually. The data pertaining to the financial cost of ADRs is, then, complex and diverse in nature. Nonetheless, ADRs clearly do place a financial burden on the NHS and the promises of PGx to identify those patients at risk of ADRs clearly align with a perceived need to reduce this financial burden.

Secondly, pre-prescription screening is also constructed as a way to identify patients who are likely to respond well to medications. Within this, PGx promises to negate the need for trial-and-error prescribing approaches and to reduce the need for repeat practitioner appointments by identifying poor- or non-responders before they are prescribed a medication. As an example, Lichter and Kurth (1997) highlighted the osteoporosis drug Fosamax which only begins to show signs of efficacy after a year of use. During this initial year, there is no way to stratify patients who are responding well, those who are responding poorly and those who are not responding at all. Hence, money and time may be wasted in treating poor responders because of the lack of pre-prescription identification. They argued that pre-prescription testing for Fosamax could pay for itself within two years by identifying good responders and only prescribing the drug to them. Although Lichter and Kurth's (1997) paper is somewhat dated, their visions for PGx in clinical practice align well with Martin *et al.*'s (2006) innovation options and feed into the concerns of public healthcare institutions around reducing the cost of ineffective prescriptions.

These concerns around reducing the cost of healthcare also become increasingly relevant in light of the ever-decreasing costs of genotyping (Service, 2006). Moreover, the promises of PGx to reduce NHS costs in this way also sit within the contemporary medicines 'optimisation' discourse noted in Chapter Two. As such, medicines optimisation is premised on increasing the efficacy of medicines for individual patients whilst simultaneously reducing NHS costs through, amongst

other things, curtailing the use of ineffective medications. Given this, the promise of PGx to reduce the financial burden of ADRs and to improve patient experience through predicting non- or poor-responders discursively locates PGx within contemporary medicines optimisation approaches.

3.4.2 Private Sector PGx Promises

Private drug development companies have previously been relatively reluctant to engage with PGx as this would necessitate something of a public acknowledgement that their products are not always effective. In 2003, however, Alan Roses, the then worldwide vice-president of genetics at GlaxoSmithKline, reported that ‘90% [of drugs] only work in 30 or 50% of people’ (Connor, 2003), which somewhat legitimised private sector interest in PGx.

When analysing the promises of PGx for private sector institutions, Martin *et al.*'s (2006) innovation options become useful once again. Three of these options are particularly relevant; PGx to improve drug discovery; PGx to improve the safety of drugs in development; and PGx to improve the efficacy of drugs in development. Within this, they noted that PGx can be used to improve drug candidates by targeting genomic sub-populations. This has the potential to decrease the risk of drugs being rejected at the later stages of clinical trials and increase the chances of effective drugs being approved, if only in a limited market. PGx is also identified as potentially improving the safety of drugs in development by screening participants to identify those with a genetic predisposition to ADRs. This, they argued, would reduce clinical trial bias, improve the safety profile of approved drugs and could ‘rescue’ products which have been abandoned due to ADRs (also see Phillips *et al.*, 2000; Shah, 2006). PGx can also be used to improve the efficacy of drugs in development by identifying trial participants who are likely to respond well and only testing on, and marketing to, them. The breast cancer therapy Herceptin, which is explored in more detail below, is an example of this application of PGx.

The promises of PGx for private drug development companies, then, centre on the potential streamlining of the R&D process and the associated reduction in R&D costs. The total cost of developing a new pharmaceutical product is subject to

much debate although the figures offered by economist Joseph DiMasi are usually the most commonly cited⁹. In 1991 DiMasi *et al.* (1991) calculated the cost of developing a new pharmaceutical product as being around \$500 million and updated this in 2003 to a figure of \$800 million (DiMasi *et al.*, 2003). More recently, Collier (2009) argued that the cost could now be as high as between \$1.3 and \$1.7 billion whereas Munos (2009) calculated the cost to be \$3.9 billion.

Irrespective of the true cost, it is a truism that the cost of producing a drug is substantial, whilst the FDA approval rate is low at 11.5% (Munos, 2009). Tollman *et al.* (2001) argued convincingly for the substantial effect that PGx could have on the cost of R&D by providing a more flexible scenario at the later stages of clinical trials. Whilst traditionally the later stages of drug development have been characterised by a binary scenario (drugs are either shown to be effective, pushed through clinical trials and marketed or shown to be in- or minimally-effective and abandoned as unmarketable), the adoption of PGx technology could allow for a more flexible model whereby drug effectiveness and ineffectiveness could co-exist through stratified populations. These changes, Tollman *et al.* (2001) argued could save \$140 of the R&D cost and see the length of the drug development process reduced by one year per drug. They also advocated the benefits of PGx technology for drug companies in terms of gaining advantages in the current ‘blockbuster’ drugs market where drugs developed using PGx technologies could be marketed as less risky and more effective. In this way, doctors would be more likely to prescribe less risky and more effective drugs, patients would be willing to pay a higher price for a decreased risk of an adverse reaction and patients who have previously avoided medication (typically owing to previous experiences of adverse side effects) would be more willing to try less risky therapies. As such, the discursive promises created around PGx could be mobilised by private sector companies in their marketing activities.

Although their paper was written a number of years ago, Hedgecoe and Martin’s (2003) reflection that many of the promises of PGx are highly speculative owing to the limited number of PGx products available in routine clinical practice

⁹ DiMasi’s figures are subject to much critique. See Light and Warburton (2005), Young and Surrusco (2001) and Collier (2009).

still holds true. As such, although private drug development companies seem less reluctant to engage with PGx principles and pre-prescription testing is routinely practised in some medical specialisms, PGx is still a fairly new paradigm of practice which has not displaced the blockbuster model in drug development or the trial-and-error model of prescribing in clinical practice. As such, it seems beneficial for this chapter to turn to an overview of the current use of PGx in clinical practice.

3.5 Putting PGx into Practice

PGx in both drug development and clinical practice is still largely in the developmental stages. In some clinical practices, genetic factors affecting drug efficacy are tested for as a matter of routine (for example, HER2 testing in breast cancer and KRAS testing in colorectal cancer) but in the majority, PGx remains more of a promise than a reality. Within this, PGx tests are most commonly carried out in hospital settings and in medical specialisms (namely Oncology) where the risk and severity of ADRs are increased. Given this, PGx has made almost no impact on clinical practice outside of hospital settings although Grice *et al.* (2006) identify the potential application of PGx principles to a number of primary care drugs arguing that at least one in four primary care patients takes a drug which causes ADRs. Moreover, elsewhere Warfarin, which is most commonly administered in primary care, is discursively framed as a key area of the application of the principles of PGx (see Rajanayagam, 2009; Wadelius and Pirmohamed, 2006).

Given this relatively limited impact to date, the translation of PGx from 'bench to bedside' (Erllich *et al.*, 2003; Weinshilboum and Wang, 2006) is subject to much debate and these debates can often raise more questions than they answer. At the development side of the process, Weinshilboum and Wang (2006) identify four challenges to be overcome to successfully translate PGx technologies into beneficial outcomes for patients. Firstly, they argue, genomic science will need continual optimisation in order to produce cost effective and clinically applicable results. This necessitates collaboration between practitioners and researchers from a diversity of fields and is, thus, echoed by the PriceWaterHouseCoopers' (2009) report which saw private and public sector scientific collaboration as a necessary future mode. Secondly, they argue that incentives will need to be created in order for drug

development companies to mobilise PGx techniques rather than the traditional blockbuster model. Thirdly, healthcare practitioners will need to be educated in genomic principles in order to provide the best service and advice to patients. This is also echoed in UK policy where the Human Genetics Commission (2003) asserted that the successful integration of genetic principles into routine medical practice would rely on, and necessitate, the cultivation of a 'genetically literate' primary care workforce. In addition, the White Paper *Our Inheritance, Our Future* (2003a) also proposed the need for increased genetic education amongst healthcare practitioners and was followed, in 2004, by the establishment of the National Genetics Education and Development Centre (NGEDC), which offers genetic training to a variety of practitioner groups, including pharmacists. Finally, Weinshilboum and Wang (2006) argue that this education needs to be expanded to include patients in order for them to understand how and why PGx principles are applied to their treatment. For Condit (2010), this incorporates both patients' understanding of the testing process and their ability to make sense of genetics-based risk information. Elsewhere, the limited understanding of, and value invested in, statistical risk-based information has been highlighted by social scientists (Gross and Shuval, 2008). Within this, Gross and Shuval (2008) highlight the rejection of this construction of risk as a rejection of the biomedicalisation of illness, disease and, in this particular case, pregnancy.

In addition to these challenges presented by Weinshilboum and Wang (2006), Erlich *et al.* (2003) pose a number of questions about PGx as part of everyday work activities which, they argue, will need to be adequately answered in order for PGx to be successfully integrated. They ask, then, who should perform PGx tests? When should a PGx test be done? What actions should be taken based on a test result? And what is the cost-benefit ratio of PGx testing? This final question is particularly pertinent to the public sector interest in PGx highlighted above. Within this, the promises of PGx to reduce the financial burden of ADRs and non-responsive patients only become relevant where pre-prescription testing is cost effective when compared with trial and error approaches to prescribing. Since different PGx tests require different scientific products and expertise and, moreover there can be a number of other non-genetic factors affecting drug response, the extent to which the cost effectiveness of PGx as a whole can be analysed is limited. For example, whilst Rosove and Grody (2009) argue that PGx testing for Warfarin treatment is not cost

effective given the inability of pre-prescription testing to identify *all* response variation, Vijayaraghavan *et al.* (2011) identify KRAS testing for colorectal cancer patients as being cost effective to the tune of \$7,500-\$12,400 for each US patient. Elsewhere, however, Payne *et al.* (2009) question the parameters of PGx economic evaluation models and suggest a cautious approach to their conclusions. Moreover, as mentioned above, the decreasing cost of genotyping technologies is likely to further shift these economic evaluations.

What this shows is that the process of putting PGx into routine clinical practice is challenging on a number levels from the everyday organisation of healthcare work to the economic evaluations which are used to assess PGx's cost-effectiveness for the NHS. A future question also arises here which is related to the *integration* of PGx into routine clinical work. Here, the internal structures of different medical practices and the social and political implications of different PGx tests come into play.

3.6 Integrating PGx

Classic STS theory has demonstrated the ways in which innovations are socially constituted and how their integration into everyday practices, infrastructures and routines is mediated by a range of heterogeneous social, political, economic and technical processes (Bijker *et al.*, 1987; Bijker, 1997). In the case of PGx, Hedgecoe (2004) argued that in some areas of medicine, practitioners may be 'resistant' to employing PGx technologies because of the perceived limited advantages they offer. In a later paper he develops a more complex model of differential integration across medical fields and PGx tests and argues for this 'resistance' to, instead, be understood more sociologically in terms of 'clinical usefulness' (Hedgecoe, 2008a). In doing so, he foregrounds the socially constituted nature of PGx tests and medical practices and the effects that this has on their integration into routine clinical work. He identifies four social aspects of medical practice which contribute to understandings of PGx tests as clinically useful or otherwise.

Firstly, he argues that clinicians do not always share the same perspectives and understandings of disease classifications with scientists developing PGx tests.

He points to genetic tests on the gene causing cystic fibrosis (CF) which have meant other diseases, such as the male infertility condition CBAVD (which is also encoded by this CF gene), being ‘folded into’ a CF diagnosis even where the other diseases are experienced without classic CF symptoms. In this way, a genetic test can provide patients with a distressing diagnosis of CF where their initial symptoms are not lung related. Secondly, as is outlined in more detail below in the case of Tacrine, Hedgecoe (2008a: 187) notes that ‘genetic tests...do not exist in a vacuum’ but can have wide ranging implications for family members vis-a-vis inherited disease susceptibility. Practitioners, then, are faced with the dilemma where the benefits of using a test to gain a more certain diagnosis need to be weighed against the potential negative impacts on the wider family network (also see Cox and McKellin, 1999). Thirdly, although one of the key visions for PGx in the UK is the reduction of the financial burden of ADRs, Hedgecoe (2008a) notes that PGx tests may not be clinically useful or cost-effective in certain medical specialisms if those departments do not bear the financial burden of ADRs. Finally, he argues that there is widespread scepticism about PGx testing in the UK healthcare system where a clinician’s diagnostic opinion is still given priority over genetic test results (also see Latimer *et al.*, 2006). Even where genetic test results contradict this professional diagnostic opinion, the latter is often still given precedence. This finding is also echoed in Will *et al.*’s (2010) study of practitioners involved in the diagnosis and treatment of familial hypercholesterolemia (a genetic pre-disposition to high cholesterol) where genetic tests were understood as being less useful than other information, namely cholesterol tests, in making diagnoses.

Hedgecoe’s (2008a) notions of ‘clinical usefulness’ is central to understanding the different levels of integration of PGx in different clinical settings and across different PGx tests. However, his framework is limited in only taking into account the perspectives of practitioners as to the usefulness of PGx tests. Elsewhere, Møldrup (2002) notes that public acceptance of PGx technologies as clinically useful or otherwise is central to their uptake and routinisation in healthcare. In a study of lay peoples’ perspectives on PGx, whilst Fuks Nielsen and Møldrup (2007) found that whilst most respondents were generally positive about PGx because of the potential improvements to patient outcomes and experiences, its perceived preventative, rather than curative, nature could weaken the public’s view of it as

useful and thus ‘weaken the motivation for adopting it’ (Fuks Nielsen and Møldrup, 2007: 235). A more recent public perception survey by O’Daniel *et al.* (2010) also highlights concerns about privacy as a factor which could restrict the clinical usefulness of pharmacogenetics from the patient’s perspective.

What this conveys is that the perceptions of PGx tests as useful or otherwise in everyday clinical practice affect the extent to which they are used, and become ‘normalised’ (see May and Finch, 2009; also see Chapter Four) in different contexts. To exemplify this, the chapter now turns to an examination of two PGx therapies which represent very different integration journeys within two different medical practice fields.

3.6.1 The Case of Herceptin

According to Hedgecoe (2004: 99), the breast cancer drug Herceptin ‘may just be the first example of a pharmacogenetic drug in regular clinical use’. Herceptin may be considered within a PGx tradition as it only works in the 25-35% of metastatic breast cancer patients whose tumours over-express the human epidermal growth factor receptor 2 protein (HER2), which is produced by amplification of the tumour’s HER2 gene. Those patients who are identified as HER2 positive (i.e. those in whom Herceptin will have some clinical benefit) are usually prescribed Herceptin as an adjuvant therapy with traditional cytotoxic therapy (Hortobagyi, 2005).

Personalisation principles are central to both the development of Herceptin and its use in everyday clinical practice. As such, clinical trials of Herceptin were conducted using specially selected samples of patients whose tumours were identified as HER2 positive rather than the traditional randomised trials in a whole patient population. This can be understood as the use of Martin *et al.*’s (2006) third innovation option whereby the development of Herceptin mobilised genomic data on patients involved in phase III trials in order to design subsequent trials to only include good responders. These personalisation principles are also translated into everyday clinical practice where therapy decisions about Herceptin are made based on the results of a PGx test.

The use of Herceptin can be analysed within Hedgeoe's (2008) model of clinical usefulness. The widespread introduction of HER2 testing in the UK faced significant financial barriers, which Roche (to whom Herceptin is licensed) overcame by funding all HER2 tests for a period leading up to, and past, Herceptin's introduction in the NHS in order to get clinicians 'into the habit' of HER2 testing (Enzing *et al.*, 2009: 66). Since there has traditionally been a culture of resistance to testing in the UK medical community whereby testing is only conducted when it is deemed absolutely necessary, Roche's funding of all HER2 testing can be understood as an attempt to alter the UK medical testing culture (Enzing *et al.* 2009)

This attempt to change testing culture was, ultimately, successful with HER2 tests now being carried out on all metastatic breast cancer patients within a safe age limit and an increase in testing for early stage HER2 positive breast cancers following recent clinical trials (Walker *et al.*, 2008). What the case of Herceptin demonstrates, then, is the successful integration and 'normalisation' of a PGx therapy within everyday clinical practice. Within this, the severity of ADRs associated with traditional cytotoxic Oncology therapies, the poor prognoses for HER2 positive metastatic breast cancer patients and Roche's decision to fund HER2 testing can be seen as biological, social and political features of breast cancer which converged to facilitate this 'normalisation' story. What the case of Herceptin also highlights is the increasing complexity of disease ontology brought about through developments in genomic technologies. Hence, whereas breast cancer may previously have been understood as one disease, genomic information can be understood as broadening and adding complexity to definitions of breast cancer by reconfiguring it as a set of heterogeneous genetic diseases (see Curtis *et al.*, 2012). Running concurrently to this genomic broadening of the definitions of diseases such as breast cancer, however, has been the narrowing of treatment options for these different disease areas. In other words, whereas genomics has created more categories within breast cancer (for example, HER2 positive and HER2 negative metastatic breast cancer), the therapy options for treating these are narrowed where Herceptin can *only* be administered to a particular genomic sub-population (those who are HER2 positive).

In contrast to the ‘normalisation’ of Herceptin, the Alzheimer’s drug Tacrine can be understood as sitting at the other end of what one might call a *continuum of integration* whereby PGx testing for potential drug response has not been adopted into routine clinical practice.

3.6.2 The Case of Tacrine

Whereas Herceptin can be understood as an example of the successful integration of PGx into clinical practice based on its clinical usefulness, the case of the Alzheimer’s drug Tacrine is an example of stalled translation and limited clinical usefulness. As such, PGx tests for Tacrine can be placed at the other end of the continuum of integration where the social and ethical implications outweigh the clinical benefits. Tacrine is used to slow the development of dementia symptoms although responses to it vary widely with up to half of the 468 patients in Farlow *et al.*’s (1998) study not improving significantly when treated with the drug. This variability in response to Tacrine was ascribed to an allele of the APOE gene (APOE4), which had been linked with increased risk of late-onset Alzheimer’s disease during the 1990s.

Despite the initial enthusiasm over APOE4/Tacrine PGx, the picture became somewhat muddled as multiple experiments were carried out and the exact relationship between APOE status and Tacrine response was increasingly difficult to determine with studies presenting conflicting results in the scientific literature (see Farlow *et al.*, 1998; Macgowan *et al.*, 1998). This tension between those who understood APOE as central to variations of response to Tacrine (and were supportive of further research in this area), and those who were more sceptical was not easily resolved and specialists in the area of Alzheimer’s disease increasingly disregarded notions that Tacrine response variation was linked to genotype. As a result, the clinical usefulness of PGx tests in the case of Tacrine therapy was questioned on a number of levels.

The case of Tacrine can be related to Hedgecoe’s (2008a) notion of clinical usefulness in two ways. In one way, the Tacrine story clearly demonstrates a difference in the interests of the scientists researching the APOE4/Tacrine link and

the clinicians who would ultimately be using the information to inform therapy decisions. Hence, whilst scientists understand the APOE4/Tacrine link as ‘interesting’ (Hedgecoe, 2004: 65) clinicians require quantifiable conclusions in order to build such genetic information into routine clinical practice. In another way, Tacrine perfectly demonstrates that PGx tests ‘do not exist in a vacuum’ and can have wide-ranging familial implications (Hedgecoe, 2008a: 187). In 1993, a link between the E4 allele of the APOE gene and late-onset Alzheimer’s disease was discovered (Saunders *et al.*, 1993). The scientific importance of this finding is ‘hard to overestimate’ (Hedgecoe, 2008a: 187) given that (i) it was the first gene discovered that increased the risk of developing a disease rather than directly causing it and (ii) that all other genes which had been identified as significant in Alzheimer’s disease were linked to early, rather than late-onset, the latter of which was, during the 1980s and early 1990s, increasingly constructed as an epidemic (see Korczyn and Vakhapova, 2007).

Following this there was much debate around the use of genetic tests for identifying Alzheimer’s risk, which feed into debates about the clinical usefulness of PGx for Tacrine therapy. Notwithstanding the debate briefly described above about the actual role of the APOE4 allele in Tacrine response, the presence of this allele is not only a predictor of drug response but also a risk factor for the development of late onset Alzheimer’s disease. As such, PGx tests for this allele would have familial implications in potentially revealing the presence of an increased Alzheimer’s risk factor. Given that the test for the APOE4 allele can have far-reaching implications for family members, but has not been shown conclusively to provide information on drug response and only increases the certainty of diagnosing Alzheimer’s disease (rather than another form of dementia) by 4% when it is used as an adjunct diagnostic tool (Roses, 1995), the clinical usefulness of PGx testing in Alzheimer’s disease is minimal. Hence, PGx testing for Tacrine was never extensively practised and, as such, can be understood as being at the opposite end of the continuum of integration from Herceptin.

Although Warfarin, Herceptin and Tacrine are used extensively as exemplars of PGx in practice they represent only three of a large number of drugs for which pharmacogenetic biomarkers have been identified which the FDA list on their

website¹⁰. The cases of Herceptin and Tacrine have, however, been used extensively to demonstrate the different patterns of integration of PGx across different medical specialisms and disease areas. These case studies are useful as a way of demonstrating that although the visions and promises created around PGx tend to construct its benefits as somewhat universal, the ethical and social issues which exist around PGx can have a pervasive influence on the extent to which it is mobilised in everyday practice. It is to these ethical and social issues in PGx that the chapter now turns.

3.7 Ethical and Social Issues in PGx

As is noted by Hedgecoe (2008a: 187), genetic tests ‘do not exist in a vacuum’ and are subject to construction and understanding through the ethical, social and political structures of wider society and medical practice. Previous sociological reflections on genetic testing have been far-reaching and have focused on a diversity of issues such as implications for doctor-patient relationships (Lehtinen and Kääriäinen, 2005; Pilnick, 2002; Pilnick, 2004); the ‘new eugenics’ (Kerr *et al.*, 1998; Rembis, 2009; Shakespeare, 1998); implications for family and kin (Cox and McKellin, 1999; McLaughlin and Clavering, 2011; Weiner, 2011); medical or lifestyle decisions (Hallowell, 1999; Hallowell and Lawton, 2002); construction of (bio)sociality and citizenships (Brekke and Sirnes, 2011; Rose and Novas, 2008); and racialised medicine and research (Ellison *et al.*, 2008; Smart *et al.*, 2006; Smart *et al.*, 2008; Tutton, 2004; Tutton, 2007b; Tutton *et al.*, 2008).

PGx, as a specific form of genetic research and clinical practice, does not necessarily involve the same ethical and social implications as other genetic methods which have been dealt with by social scientists. For example, where Hallowell and Lawton (2002) found that results indicating an increased risk of ovarian cancer prompted some women to undergo major invasive surgery, the focus of PGx on predicting drug response is unlikely to involve such significant clinical or personal decisions. As another example, whilst Rose and Novas (2008) argue that genetic information around increased disease risk might lead to the configuration of new social identities, it is unlikely that such biocitizenship would be organised around

¹⁰ See <http://www.fda.gov/drugs/scienceresearch/researchareas/pharmacogenetics/ucm083378.htm>

potential drug responses as ascertained from PGx tests. Hence, although the ethical and social implications of PGx are central to its nature and of sociological interest, Buchanan *et al.* (2002) argue that the ethical and social challenges of PGx should not be over-analysed and aligned with other more ethically challenging fields arising from genomic science. They argue that this ‘genetic exceptionalism’, which assumes that genetic research and clinical practice involve a particular set of exceptional ethical circumstances, should be avoided (this is echoed by the Nuffield Council on Bioethics, 2003). They also highlight ‘overbroad genetic generalisation’ as a potential issue in considerations of the ethics of PGx. Within this, they argue that PGx tests should not all be arbitrarily amalgamated and assumed to involve the same social and ethical considerations. In a more general sense, Martin and Dingwall (2010: 524) note that the extent to which genetic information is ‘exceptional’ is highly dependent on the social and clinical setting within which it is constructed. Hence, whilst genotype information may be useful for predicting future health in the context of practices which deal with monogenic diseases (i.e. those caused by a single gene), this genomic information is ‘significantly less valuable’ in the context of common diseases within which genetic changes are linked to risk (Martin and Dingwall, 2010: 524). In this instance, then, genetic information may be of little more value than other clinical information, such as blood test data.

Nevertheless, there are a number of ethical and social issues which are central to the PGx story. Here, these are identified under the broad headings *Privacy and Confidentiality* and *Inequality and Access*. An examination of each of these is taken in turn.

3.7.1 Privacy and Confidentiality

Issues of privacy and confidentiality are central to social science analyses of PGx in both drug development and clinical practice. In a response to the Nuffield Council on Bioethics’ (2003) report on PGx, Corrigan (2005) highlights the potential for an increased burden on patients involved in PGx clinical trials. She argues that because consent in PGx trials gives companies the ability to link patients’ genetic samples with personal medical information and to store patients’ samples indefinitely to be used in future unspecified genetic tests, the limits of participants’ informed consent

are ‘transgressed’ (Corrigan, 2005: 146). She notes that these compromises in the consent process cannot be offset against the benefits of trial participation as in regular clinical trials given that participants’ receive no direct benefit in PGx clinical trials.

This issue of informed consent is also evident in using PGx in clinical practice where Buchanan *et al.* (2002) question whether specific informed consent is necessary every time a PGx is undertaken. They argue that most PGx tests have a limited capacity for causing psychological harm and so should be treated in the same way as more routine clinical tests to avoid genetic exceptionalism. In a review of current PGx practice in Europe, Woelderink *et al.* (2005) demonstrate that informed consent for PGx tests is not always requested by practitioners although the authors argue that written consent for each test is ‘of great importance’.

Elsewhere, privacy and confidentiality issues are foregrounded. Within this, the ability of some PGx tests to also identify disease susceptibility means that sufficient anonymisation of patients’ genetic samples and medical records to avoid them being linked back to a particular individual is key. In the insurance-based US healthcare model, the issue of genetic discrimination is particularly notable. In this context, concerns around genetic discrimination led to the passing of the Genetic Information Non-discrimination Act (GINA) in 2008, which prevents employers and health insurers discriminating against individuals based on their genetic information. Although genetic discrimination was already illegal before the passing of the GINA, most lay people believed that such discrimination was legal and so those who might have benefitted from genetic testing sometimes opted out. This misunderstanding of the law by lay people, according to Rothstein (2008), was the main impetus behind the GINA and other anti-discrimination legislation at the federal level. Despite this legislation, however, individuals in the US are still vulnerable to discrimination based on genetic information as the GINA does not apply to life insurance, disability insurance, long-term care insurance or other uses of genetic information. The GINA, then, only applies to asymptomatic people and although GINA prevents employers requesting genetic information specifically as a condition of employment, they can, under the Americans with Disabilities Act (1990) request all health records as a condition of employment (Rothstein, 2008; Slaughter, 2008). As such, the extent to

which anti-discrimination legislation is wholly effective is questionable (Martin and Dingwall, 2010).

In the UK, similar concerns about employment and insurance discrimination on the grounds of disease susceptibility are present with Tutton (2007a) noting that concerns around genetic discrimination partly underpin ambivalence to UK Biobank participation (also see Kerr *et al.*, 2007). Elsewhere, Joly *et al.* (2010) note that the UK insurance model takes a combined ‘moratorium/fair limit/rational discrimination approach’ where insurers do not request genetic information unless it is clinically significant and scientifically valid or the insurance policy is above a specific monetary amount. Moreover, Morris (2010) notes that UK insurers are bound by the Data Protection Acts of 1988 and 2003 to handle personal and medical information in the same confidential way as doctors. Her interviews with lay people in the Republic of Ireland highlight a concern that genetic information is too ‘personal’ to be shared with people and companies outside of the medical profession or the family. As such, despite legislative moves to restrict genetic discrimination, the nature of genetic information as a central facet of personhood continues to fuel concerns around privacy and confidentiality in genetic testing practices (Morris, 2010). It would also appear that as genetic testing increases in sophistication and, potentially, becomes more widely available in primary care and retail settings these concerns will become more acute.

Ethical questions about the use of PGx information also incorporate confidentiality issues when considered in the context of potential familial implications. The question of whether family members who may be affected by the results of a PGx test should be informed is a recurrent ethical challenge which is not adequately, or explicitly, addressed by the Data Protection Acts of 1988 and 2003. Knoppers (2011) argues that although the decision to have any genetic or PGx test should always be the decision of the individual patient alone, it ought to be acknowledged that the results are necessarily familial and, as such, the needs of and risks to, other family members ought to be taken into consideration during any genetic testing process. This ties in with Martin and Dingwall’s (2010) assertion that the nature of medicine itself is, ultimately, family or community medicine in which individuals cannot easily be separated from their social or cultural environments

given the genetic ties (and responsibilities) with which they are bound (also see Finkler *et al.*, 2003; Rapp, 1998; Rapp, 2000). The Nuffield Council on Bioethics (2003) note that such decisions around familial implications cannot be arbitrarily legislated and, instead, recommend that decisions about informing family members about genetic test results and risk should be taken by the healthcare practitioner involved in the testing and results counselling process based on the circumstances of each individual case.

What this section has demonstrated is that privacy and confidentiality issues are central to the ethical and social nature of PGx research and practice. These issues are inherently tied in with kinship and familial risk and, has been demonstrated above in the case of the Alzheimer's drug Tacrine, can have significant impacts on the clinical uptake of PGx testing in everyday clinical practice.

3.7.2 Inequality and Access

A second issue which has been prominent within sociological analyses of PGx is to do with inequality and access to biomedical innovation. Healthcare inequality is of central importance in medical Sociology and has a lengthy history within the discipline. The recent expansion of genomic medicine has generated a focus on the (in)equality of access to biomedicine and the ways in which existing patterns of (in)accessibility are reproduced in genomic practices.

To being with, Barash (2001) questions whether the resources allocated to PGx drug development in the wealthy West would be better spent on national and international public health concerns, such as the provision of clean water in developing countries, which she understands as being more 'urgent'. These sentiments are also echoed by Holm (2008) who questions how useful PGx will be for low- and middle-income countries where access to basic healthcare provisions is problematic. Global healthcare inequalities may, then, be reproduced through the apportioning of genomic research resources within wealthy Western countries. As a result, the chasm between Western 'lifestyle' diseases and those which are endemic in poor countries (see Trouiller *et al.*, (2001) for an overview) may widen as genomic interventions are identified for the former but neglected for the latter.

In contrast, Pang (2009) argues that PGx will in fact be useful for developing countries in providing genomic solutions to tropical diseases, problems associated with increased globalisation and by allowing these countries to make valid contributions to global expertise in this area. This final point is also echoed by Boulyjenkov and Schapper (2007) who argue that genomic variation research (they particularly note research in Mexico, India and Thailand) will allow developing countries to compete in the global knowledge economy as well as improving health in these countries. Although Boulyjenkov and Schapper's (2007) and Pang's (2009) papers provide useful counter-arguments to traditional views of PGx as out of reach of developing countries, these papers do not fully analyse the existing structures of inequality in these countries which place biomedical expertise and techniques out of reach of certain population sub-groups.

Other commentators have explored the potential for PGx to compound or transgress existing structures of 'race'¹¹ and race inequality in biomedicine and scientific research. Briefly, whilst some scientists argue that racial categories are a potentially scientifically valid and important way of categorising populations (see for example Ioannidis *et al.*, 2004; Shriver *et al.*, 2004), others argue that race is socially and politically constituted and is 'a proxy for socio-cultural, economic, and particular historical processes and experiences' (Lee, 2009: 1184). Race as a means of categorisation is a pervasive issue and was addressed in a 2004 special issue of *Nature Genetics* which examined the links between race, ethnicity and genetics. In interviews with the then editors of *Nature*, Smart *et al.* (2006) note that this special issue was produced as a way of addressing the potential measurement and communication problems raised by using race as a means of stratification. They identify two broad strategies for addressing these problems; continuing to use race and ethnicity for categorisation until these become scientifically obsolete or replacing racial and ethnic categories with alternatives based on socio-cultural and geographical ancestry. This first strategy bears similarities to Cooper (2003) who argues that genomic technologies could offer a way in which the contentious use of

¹¹ 'Race' has been acknowledged as a problematic term and is, as such, commonly presented in inverted commas (see Ware and Back 2002, Gilroy 2000). For stylistic reasons, 'race' is not presented in this way throughout the thesis.

race for characterising variations might be questioned and undermined. He notes that whilst genomics has identified variations between racial groups, it has also identified that these are minimal when compared with variations within population sub-groups and, so, race as a means of categorisation should be questioned.

However, contrary to Cooper's (2003) reflections in interviews with genetic scientists Ellison *et al.* (2008) found that the minor differences between racial groups identified by genomic science provided scientists with evidence of the importance and scientific validity of racial categorisations. As such, they argue that there has been a resurgence of race in genomic research where racial groups are redefined by these scientists as 'genetically-distinct subspecies', despite efforts to move to a more socio-cultural definition of 'ethnicity' (Williams, 2011).

In terms of PGx specifically, it has been argued that race is a poor proxy for PGx knowledge (Holm, 2008) and that race-based PGx risks 'medicalising' (Hansson, 2010), 'geneticising' (Ellison *et al.*, 2008) and 'molecularising' (Fullwiley, 2007) race. Fullwiley (2007: 21) argues that the structure of PGx science in the US compounds and reproduces racial distinctions through the recruitment, organisation, storage and comparison of DNA mandated by the National Institutes of Health (NIH). As such, racial distinctions are practised in everyday laboratory work without discussion or critique and scientists cultivate a 'racialised gaze' whereby DNA is labelled in racial terms before it is even extracted from the participants' body. Central to much of these sociological debates about race and PGx is the congestive heart disease drug BiDil, which was licensed by the FDA in 2005 for use in African-American patients only. As such, Duster (2007: 702) understands BiDil as the world's 'first racial drug' and argues that characterising drugs and drug responses along racial lines attributes health purely to biological factors and so risks overlooking the environmental inequalities, such as education, housing and nutrition, which can have significant effects on health (also see Kahn, 2005). Elsewhere, Duster (2005) argues that such racialised categorisation can lead to the simplistic construction of 'black' and 'white' diseases where large private companies are more likely to make profits on the latter owing to the, generally, greater wealth of white populations. This echoes Trouiller *et al.*'s (2001) work where they argue that

diseases found in developing countries are neglected by pharmaceutical companies who are likely to see larger profits from treatments of white, Western diseases.

Elsewhere, taking BiDiI as their point of departure, Tutton *et al.* (2008) interviewed PGx scientists and found that high throughput DNA technologies in both research and clinical settings may overcome racial categories as patients become defined by their allelic variations rather than their race-based genetic traits (also see Foster *et al.*, 2001). As such, Tutton *et al.*'s findings suggest that Cooper's (2003) vision of genomic techniques undermining racial categorisation may be a possibility.

Also central to the concerns around inequality and access to genomic medicine are concerns around the creation of a 'genetic underclass'. Writing some years ago, Nelkin and Tancredi (1994) argued that the widespread availability of genetic testing could mean the evolution of a class of people who are socially and politically marginalised and economically disadvantaged as a result of genetically-based discrimination (also see Emmott, 2011; Wilkinson, 2010). Most of the work examining this potential 'genetic underclass' has focused on the insurance and employment problems potentially faced by those identified as being at an increased risk of developing a disease (Evans, 2007; Lee, 1993, Mehlman and Botkin, 1998; O'Hara, 1992), although Jasny and Zahn (2011: 872) argue that such fears were 'much overblown' in the early days of genomic science.

As, primarily, a means to identify drug response variations, PGx testing does not have the same potential as regular genetic testing to contribute to the production of a supposed 'genetic underclass'. However, there is the potential for the creation of a '*pharmacogenetic* underclass' (Brown *et al.*, 2001: 52 (emphasis added)) whose drug reactions fall outside of those which are most common (Hansson, 2010). Elsewhere, Webster *et al.* (2004: 666) conceptualise this as creating 'orphan patients' (as opposed to orphan drugs) who are denied access to mainstream drugs because of their rare metabolism and reaction patterns (also see Robertson *et al.*, 2002). Wertz (2003: 194) notes that in countries without nationalised healthcare systems, legislation may be necessary to ensure the insurance coverage for those who are 'pharmacogenetically different'.

What this section highlights is that the ethical and social concerns and commentaries around PGx fit into a wider social science focus on the impacts of genomic medicine whilst also presenting a number of distinct ethical and social concerns related to PGx specifically. Within this, the ethical and social impacts for patients (or consumers) are, necessarily, central. What is not extensively analysed within these frameworks are the potential impacts of PGx, or genomics more generally, on the professional identity, status and everyday work practices of the healthcare professionals using them as part of their routine practice. Where social scientists have been concerned with the positioning of practitioners, they have tended to be concerned with genetic counsellors (for example Pilnick, 2002, Lehtinen and Kääriäinen, 2005) and, as such, the role of more generalist practitioners such as pharmacists, has been neglected.

Outside of the social science literature, there has been some speculative work examining the potential impacts of PGx on pharmacy practice but little of this has utilised empirical data or analysed the issue in sociological terms. Nonetheless, this work provides a useful entry point into understanding the potential impacts of PGx on pharmacy practice.

3.8. PGx in Pharmacy

PGx has been presented as the ‘next challenge’ for pharmacy practice (Clemerson *et al.*, 2006) where pharmacists are said to have an ‘essential role to play’ (Akthar, 2002: 299) in delivering PGx medicine in the future. Within this, PGx is understood as a way in which the work of supplying safe and effective medicines could be supported and extended by introducing gene-drug, as well as drug-drug interaction information into pharmacy (Clemerson *et al.*, 2006; Dotson Jagers, 1999; Ensom, 2001; Penick Brock *et al.*, 2003). Here, then, pharmacists’ expertise in the area of pharmacology is married with genomic techniques to improve the safety and efficacy of prescriptions in line with the promises outlined above (Hedgecoe and Martin, 2003). This expertise, moreover, is imagined as a way in which pharmacists might offer increased support to clinicians in the prescribing decisions (Johnson, 2002; Penick Brock *et al.*, 2003). In doing so, PGx is framed as a mechanism through which pharmacists can work more collaboratively with other healthcare

professionals and researchers (Cryan, 2004; El-Ibiary, 2008; Jagers, 1999; Maitland van de Zee *et al.*, 2004; Penick Brock *et al.*, 2003) and may, as a result become a more central part of what Petrakaki *et al.* (2012) call the 'NHS family'. In this way, PGx could be understood as a way in which the professional status of pharmacy, which in the community setting has traditionally been characterised by isolated practice models (Cooper *et al.*, 2009), may be shifted towards a (re)professionalised identity. PGx is, thus, identified by Streetman (2007: 2040) as a way to 'help the profession transition to the future'.

This potential for PGx to bring about a shift in the professional identity of pharmacy is also evident in works which posit pharmacists as healthcare practitioners vis-a-vis providing 'in-house' testing services (Clemerson *et al.*, 2006: 129) and advising patients on the clinical implications of PGx test results (Akhtar, 2002; Ellingrod and Moline, 2007; Streetman, 2007). In this 'logical progression' (Akhtar, 2002: 289) of the extended role, community pharmacists will potentially be positioned as genomic healthcare practitioners if PGx tests for common, primary care conditions become more mainstream. Sociologically, this can be understood as representing a move towards a more biomedicalised (Clarke *et al.*, 2003) form of pharmacy practice based on more technoscientific ways of knowing (Pickstone, 2000) medications and the patient body. This echoes Johnson *et al.*'s (2002) assertion that the integration of PGx into pharmacy will make the practice 'less of an art and more a science'.

Much of the literature in this area has, then, been fairly optimistic about the role of pharmacists within PGx practice. In contrast to this, Morley and Hall (2004) are sceptical about the practicalities of community pharmacists' involvement with PGx given the current structures of practice which mean that the storage and utility of patient PGx information is problematic given that (i) patients do not have one dedicated pharmacy from which they collect all prescribed medicines and (ii) community pharmacists receive very little patient-specific information to assist them with the safety aspects of the dispensing process. Integrating PGx into community pharmacy practice, they argue, would necessitate a significant and impractical restructuring of the primary care practice structure primarily based on pharmacists' increased access to patient medical information. This issue has, however, previously

been approached with consternation by members of the UK Patients Association who demonstrated a clear belief that community pharmacists were not in a position to be able to claim legitimate access to such confidential information (The Patients Association, 2008). Two primary strategies to overcome this are found in the literature. Firstly, Maitland-van der Zee *et al.* (2004) propose a software-based approach where PGx test results are included on patient prescriptions and can be cross-referenced with gene-drug information software which ought to be available in all community pharmacies. Secondly, medical identification cards containing information about patients' genetic profile, prescription history and external risk factors, such as smoking and drinking habits may be an alternative to a full medical record in the pharmacy setting (Akhtar, 2002; Maitland-van der Zee *et al.*, 2002). Access to such information raises questions around pharmacists' knowledge of issues of privacy and confidentiality and the risks of other pharmacy staff coming into contact with sensitive information about patients. Moreover, the assumption that pharmacists want access to such patient information should not be too readily made. This issue of medical record access is returned to in the later empirical chapters.

Elsewhere, Alcade and Rothstein (2002) identify ethical, social and educational implications as potential challenges to the full implementation of PGx into pharmacy practice. They also argue that PGx will present increased challenges for pharmacists in their dispensing activities as the greater range of drug dosages mean that there will be an increased risk of prescribing and dispensing errors which will place more responsibility for spotting mistakes on pharmacists who are already overburdened by their workloads.

Alcade and Rothstein's (2002) focus on the educational challenges of integrating PGx into pharmacy sits within a wider body of work on this topic (Clemerson *et al.*, 2006; Cryan, 2004; Newton *et al.*, 2007). The extent to which PGx is currently incorporated into pharmacy training is difficult to accurately measure although there is a general agreement that pharmacists' present knowledge of this area is 'relatively poor' (Streetman, 2007: 2040) owing to the limited PGx teaching pharmacology students receive during training. As an indication, in a survey of nineteen UK medical schools, Higgs *et al.* (2008) found that, in 2005, 84% of the institutions surveyed provided some PGx training, although this varied

between less than 1 hour and 8-12 hours of teaching in this area throughout the course of the degree, despite the International Society of Pharmacogenomics' (ISP) (Gurwitz *et al.*, 2005) recommendation that medical students receive a minimum of four hours of pharmacogenetic teaching. The extent to which pharmacy students are taught PGx in the UK is under-explored but, in the US context, Figg and Cox (2003) found that only 5 out of 85 pharmacy schools offered any form of genetics education, leading them to question how far graduating pharmacists will be able to engage with future (pharmaco)genetic medicine if they do not possess an adequate grasp of the basic principles of genetics. These concerns around pharmacists' education in PGx medicine have also been voiced in the UK where Burton and Shuttleworth (2003) noted that although genetics was present in some areas of the UK undergraduate curriculum, it was not prioritised during preregistration training or professional development. Following recommendations from the UK Department of Health's White Paper *Our Inheritance, Our Future* (2003a), the National Genetics Education and Development Centre (NGEDC) was established in 2004 with a specialist dedication to pharmacy education in British universities. In 2007 this centre, in collaboration with the Royal Pharmaceutical Society of Great Britain (RPSGB; as was) published a report which highlighted the need for increased PGx education for undergraduate, preregistration and more experienced pharmacists (Newton *et al.*, 2007). In this report, Newton *et al.* (2007) highlighted the need to implement specialist PGx training (for example, Oncology pharmacists will require specialist knowledge of family history methodologies whereas this will not be as relevant for generalist community pharmacists) which is relevant to contemporary and immediate future practice since pharmacists may not see PGx as wholly relevant at the moment.

Important here is what the potential implications of this relative lack of engagement with (pharmaco)genetic principles may be for pharmacy. Fargher *et al.* (2007) conducted semi-structured interviews with patients and healthcare professionals and identified a problematic gap between patients' high expectations of PGx test results and healthcare professionals' limited literacy in PGx principles. This could affect how far patients understand pharmacists as important practitioners in their PGx experiences, which could affect pharmacy's claims to a legitimate role within the PGx medical team (Streetman, 2007).

What is shown here is that the particularities of integrating PGx into pharmacy practice have been explored elsewhere but little of this has taken a sociological perspective. Ryan *et al.* (2004: 51) argue that since pharmacists are likely to be ‘at the forefront’ of PGx medicine, it is important to develop a sociological understanding of the ways in which pharmacy constructs PGx and the ways in which PGx may (re)construct pharmacy. This acknowledges that within previous papers looking at PGx in pharmacy, the nature of pharmacy and its patients is somewhat taken for granted. Hence, whilst Morley and Hall (2004) identify the need for a restructuring of community pharmacy practice in light of the demands of PGx, there is a paucity of work undertaken to ‘map’ the actual nature and lived experience of this work structure. This thesis addresses this gap in the literature.

3.9 Conclusion

In sum, this chapter has located PGx within the genomic turn in biomedical research and practice which arose from the HGP in the 1990s. Within this, PGx is understood as one of the key applications of the data and technologies arising from this Project and has, more recently, started to make inroads into clinical practice through specialisms which are characterised by particularly problematic ADRs (such as Oncology). It has been demonstrated here that PGx is central to contemporary social science reflections on genetic medicine more generally, and the implications of PGx specifically. Within this field, the ethical and social implications of PGx are shown to be different from those in more general genetic medicine but, nonetheless, central to the PGx story.

The chapter finished by highlighting previous work which has considered the specific nature of PGx in pharmacy. Here it was shown that although these reflections provide a useful platform from which to begin an analysis of PGx in pharmacy, the lack of empirical data and social scientific analyses are areas which need addressing.

Although the sociological and scientific reflections on PGx in drug development and clinical practice are fairly extensive, there are a number of areas in

which these analyses are limited. Firstly, the patient body has a limited presence within sociological understandings of PGx. Although some sociologists have focused on what might be understood as a racialised body, the body is mostly constructed as a space in which the genome resides and, subsequently, an object to which tests are done, medications are administered and within which PGx research is carried out. As such, sociological analyses have tended to view the patient body as a tacit element of PGx without extensive analysis of how this body is brought into being in research and clinical settings involving *medicines*, compared with the considerable body of work on the sociology of *medicine*.

Secondly, there has been no social science research undertaken exploring the role of pharmacists within PGx practices. This is despite pharmacists being involved in drug development processes (with 4.1% of active pharmacists being employed in industry), pharmacists being the dispensers of PGx drugs within hospital settings, hospital pharmacists being involved in PGx clinical trials (especially in Oncology) and community pharmacists being likely to be increasingly familiar with PGx if these personalisation and stratification principles continue to be applied in drug development. This lack of social science research also extends, as mentioned above, to a lack of research examining the nature of the contemporary pharmacy practice landscape into which PGx technologies may be integrated.

Thirdly, there is a lack of focus on the micro-level (re)organisation of everyday work practices to define and accommodate PGx. Specifically for this project, there has been no work done examining the micro-level work undertaken in hospital and community settings to integrate PGx practices. Hence, whilst the reflections on PGx in pharmacy presented in this chapter highlight the implementation of PGx into pharmacy *as a whole*, there is a lack of research examining the ways in which this comes to played out in everyday practice and interactions. Moreover, an investigation of the effects of integrating PGx into pharmacy practice vis-a-vis professional identity, status and autonomy as outlined in Chapter Two, seems timely.

Given this, then, the following research questions have been identified from the literature outlined in this chapter;

- How is the patient body configured by PGx in clinical practice?
- How might pharmacists be involved in PGx? And what might be the impacts of this?
- How might the contemporary pharmacy landscape be sociologically mapped?
- How is everyday work in pharmacy settings (re)organised to integrate PGx practises?

Findings from the empirical data are key to answering these questions in the later analytical chapters. The thesis now turns to an examination of the theoretical frameworks which are mobilised in analysing the qualitative data collected. Within the next chapter, then, the sociology of the body and May and Finch's (2009) NPT are highlighted as being of central importance in answering the research questions which have been identified in Chapters Two and Three.

Chapter Four: Theoretical Insights

4.1 Introduction

The empirical chapters in this thesis develop a novel framework within which to analyse contemporary pharmacy practice and the integration of technologies and PGx into it. This novel framework draws on a number of theoretical notions presented in the academic literature, broadly related to the sociology of the body and the process of integrating new technologies into medical practice.

Chapters Two and Three both concluded by noting that sociological work in the areas of pharmacy practice and PGx has tended to neglect the patient body. This thesis argues, however, that the patient body is a central component of pharmacy practice and in examining the construction of the body in pharmacy addresses this gap in the literature. This chapter, then, outlines the theoretical framework of the sociology of the body with particular attention to Foucault's 'clinical gaze' which forms a key starting point for the later analysis.

It is shown here that central to sociological understandings of the body are new medical technologies and the terms in which they configure it. Despite this, the micro-level interactional work undertaken to integrate technologies into everyday practices and discourses is neglected within sociology despite being noted as an area of interest some years ago (Kinmonth *et al.*, 1998). In order to analyse the micro-level interactional work involved in integrating PGx into different pharmacy settings, May and Finch's (2009) NPT is identified as a useful framework which is mobilised as a tool for data analysis in the empirical chapters.

4.2 Centring the Patient Body

The body is subject to much contemporary sociological attention, so much so that Williams (2003: 3) notes that 'many bodies...now roam the sociological landscape'. Within this, Nettleton (2010) posits three key sociological approaches to the body; the regulation of the body, the ontology of the body and the lived experience of the body (embodiment). Pervasive throughout these approaches is the notion of 'medicalisation' which emerged in the mid twentieth century from neo-Marxist

perspectives and centres on the increasing power and influence of contemporary medical science and its practitioners. This perspective understands society and bodies within it as being increasingly subject to control by the medical profession and ‘facts’ about society being increasingly constituted through medical knowledge and expertise. Within this, medicine is understood to have taken on the regulatory role previously occupied by religion and law (Zola, 1972). In doing so, Ivan Illich (1975) argued that medicine severely diminishes lay people’s capacity to exert autonomy over their own health, bodies and wellbeing and, paradoxically, undermines health through this diminished autonomy and the side-effects produced by contemporary blockbuster medicines.

Through these seminal writings medicalisation was posited as a negative phenomenon where, as Lupton (1997: 97) puts it, ‘to be ‘medicalised’ is never a desirable state of being’. Proponents of this medicalisation critique argue for ‘de-medicalisation’ as a tool of resistance where challenging doctor’s decisions, joining patient groups and seeking the expertise of complementary and alternative (CAM) practitioners are emphasised. As an example, Lindenmeyer *et al.* (2011) identify a ‘political-critical’ approach in women’s uses of CAMs for menopausal symptoms where utilising the expertise and products of CAM is understood as a way of critiquing and resisting the power of mainstream medicine over the female body.

At the core of the medicalisation critique is the proposal that increasing medicalisation constructs the body in medicalised terms where ‘social’ issues become redefined as ‘medical’ issues (Conrad, 1992). Scull (1975) and Schneider (1978) provided examples where mental illness and alcoholism entered into the jurisdiction of the medical profession and, thus, became subject to medical control. Within this, the body is understood to become subject to increasing surveillance, definition and enhancement by expert medical practitioners where expert knowledge is increasingly given precedence over embodied experiences. Pregnancy, as a highly medicalised bodily experience, is a key example where expert knowledge and ultrasound images of the foetus have displaced women’s embodied experiences of their own pregnant bodies where being pregnant only becomes ‘real’ when it is defined and represented in clinical terms (Duden, 1993). Given its focus on

discursive construction, surveillance and control, links can be seen between the principles of medicalisation and the work of Michel Foucault.

4.3 From Medicalisation to Biomedicalisation: Redefining Body Boundaries

More recently, the medicalisation critique has been questioned in the context of developments in scientific research and medical practice. Conrad (2005) argues that changes in medical knowledge and organisation have engendered a shift in the 'engines' driving medicalisation. He argues that patients acting as consumers, increasing managed care organisations in the USA and the dominance of the pharmaceutical industry have all become new 'engines' driving contemporary medicalisation. Within this, genetic medicine is positioned as occupying a central place in pharmaceutical companies' agenda of medicalisation. As such, he argues that genetic testing has the potential to medicalise social, but (potentially) genetically-based body-specific 'problems' such as baldness and obesity. This, he argues, may lead to demand for genetic enhancement of bodies and may also create a new category of patients which he describes as the 'potentially ill' (Conrad, 2005: 8)

Whilst Conrad (2005) understands the contemporary organisation of medicine as *shifting* medicalisation, Clarke *et al.* (2003) understand this organisation as *transforming* medicalisation. They argue that increasingly 'technoscientific' approaches and methods in research and clinical practice mean that older practices in medicine, what may be labelled as medicalisation practices, become displaced by more technoscientific innovations and approaches which seek to control the *interior* of the patient body. As such, these technoscientific developments are understood to involve a more molecularised construction and management of the patient body than in previous medicalisation processes. Within this biomedicalisation thesis, developments in genomic science are key to contemporary constructions of, and alterations to, the body. As such, they suggest that genomic biomedical science and practice are engendering a move away from the 'normalisation' of bodies to their 'customisation'. Within this customisation, individualised gene therapies and PGx are understood as ways in which genomics focuses on changing (or in the case of PGx, targeting medicines to) individual bodies rather than universalising bodies

through, for example, one-size-fits-all drug development and prescribing. They argue that this move away from bodily homogeneity in medicine has created multiple ‘technoscientific identities’ (Clarke *et al.*, 2003: 182) wherein bodily identities are created through the application of technoscientific methods.

Gross and Shuval (2008) note that this move from medicalisation towards increasing biomedicalisation has recreated the terms through which bodies, and their pathologies come to be known and defined. As such, they argue that whereas medicalisation was centred on the process of *diagnosis* (meaning through-knowing), biomedicalisation is centred on *prognosis* (meaning before-knowing) and the definition of the body in terms of the risks presented by, and to, it. Elsewhere, the characterisation of contemporary society in terms of risk has been well documented with Beck (1992) and Giddens (1999) perhaps being the most pervasive scholars within this tradition. Within contemporary risk society, it has been argued, the body becomes a site within which risks may be manifested and through which risks need to be managed. Biomedicalisation, then, focuses on the maintenance of health and the minimisation of potential risks rather than the fighting of acute illnesses when they occur. This maintenance of health is, elsewhere, argued to be an individual social and moral responsibility within which the maintenance of an individual’s health becomes beneficial for the health of society as a whole (Bunton *et al.*, 1995).

Central to such health maintenance projects, Clarke *et al.* (2003) argue, is surveillance medicine (Armstrong, 1995). Within this, surveillance and risk are understood to co-construct each other with surveillance being necessary in instances of increased risk and increased risk being identified through surveillance. This risk is understood as being increasingly constructed through technoscientific tests for understanding the patient body where such tests construct both epidemiologically and individually significant results where, for example, ‘high risk’ breast cancer patients are offered interventions for the breast cancer which they do not have yet. Clarke *et al.* (2003) position such risk and surveillance practices within the disciplinary nature of the Foucauldian clinical gaze and argue that genomic and profiling technologies represent the ‘next wave’ of risk assignments.

This salience of risk discourses leads to the development of ‘uncertain bodies’ where new medical and health technologies increasingly construct bodies in uncertain terms. Hence, emerging medical technologies are shifting the boundaries of what bodies actually *are*. Elsewhere, this has been characterised as ‘reordering life’ (Brown and Webster, 2004) and leading to the development of ‘cyborg’ bodies (Balsamo, 1996; Haraway, 2000), constituted by a marriage of human organisms and machines; the cyborg body, then, is part-human, part-machine on account of the technologies which have variously enhanced, altered and acted upon it. For Shilling (2003; 2005) this blurring of body boundaries through new technologies represents a key paradox; whilst expertise and knowledge of the body is increasing through these technologies, certainty about what the body actually *is*, what its boundaries are and what it might be in the future is decreasing.

4.4 Foucault and the Body

The work of Michel Foucault is central to the medicalisation and biomedicalisation theses and the sociology of the body more generally. Lupton (1997: 94) notes that whilst Foucault and his followers have not necessarily subscribed to the visions of power and dominance presented within the medicalisation critique or mobilised the term ‘medicalisation’ specifically, they nonetheless represent a ‘vision of a world in which individuals’ lives are profoundly experienced and understood through the discourses and practices of medicine’. In *The Birth of the Clinic* (1975), Foucault argues that medical paradigms have developed over time and have provided frameworks through which bodies have been defined, understood and experienced. According to Foucault, then, medical expertise and power is the framework through which bodily pathologies are identified and dealt with in various epochs of history¹².

A point of departure between Foucauldian perspectives and those forwarded by proponents of the medicalisation critique is the existence of an ‘authentic’ human body. Whilst the medicalisation critique understands the body as being an essential object, albeit a socially and politically constituted one, Foucauldian analyses understand the body and its component parts as being constituted *only* through

¹² Tentative links can perhaps be made here between Foucault’s ideas and those found within Pickstone’s (2000) way of knowing presented in Chapter Two

discourses and practices through the ‘clinical gaze’ which is exerted by medical practitioners. This clinical gaze is used by Foucault to describe the ways in which medical practitioners from the eighteenth century onwards became increasingly focused on the observation of patient bodies as a series of symptoms and signs to be managed through discourse and practice (Armstrong, 1997). Unlike in the medicalisation critique, medical power is not imagined in Foucauldian terms to be consciously cultivated and reproduced by medical practitioners but is, instead, regarded as a form of disciplinary power within which medical practitioners mobilise their clinical gaze to observe individuals and compare them against the ‘norm’ in order to arrive at a diagnosis.

Foucault’s notion of the clinical gaze is pervasive within sociological analyses of the body and a full representation of the span of its employment would be impossible here. However, the notion of a practitioner gaze has previously been empirically employed where the characterisation of a ‘nursing gaze’ has been developed (see Gastaldo and Holmes, 1999; Henderson, 1994; May, 1992). As an example, May (1992) highlights the ways in which the nursing gaze is employed as a way to ‘know’ patients, their bodies and their clinical needs. He suggests that nurses develop foreground and background knowledge of patients, the former of which establishes a clinical definition of the body and the nursing work which it necessitates whilst the background knowledge constructs patients as private idiosyncratic subjects upon which appropriate nursing work is carried out. The structures of nursing work (for example, being based on wards, having more time than doctors to talk with patients and building more personal relationships with patients) and their relatively subordinate position within hospital divisions of labour are posited in May’s (1992) paper as facilitating the development and employment of this specific nursing gaze. In the case of pharmacy, Ryan *et al.* (2004) argue that a Foucauldian analysis of pharmacy could be employed in a number of ways such as an examination of discursive construction of pharmacy in different countries, the power relations within healthcare teams and the position of the body in pharmacy vis-a-vis medications adherence practices.

Barber (2005) argues that pharmacists employ a ‘pharmaceutical gaze’ in their everyday practice given their ability to ‘see’ the properties of medicines and

their potential effects. Despite employing a Foucauldian framework to analyse pharmacy, however, he suggests that pharmacy practice ‘is not based on parts of the body...manipulating, cutting or caring for the body’. It is argued below, and demonstrated throughout the later empirical chapters, however, that in fact the body is central to pharmacy practice as Ryan *et al.* (2004) suggest. Nonetheless, Barber’s (2005) tentative employment of the Foucauldian gaze perspective highlights its widespread applicability.

Despite this widespread application of Foucauldian perspectives, his understanding of the body as ‘totally imprinted by discourse’ (Butler, 1990: 130) and having no ‘essential’ physical qualities (see Nettleton, 1992) has provided the basis for critiques of his construction of ‘docile bodies’ subject to, but unable to challenge, the clinical gaze. As such, in Foucauldian terms, to attribute agency to a body would be to provide it with some essential qualities which is in opposition to Foucault’s idea of body being wholly constituted through discursive practices. Bodies, then, must lack agency on account of their wholly discursive constitution. To proponents of the medicalisation perspective such an understanding of the body is problematic as this limits the capability of the patient body to exert agency and resist medical power. This construction of docile bodies also presents a paradox within Foucault’s own terms where he purports that ‘power, after investing itself in the body, finds itself exposed to a counter-attack in the same body’ (Foucault, 1980: 56), suggesting that power itself generates resistances. The contradiction, then, comes from the inability of docile, discursively constructed bodies to exert resistance to power. Within this Foucauldian understanding of the body it becomes ‘futile’ (Armstrong, 1997: 21) to speculate on any essential features that the body might have. This understanding of the body, it is argued, is challenging for sociologists to effectively engage with as sociological analyses are more often premised on a body which represents an interface between elements such as the biological and the social; the collective and the individual (Fox, 1997: 41)

Foucault’s influence on the work examining the sociology of the body is empirically wide and theoretically deep and only its very surface can be scratched here. Nonetheless, the overlaps between increased (bio)medicalisation and Foucault’s clinical gaze are important here as new technologies redefine bodies

through altered practitioner gazes. This is reflected on in more detail in the case of PGx in the later empirical analysis.

4.5 Positioning the Body in Pharmacy

Despite the centrality of the body to sociological analyses of contemporary health and medicine practices, Chapters Two and Three noted that the body has been markedly absent from analyses of pharmacy practice and PGx research and clinical practice. Ryan *et al.* (2004) suggest that a Foucauldian analysis of pharmacy practice is necessary, although little empirical work has been subsequently forthcoming from within Sociology. As mentioned, they propose a number of ways in which pharmacy might be subject to a Foucauldian analysis such as an analysis of the discursive construction of pharmacy across different countries, a focus on the power relations between pharmacists and other practitioners working collaboratively and a focus on the positioning of the body within pharmacy.

In the later empirical chapters, this thesis analyses the construction of the body within pharmacy practice and the ways in which it might be altered by the integration of PGx technology. In doing so, the thesis takes Foucault's 'clinical gaze' and Barber's 'pharmaceutical gaze' as its points of departure to posit the novel concept of the 'pharmacy gaze' where the patient body and the medications administered to it are argued to be co-constructed through a focus on the management of risk and toxicity based on pharmacists' pharmacology expertise. In doing so, this thesis goes some way to addressing a gap in the academic literature where Ryan *et al.* (2004: 50) argue that pharmacy 'has not been subjected to a Foucauldian exploration'

4.6 New Technologies in Healthcare

The medicalisation and biomedicalisation theses outlined above are premised on the increased availability and use of new medical technologies. More latterly, the move towards biomedicalisation posited by Clarke *et al.* (2003) is underpinned by an increase in genomic technologies in medical research and practice. Hence, medical innovations are central to the (re)constitution of patient bodies in practice. Despite this, there is limited sociological attention given to the ways in which new innovations

are integrated into everyday medical practices. Whilst there is a wealth of literature within what might be labelled the *diffusion theory* body of work dealing with innovation integration within a macro structure, there are few sociological frameworks which deal with the micro-level interaction and work which occur to integrate new technologies into routine practice structures. Given this, May and Finch's (2009) NPT is identified as a useful framework for an analysis of qualitative data pertaining to the integration of PGx in hospital and community pharmacy settings because of its focus on the micro-level work undertaken to define and integrate new innovations into routine practice and capture the effects of new innovations at this micro-level. What follows here is a rationale for use of this framework as a key reference point in the later empirical chapters.

4.7 Defining 'Innovation'

Despite increased academic interest in technology and innovation, there has been 'little attempt to define the actual nature of innovation' (Osborne, 1998: 1133). Rogers (2003: 12) defines innovation as 'an idea, practice, or object that is perceived as new by an individual or other unit of adoption'. Within this definition, innovation does not have to *be* new, only perceived as such by those employing it. As such, innovation may as easily be a reconfiguration of existing ideas or technologies as a new category or paradigm (Van de Ven, 1999).

According to Greenhalgh *et al.* (2005) this definition is useful for analysing the behaviour of individual innovation adopters, but not as useful when the process of adoption by organisations is considered since innovation tends to only be considered in this way within organisations when it precipitates a structural or systematic change. Hence, people within organisations need to go beyond simply perceiving an innovation as new, 'they must *do* something-adopt new roles, make different decisions, form new relationships, use new technology, develop new systems and so on' (Greenhalgh *et al.*, 2005: 26 (emphasis in original)). Osborne (1998) proposes a typology of innovation which addresses this oversight by extrapolating the key characteristics of innovations. He argues, then, that there are four core characteristics which are central to innovation;

1. An innovation represents newness in terms of the first use of a piece of information.
2. An innovation is not the same thing as invention; the latter is concerned with the discovery of new ideas whereas the former is concerned with their application.
3. An innovation is both a process and an outcome whereby innovating and innovations it produces can both be studied.
4. An innovation involves discontinuous change for both the beneficiaries and developers of innovation.

For Osborne (1998) this final point is the key issue which differentiates innovation within an organisation from incremental change outside of it whereby such organisational innovation represents a paradigmatic shift (see Tushman and Anderson, 1986). In other words, discontinuous innovation within organisations can be understood as representing a paradigmatic shift in thinking and practice and can be located with something of a ‘catastrophe model’ (Herbig, 1991) whilst innovation outside of organisations tends to occur as a more incremental change based on the decisions of individual actors.

Writing some years ago, Damanpour (1996) distinguishes between ‘product innovations’, which are new physical technological artefacts, and ‘process innovations’, which are additions to administrative and service processes, which are in place to produce a product or provide a service. Identifying technological product innovations is relatively easy compared with constructing a definition of process innovation given that processes are fluid irrespective of innovation and many product innovations also require process innovations (see Westphal *et al.*, 1997).

PGx can be understood as straddling Damanpour’s (1996) product and process innovation categories by requiring a shift in pharmacists’ working practices (process) to accompany the technological artefacts of PGx testing kits (product). Moreover, PGx could be understood as representing something of a paradigmatic shift for pharmacy in line with Osborne’s typology of innovation, as genetic medicine in general, and PGx more specifically, has previously not been central to pharmacy education or practice. However, the discontinuity of PGx in pharmacy should not be overstated given that the integration of PGx across pharmacy settings

and specialist areas is not experienced as a universal paradigmatic shift. In other words, whilst the successful integration of HER2 testing could be understood as something of a paradigmatic shift towards a more genetic configuration of breast cancer and the patient body, the lack of pre-prescription testing for primary care drugs means that such a shift in approach has not occurred in the community pharmacy setting. Hence, a universal paradigm shift in pharmacy is unlikely given that PGx innovations are developed in different medical fields at different times.

Nonetheless, the shift towards an increasingly molecularised approach in pharmacy can be linked with Pickstone's (2000) 'ways of knowing' framework whereby the increased presence of genetic information in pharmacy can be understood as a shift towards a more technoscience way of knowing. Moreover, this also represents a shift towards an increasingly biomedicalised patient body within pharmacy (Clarke *et al.*, 2003).

These attempts to define what is meant by innovation all highlight the socially constructed nature of technologies which underpins STS approaches. Surry and Farquhar (1997) argue that philosophical approaches to technologies as social objects can be located at different points along a continuum of understandings of technology. In this, technological determinism, whereby technologies are understood as being a key driving force behind social change, and social essentialism, whereby technologies are understood as 'blank slates' on to which social meanings are projected, are located at opposite ends of this philosophical spectrum (see Timmermans and Berg, 2003).

Where technological determinism and social essentialism are flawed because of their positions at the extreme ends of the construction of technology continuum, STS approaches, Timmermans and Berg (2003) show, highlight a reciprocal relationship whereby technology is viewed as neither a blank slate or a 'super' actor, but as one actor among many in the continual reconfiguration of the social and technical order. Within this, the social system shapes the design, use and understandings of technologies and technologies, in turn, shape the social interactions and environment around them. As such, STS approaches are concerned with science and technology in action (see Latour, 1987) and keep the question of

what technologies do, and how they accomplish things, open (Timmermans and Berg, 2003). This inevitably leads to a broad definition of technologies which incorporates a spectrum of mundane to highly sophisticated devices, instruments and regimes where individual technologies cannot easily be singled out for investigation since they are entwined with and embedded into relations of other tools, practices, groups, professionals and patients (Timmermans and Berg, 2003: 104).

Such social constructivist approaches, then, are offered as a direct critique of technological determinism where the co-constitutive nature of technology and society is centralised. Within this, both 'failed' and 'successful' technologies and scientific knowledge become empirically important rather the latter being discursively framed as a matter of 'truth' (see Bloor, 1991). As an example, in their seminal article Pinch and Bijker (1984) apply this methodological symmetry to analysing the development of the bicycle and trace the social dimensions underpinning the success of some bicycle designs and the failure of others. Within this, the role of different social groups in shaping technology and its meanings are central. Whilst the users or consumers of given artefacts are the most obvious social group to consider, social groups who are not users also have a role in shaping the social meaning of artefacts. Additionally, Pinch and Bijker (1984) note that social groups which have a relationship with an artefact (both users and non-users) should not be homogenised under broad and inadequate headings but should rather be subdivided into specific categories. Here, they use the example of women cyclists who, during the nineteenth century, were only permitted to use certain types of bicycle and not others. By sub-dividing the social group of users along the axis of gender, certain stages of the bicycle's development can be more fully documented and explained.

By identifying all of the social groups which are relevant for a particular artefact, its development can be traced through an examination of the specific problems it presents for these different social groups. This continual negotiation of problems and solutions by interested social groups leads to continually increasing and diminishing degrees of stabilisation across various groups as problems, which can be technical, judicial or even moral, are solved for different groups and different phases.

In terms of relating this to PGx, this thesis takes an STS view of the devices and artefacts within this paradigm of practice. As such, the thesis takes the perspective that these artefacts are social and political objects which are neither completely ‘blank slates’ nor super technologies with extensive organisational power. Instead, the thesis demonstrates that PGx technologies are constructed, and experienced, differently across different pharmacy settings and medical specialisms. Hence, PGx technologies are constructed by the settings into which they are integrated and, concurrently, these settings and the work which occurs within them are co-constructed by these technologies.

Given this, the thesis is concerned with the micro-level work which is undertaken to define and accommodate these technological artefacts into everyday practices and the effects that this has on changing practices and the patient bodies within them. As such, the thesis departs from traditional diffusion of innovation theories which have tended to focus on the macro-level work undertaken to implement technologies into large scale structures and organisations.

4.8 Moving Away From Diffusion Theories

Everett Rogers (2003) is perhaps the best known innovation diffusion theory scholar and draws on ‘diffusion stories’ (Swanson, 2001) from various sociological traditions to present a comprehensive model of the ways in which new innovations are diffused throughout a social system. Briefly, Rogers (2003) argues that there are four key elements in the diffusion of innovations; the innovation itself, the communication channels through which messages about innovations are communicated, the timeframe within which innovations are adopted and the social system into which innovations are adopted. For Rogers (2003) diffusion is the process whereby an innovation is communicated through particular channels within a social system over a certain period of time, which feeds into the rate at which innovations are adopted. Also underpinning this, he argues, is the categories of adopters where ‘innovators’ tend to adopt early and launch new ideas within a given social system whilst, at the other end, ‘laggards’, who have been compared with nineteenth century Luddites (see Jones, 2006), are the last to adopt a new innovation given its discontinuation with existing technologies and routines.

Such diffusion theories are normative and linear in their understanding of the implementation of innovations. As the cases of the integration of PGx tests for Herceptin and Tacrine into routine clinical practice outlined in Chapter Three showed however, both innovations which are widely adopted and those which are not are highly dependent on the play of social processes and contexts. As such, whilst diffusion theories may see the failure of integration as symptomatic of, for example, a communications failure, these two case studies demonstrate the ways in which the social discourses surrounding innovations are manifested in this diffusion and integration process. Traditional diffusion of innovations theory has also been critiqued elsewhere.

Bayer and Melone (1989) argue that diffusion theories fail to provide a precise definition of the term ‘adoption’ or clarify how far this term extends. In classical diffusion research, then, adoption is conceptualised as a binary phenomenon- an actor either adopts or does not adopt an innovation. Hence, partial-adoption, reinvention, rejection and discontinuation are under-emphasised. Greenhalgh *et al.* (2005) argue that this ‘pro-innovation’ bias conceptualises the artefact as a fixed phenomenon and does not provide adequate room for processes of reinvention and modification. The interpretive flexibility of STS approaches remedies this issue by focusing on both successful and failed adoptions. Using STS to document the development and diffusion process of an innovation presents ‘an alteration of variation and selection’ whereby the multi-directionality of the approach is central (Pinch and Bijker, 1984: 411).

Early diffusion research also failed to adequately address the consequences of innovation and this has led to the inadequate appreciation of the different socioeconomic consequences of innovation within a given social system and between different social systems (Greenhalgh *et al.*, 2005). For example, Mossberger *et al.* (2003) show that as information technology became more widely diffused and increasingly ubiquitous, the ‘digital divide’¹³ opened up on different fronts whereby

¹³ Mossberger *et al.* (2003: 1) define the ‘digital divide’ as a conceptual tool for describing ‘the patterns of unequal access to information technology based on income, race, ethnicity, gender, age and geography’.

the inequality of computer access becomes too simplistic a framework for analysing digital inequality. They argue that as information technology passes through the innovation diffusion process, inequality of digital access becomes extended to inequality of skills; inequality of economic opportunity; and an inequality of democratic opportunity. As such, whilst traditional diffusion theory might conceptualise the ubiquity of computers as a successful innovation story, the social, economic and political consequences and meaning of this success are overlooked.

Individual-blame bias is also identified as a conceptual flaw in diffusion theory whereby adopters are categorised based on mathematical formulae rather than psychological or socioeconomic characteristics and micro-level interactions. Instead, adopters' socioeconomic or psychological characteristics are attributed to them once their place on the S-curve of adoption has been established. This assumes that individuals who adopt late are at fault for doing so rather than being either economically unable, or psychologically unwilling, to do so. These adopter categories are, for Bayer and Melone (1989: 165), 'arbitrary in the abstract'.

Diffusion theory often neglects the importance of context for differential adoption rates (Greenhalgh *et al.*, 2005). Hence, although studies may present a rigorous and systematic overview of the adoption of an artefact within a particular context, these findings may not be applicable to other artefacts or contexts. Resonances can again be seen here with the Herceptin and Tacrine case studies presented in Chapter Three. Within this, the clinical context of dementia and cancer treatments contribute to the extent to which these therapies are defined as useful and used in everyday practice (Hedgecoe, 2008a). Relatedly, diffusion studies tend to concentrate on one aspect of diffusion at a time (i.e. the individual as an adopter *or* the organisation as an adopter). Bayer and Melone (1989) echo this and argue that although an innovation may have been adopted by an organisation, this does not necessitate it having been fully accepted or adopted by those within that organisation. Instead, Greenhalgh *et al.* (2005) argue that a 'whole-systems' approach to innovation diffusion research would be beneficial whereby the various levels and systems involved in all stages of the innovation diffusion process are examined within the same research programme. The later chapters in this thesis

demonstrate that the integration of PGx in pharmacy encompasses processes at both the organisational and individual practice levels.

In another critique, the methodology of traditional innovation research is identified as being problematic. Since time is a central tenet of diffusion theory and research, it necessarily relies on research participants recalling their experiences of adopting innovations, which Haider and Kreps (2004: 8) argue carries an inevitable risk of gathering incorrect data as ‘many persons cannot recall what they had for dinner... never mind looking back in order to recall past history with innovation experiences’. Garud and Rappa (1994) and Latour (1987) note that a central tenet of the STS co-evolution paradigm is the ‘contemporaneous’ study of technological development, which allows scientists and stakeholders to be observed and followed through the innovations’ invention, development and diffusion rather than relying on data gleaned from memory alone.

In the context of the present research, diffusion theory can also be critiqued for failing to distinguish professionals as a distinct sub-group of adopters or users. Hence, whilst individuals within a social system are relatively autonomous in their innovation decision making and whilst individuals within an organisation are relatively controlled by, and restricted to, their organisations’ approach to innovation, professionals exist somewhere between these two poles. As such, a professional may have the autonomy to decide when and how a given artefact is used within their everyday practice, but this artefact can only be used once it has been approved by their regulatory body or its use is actively encouraged by members of the regulatory or professional body. An example of this can be seen in Lapointe and Rivard’s (2006) study of the diffusion and adoption of clinical information systems (CIS) in American hospitals. In this study, Lapointe and Rivard found that although the use of CIS was being actively encouraged by hospital management, doctors mobilised their professional autonomy and actively resisted using CIS as they experienced the technology as negatively impacting on their everyday professional practice. This use of professional autonomy sits in contrast to ‘forced adoption’ of innovations within organisations where those occupying senior positions make decisions on behalf of the entire organisation and then ‘force’ this innovation on

those individuals who lack the professional autonomy to resist (Ram and Jung, 1991).

In the present study, there are interesting questions around how PGx innovations will be diffused throughout, and integrated into, pharmacy practice. The above critiques demonstrate that diffusion theories are of limited use in understanding this integration process given their linearity and focus on macro-level integration. Moreover, diffusion studies are limited in not providing enough analytical space for the examination of *effects* of innovations. Within the later chapters the effect that PGx has on the pharmacists' construction of the patient body is shown to be of critical importance which cannot be easily analysed through such diffusion models. Instead, STS approaches to technology offer a useful way of understanding the complex and multidirectional nature of integrating genetics within diverse pharmacy practices. This diversity of practices in pharmacy is likely to be of central importance in framing the ways in which PGx becomes part of everyday work. In other words, the process of integration in community pharmacy is likely to be different from that in hospital pharmacy given the different structures, professional interactions and everyday work in both settings.

Given the limited value of traditional diffusion theories, then, May and Finch's (2009) NPT is identified as a useful reference point for understanding the definition and integration of PGx innovations in pharmacy. Where traditional diffusion theories focus on the macro-level adoption of innovations within a fairly linear model, NPT examines the micro-level interactional work undertaken to integrate new devices and practices into everyday work structures and relationships. The next section of this chapter examines NPT in more detail.

4.9 'Normalising' Innovation in Healthcare

Understanding and predicting the integration of innovations in healthcare is vital for NHS financial forecasting. This is particularly the case given the contemporary financial environment and the subsequent need to optimise services and products (see Department of Health, 2010). Moreover, understanding the effects of new innovations on constructions of the patient body and practitioner work activities is

sociologically interesting. In spite of this, there is a relative paucity of research examining the integration of new, non-pharmaceutical technologies in healthcare (Robertson and Jochleson, 2006). Moreover, the particularities of integrating non-pharmaceutical technologies into pharmacy are particularly neglected.

In addition to the limitations outlined above, diffusion theory also fails to examine the specific conditions and impacts of integrating innovations into *healthcare* settings specifically (i.e. rather than other social settings). Roberts (1981) argues that the ways in which innovations are implemented into healthcare settings are different from the ways in which they are adopted in other settings for a number of reasons such as the highly politicised nature of healthcare and the extensive regulation found within it. Greer (1988) notes that in understanding the nature of innovation in healthcare, it is important to differentiate between ‘formed’ and ‘dynamic’ technologies where the former refers to artefacts which are largely complete when they are introduced and the latter refers to technologies which are ‘still emerging, still in part ideas and experiments’ (Greer, 1988: 6). In diffusion theory, the emphasis has tended to be on ‘formed’ technologies which is less useful in understanding technologies in healthcare settings given that these tend to be more ‘dynamic’ and, thus, develop as they become integrated (Greer, 1988). In this way, it can be seen that new healthcare innovations and the settings into which they are integrated are co-constructed during this adoption process. In order to understand the specific social actions and phenomena involved in this process, a focus on the micro-level interactional level of integration processes is more useful.

May and Finch (2009) highlight the importance of this micro-level interaction in understanding medical innovation. Their model proposes that innovations are implemented, embedded and integrated into everyday practice through micro-level work and interaction. Hence, their notion of ‘normalisation’ focuses on ‘the conditions of use and the behaviour of everyday users rather than the special champions and early adopters so important to diffusion theories’ (May, 2006: 86). Central to NPT, then, is the everyday types of work that are done to embed innovations into routines and integrate them into existing practice. Crucially, this work is represented in NPT as being ‘dynamic and contingent’ whereby different forms of work are acknowledged as being different across varying contexts (May

and Finch, 2009: 542). In implementing interventions, May and Finch (2009) argue that there are four mechanisms;

Coherence draws together the work undertaken to define and organise objects of a material practice. Within this, identifying differentiation from existing practice is important in the construction of innovative practice as meaningful or otherwise. This differentiation process is undertaken both communally, where the practice is rendered in terms understandable and applicable to all of the actors working in the area or field, and individually, where this differentiation is cohered as meaningful or otherwise within individual practitioners' everyday routines.

Cognitive Participation refers to the real and symbolic engagement of actors with innovations. This process of cognitive participation is highly context-dependant as the norms and conventions of professional groups and practices change. Within this, the processes of initiation, enrolment, legitimation and activation occur. Initiation refers to bringing a practice to the attention of a group of practitioners or stakeholders; enrolment refers to actors working collectively to participate in a new practice; legitimation, in contrast to enrolment, requires actors to 'buy into' an innovation rather than being naturally enrolled through their networks; and finally activation refers to the provision of the means and materials for an innovation to be used in everyday routine practices.

Collective Action refers to the mental and material work which is done to organise and enact a practice. This action is located within the conditions of interactions between practitioners and within these conditions, interactional workability (the operationalisation of innovations within everyday interaction and encounters) and relational integration (the ways in which a practice is mediated within the networks around it) are central. Moreover, NPT highlights two further important qualities; skill-set workability, which describes the distribution of innovation within a division of labour and contextual integration, which describes the incorporation of innovation within a given social context.

Reflexive Monitoring refers to the continuous formal and informal evaluation of collective action processes. Within this, systematisation refers to the methodological

formality of this evaluation work where judgements about the value of innovations made in everyday practice are positioned alongside more formal modes of evaluation such as clinical trials. This evaluation is then undertaken at two levels- communal and individual appraisal where communal appraisal refers to collective evaluation within a network of practitioners whilst individual appraisal refers to experiential and unsystematic judgement processes within everyday practice. These evaluations may, then, lead to reconfiguration where ideas about the use and utility of innovations may be reconstructed or modified.

This model of understanding innovation in healthcare settings provides a more useful framework than diffusion theory for analysing qualitative data around a particular healthcare innovation, in this case PGx. Although NPT has this relative advantage over traditional diffusion studies, the model does present a number of limitations. Firstly, the notion of 'embeddedness' is at the centre of NPT where work is understood to be organised around the process of embedding new innovations within particular settings. This concept, however, can be problematic since there are no clear measures of embeddedness beyond the idea that a complex intervention can be operationalised as being embedded once it becomes part of the 'matrices of already existing, socially patterned, knowledge and practices' (May and Finch, 2009: 540). This definition, however, assumes general agreement about the nature of these 'matrices' of knowledge and practice.

Secondly, NPT presents routine clinical practice, into which new innovations are integrated, as something of a stable phenomenon. Hence, innovations are presented as being introduced into a practice landscape and a population of practitioners which are fairly robust. Normalisation work, then, is represented as being undertaken within the confines of this relatively rigid landscape. This seems at odds with the nature of healthcare settings, however, which are fairly fluid and highly changeable through both local and national reconfigurations. Hence, the normalisation work undertaken within them is not undertaken within a set of rigid boundaries but is, instead, part of the perpetual renegotiation of work and routines.

Despite these shortcomings, NPT could be used in one of two primary ways in the current qualitative data analysis; as an *a priori* coding frame or as a reference

point for an emergent coding approach (see Stemler, 2001). The somewhat normative *a priori* use of any theoretical approach within this thesis would seem to limit the analytical freedom which is presented. Hence, the empirical data presents a number of potential options for theoretical applications and so an analysis limited to the confines of any particular one of these risks simplifying its complexities. As such, a number of components of NPT are mobilised as a way through which PGx in pharmacy can be understood. Coherence work, contextual integration and reflexive monitoring resonate with the data and so are used as reference points within which the importance of everyday micro-level work can be demonstrated. As such, NPT is not used *a priori* but, instead, informs the emerging novel analysis where relevant.

4.10 Conclusion

In sum, this chapter has outlined the theoretical frameworks which underpin the subsequent analytical chapters. The chapter has shown that the body is of central importance in sociological analyses of medical practice and, within this, Foucault's work around the clinical gaze is of particular note. Sociological discourses of medicalisation and, more latterly, biomedicalisation (Clarke *et al.*, 2003) have been shown to be relevant to understanding the body and the development of PGx in relationship to it. Despite this centrality of the body in contemporary accounts of medical practice, the patient body is argued to be markedly absent from analyses of pharmacy practice. Moreover, despite Ryan *et al.*'s (2004) assertion that Foucauldian principles may be useful in sociologically characterising contemporary pharmacy practice, the body remains absent from his analysis and, more surprisingly, from Barber's (2005) Foucauldian 'pharmaceutical gaze'. In mobilising Foucault's notion of the clinical gaze to posit the novel concept of the 'pharmacy gaze', this thesis addresses this gap in the literature.

It is shown here that the biomedical configuration of the body is centred on the use of innovative technologies within contemporary medical practice. Despite this, there has been limited attention given the ways in which new technologies are integrated into medical practice at the micro-level. The chapter argued that in order to understand this, the thesis adopts an STS perspective in conceptualising new technologies as socially constituted by the contexts in which they are located and the

practitioners within. Given this, the chapter argues that the rigidity and linearity of traditional diffusion theory does not provide an adequate framework within which to analyse the micro-level interactional work undertaken around PGx technologies in diverse pharmacy settings.

Here, May and Finch's (2009) NPT is deployed as a useful alternative framework for a qualitative analysis given its divergence from this macro-level focus and fairly rigid linearity of diffusion theory. In its focus on everyday practice and interactions and work activities with it, NPT offers a useful tool upon which to loosely base analyses. In other words, this thesis does not adopt a wholly NPT perspective in the analysis but, rather, the components of NPT are mobilised as analytical tools where they clearly resonate with the empirical data.

4.11 Research Questions

The preceding chapters have contextualised this research project by locating it within sociological analyses of pharmacy and PGx and, subsequently, at the juncture of both of these. At the end of Chapters Two and Three, a number of research questions arising from the sociological literatures have been proposed. These research questions are central to the empirical fieldwork undertaken and, as such, it is useful here to present an overview of the key research questions and their sub-questions as they relate to the structure of the empirical chapters of the remainder of this thesis. What follows this is an overview of the methodology employed to answer these research questions.

4.11.1 Conceptualising Contemporary Pharmacy Practice

In order to characterise the potential integration of PGx into pharmacy, its effects on practice and the construction of the patient body within it, it is important to present a sociological characterisation of contemporary hospital and community pharmacy practice. As such, it is asked;

- What are the defining structures of contemporary pharmacy practice in hospital and community settings?

- How do these structures shape pharmacists' everyday work and communication?
- What practices or approaches intersect both of these sectors?
- How is the patient body configured in hospital and community pharmacy practice?
- Through what discourses or technological practices is the body known in pharmacy?

4.11.2 Technology in Pharmacy

It is doubtless that technology plays a central role in both dispensing and clinical activities in pharmacy. Understanding the ways in which technologies have been integrated into hospital and community and the effects that these have had on the patient body is important in providing a framework through which the integration of PGx can be approached. As such, it is asked;

- What technologies are important in everyday pharmacy practice?
- How have these technologies been understood and integrated into hospital and pharmacy settings?
- How have these technologies contributed to the (re)configuration of the patient body?
- How have everyday work routines and activities been altered by these technologies?
- What effects has this had on practice structures previously outlined?

4.11.3 Pharmacogenetics in Pharmacy

The development of a sociological characterisation of contemporary pharmacy practice and the position of technologies within it provides a framework through which the integration of PGx can be analysed. As such, it is asked;

- What impact has PGx made on pharmacy practice to date?
- How might pharmacists be involved in PGx in the future?
- What might be the impacts of PGx on the practice structures within hospital and community pharmacy?
- What might be the impacts of PGx on pharmacists' construction of the patient body?
- How is PGx evaluated by pharmacists within the framework of their everyday practice?
- What challenges does the integration of PGx present for hospital and community pharmacy?

Chapter Five: Methodology

5.1 Introduction

The preceding chapters have outlined the rationale behind the examination of the pharmacy profession and PGx technology and have outlined the research questions which underpinned the fieldwork which was undertaken. This chapter moves on to describe the methods through which the data informing the conclusions of this project was gathered. The chapter begins with an outline of the rationale behind using semi-structured interviews as a data collection tool; it then moves on to examining the specific challenges raised by conducting interviews with ‘elites’- in this case professional elites; the methods which were used to identify and recruit participants are then outlined; and the data analysis techniques and processes are then addressed.

5.2 Choosing Interviews as a Research Tool

Arguably, semi-structured interviews represented the most logical and appropriate method through which the questions raised in the previous chapters could be addressed. This method of data collection was the most suitable for this research as it allowed the opinions, experiences and perspectives of practitioners who are currently, or potentially, involved with PGx technology and/or pharmacy practice to be elicited through in-depth, detailed conversations. Whilst focus groups and survey research represented alternative methods through which these opinions could be captured, these approaches have a number of drawbacks which made them unsuitable for this particular project. As such, the practical challenge of gathering numerous busy healthcare practitioners together in the same setting was perceived as disproportionate to the relatively limited advantages that using focus groups would have presented. Moreover, survey methods were also inappropriate for the research as, although open-ended questionnaires can provide a space for participants to express their opinions and experiences, they do not allow the motives and meanings behind such responses to be fully explored as they can be in semi-structured interview scenarios.

Semi-structured interviews were selected as the primary method of data collection not simply because they represented the most effective way of collecting appropriate data for this project but because they were particularly useful for researching healthcare settings and healthcare interventions.

Semi-structured interviews have been acknowledged as a particularly apt method for capturing the perspectives and reflections of healthcare practitioners owing to the nature of the interview encounter being akin to the practitioner-patient encounter in the clinic (Holloway and Wheeler, 2010). Owing to pharmacists' extended clinical role and increased contact with patients, a form of interview is also 'an integral part' of the work of pharmacists (Gantley, 2001: 458). As such, the semi-structured interview format was one that participants in the sample were thought to be familiar with. Nevertheless, conducting interviews with professional participants presents a number of challenges, which this chapter now addresses.

5.3 Interviewing Professionals

The specificities of interviewing different professional groups are under-explored in the academic literature. As such, the process of interviewing healthcare professionals is represented as a homogeneous process and experience irrespective of the particular professional field of participants. In practice, different fields of work place different pressures and constraints on professionals, which can impact on the research conducted with them, particularly in terms of recruitment and the practicalities of conducting an interview. This means that researchers need to be sensitive to the appropriate ways of approaching professionals from different fields rather than only mobilising one recruitment and interview strategy for all participants because they can all be classed as 'professionals'. As an example, for this project, recruitment of community pharmacists mostly took place through snowballing techniques beginning with an initial gatekeeper who established informal contact between the researcher and other potential participants. This is in contrast to the recruitment of oncologists which took place through formal e-mail channels and, usually, via the potential participant's personal assistant. Moreover, all of the interviews conducted with community pharmacists were done outside of their work setting and working hours whereas all but one of the hospital pharmacists were

interviewed during their allocated breaks at work. What this shows, then, is that the different work structures between community pharmacists, hospital pharmacists and oncologists mean that different recruitment techniques and interview methods had to be mobilised to undertake qualitative research with these diverse professionals. As such, amalgamating the methods used for these interviews under the rubric of ‘professional interviews’ would be simplifying a complex methodological phenomenon.

For junior researchers, the process of interviewing professionals can be particularly challenging. Drawing on his experiences of interviewing CEOs, vice-presidents and directors of pharmaceutical and biotechnology companies during his doctoral and post-doctoral research, Harvey (2010) provides a useful guide for junior researchers conducting interviews with ‘elites’. He argues that junior researchers interviewing professionals have to be more organised, flexible, transparent and persistent and better at maintaining good etiquette than their colleagues who are interviewing the lay public. For junior researchers their lack of experience and publications and their potential (although not necessarily problematic) vagueness about their research questions makes the recruitment process particularly challenging when busy professionals in positions of responsibility are targeted for study inclusion.

Whilst Harvey’s guide proved to be useful as an introductory source for this project, he does not adequately address the issue of power within the research process and how this might be experienced by junior researchers. Traditional approaches to the power relationship between interviewers and their participants rely on a fixed notion of power as being an ‘inscribed capacity...which is appropriated by particular individuals’ (Smith, 2006: 644). Traditionally, the researcher is understood to possess the power within a research encounter but research involving elite participants has tended to assume that those with power in professional spheres will transfer this power directly onto the interview encounter and remove the power from the interviewer (Smith, 2006). Post-structural approaches have, however, rejected this notion of power as a zero-sum game and have concentrated on power as a fluid and mobile phenomenon. In research involving elites, it has been argued that the traditional idea of elites transferring their professional power onto the interview

encounter is unfounded in the reality of such research (Puwar, 1997; Sabot, 1999; Smith, 2006). As such, these researchers have argued that ‘studying up’ presents a less challenging research endeavour than ‘studying down’ in that participants tend to be easier to identify due to their online presence; the response rate to invitations to participate tends to be higher; and interviews rarely present significant physical risks to the researcher (Smith, 2006).

For junior researchers, the power relations of research encounters with professional elites can raise important questions. Mullings (1999) notes that junior researchers in particular occupy an ambiguous position whereby they can be perceived as ‘inexperienced’ or ‘at the cutting edge’ in contrast to senior researchers who are either ‘world experts’ or ‘out of touch’. As such, it is important for junior researchers to be aware of the power dynamics of each research encounter. Moreover, Mullings (1999) assumes that it is *only* researchers who are positioned in these experiential terms. During the fieldwork, however, it became apparent that what might be called a *disciplinary chasm* between the participants and I was a useful tool in building a mutually beneficial and intellectually reciprocal relationship. In other words, as well as my relatively limited knowledge of pharmacy and PGx, the participants’ relative ‘inexperience’ in Sociology and its applicability to pharmacy and PGx meant that research encounters were, more often than not, a mutual learning experience where the participants and I were positioned as ‘experts’ at various points during the encounters. As such, the experience of interviewing professional elites for this project was experienced in line with the post-structuralist view that power is not a zero sum game.

5.4 Identifying a Sample

In order to understand the ways in which PGx technology may impact on the pharmacy profession in England, it was important to capture the perspectives of a range of participants from a number of fields. The necessity of this diversity was grounded in the nature of PGx technology as a collaborative medical intervention (see El-Ibiary *et al.*, 2008; PricewaterhouseCoopers, 2009). Moreover, it was important not to limit reflections on PGx in pharmacy to just the pharmacists who may use PGx in the future but, instead, to capture the perspectives of actors who are,

or may be, involved in PGx at various stages of its development and use in clinical practice. In doing this, the interviews were able to create a map of PGx technologies from the lab bench to the patient bedside incorporating the views of scientists and practitioners as well as those who may be positioned as PGx gatekeepers.

In doing this, six fields of practice were identified as being important to the current development of PGx and its future use in medical practice. These fields were identified as pharmacogenetic research, Oncology, general medical practice, pharmacy at the administrative and policy level (herein pharmacy stakeholders), hospital pharmacy and community pharmacy. Table 3 outlines the rationale for selecting these fields of practice and the number of participants from each.

Field of Practice	Rationale for Inclusion	Number of Respondents (specialisms within these practice groups)
Pharmacogenetic research	Development of PGx technologies Overview of contemporary PGx landscape	10 (1 Medical technology consultant)
Oncology	'Promising' field for PGx (see Houtsma <i>et al.</i> , 2010) PGx currently used in routine Oncology practice	2
General medical practice	Likely gatekeepers to PGx in primary care Medicines prescribers in primary care Relationship with pharmacists	2
Pharmacy stakeholders	Taking decisions about PGx implementation and education Overview of contemporary pharmacy profession	4
Hospital pharmacy	Currently practising with PGx in some specialisms Most likely setting to be implemented first Professional relationships and occupational structure	10 (1 Health economist) (2 Oncology pharmacists) (2 Chief pharmacists)
Community pharmacy	Potential impact on future practice Professional relationships and occupational structure	10 (1 special interest in Warfarin)

Table 3: Participants' professional groups and the rationale for their inclusion

It should be noted that these six categories represent the capacity in which participants were approached for inclusion in the study rather representing the entirety of their professional activities. As such, the oncologists interviewed also participated in PGx research but were approached primarily in their capacity as Oncology practitioners. Similarly, two of the hospital pharmacists that were interviewed specialised in the field of Oncology and, therefore, could have been categorised within the Oncology field of practice. However, these two participants were primarily approached for inclusion in their capacity as pharmacists, albeit in the specialist area of Oncology.

Within these six fields, potential participants were identified using a purposive sampling approach given their likely knowledge of PGx and/or pharmacy. Within this, a number of 'key' participants were identified by their eminence in their given field or by some professional activity or specialism relevant to the research. The mistake should not be made that these key participants were identified due to their role as innovators (Rogers, 2003) or opinion leaders (Greer, 1988). Rather, these key participants were selected for inclusion on the basis of their deeper engagement with PGx technology or pharmacy practice rather than their activities in championing these phenomena, although the two are not mutually exclusive.

Deeper internet research into the professional activities of these key participants located them within wider professional networks, whose other actors were then also identified as potential participants. Here, there is a risk that this network mapping could have continued indefinitely if each of the key participant's collaborators were to be taken as a new subject around whom to build a network map. In order to avoid this, each key participant's network map was developed to a point at which it was unlikely that new participants would offer novel insights. An example of one of these network maps that was developed around one key participant is shown in Figure 1 below.

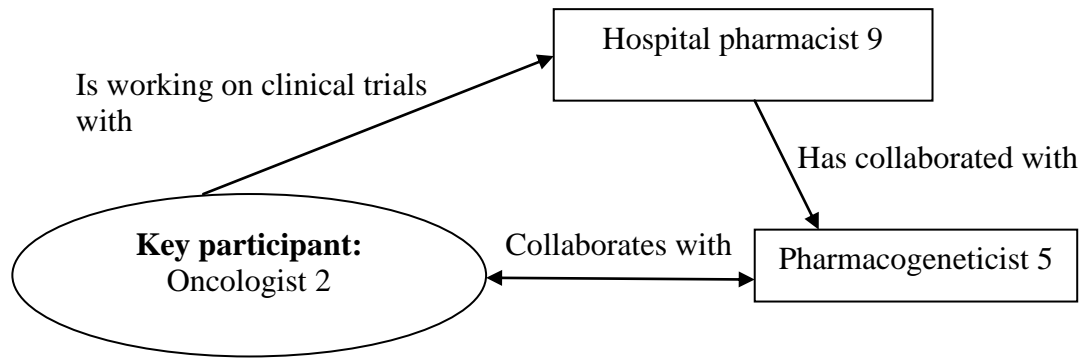


Figure 1: An example network map for Oncologist 2

Such network mapping was not possible, or advantageous, for participants from all of the six practice fields. For example, such network mapping for community pharmacists was not possible given the relative isolation of community pharmacy practice. As such, those participants who were not recruited through such network mapping were targeted based on the feasibility of their inclusion and/or snowballing techniques. The contact details of these potential participants were identified through internet searches, which supplied contact details through academic papers, professional articles, professional network websites (such as LinkedIn), employers' websites and conference documentation. Where snowball sampling was used, contact details were obtained from gatekeepers.

5.5 Gaining Ethics and Governance Approval

Once the sample had been identified, the research was subject to approval by a number of committees. The ethics review process comprised four stages: obtaining institutional ethics approval, obtaining local Research Ethics Committee (REC) approval, obtaining a Research Passport (RP), and gaining governance approval for each NHS Trust within which the research took place. This NHS ethics review process was implemented in 1991 as a way for the NHS to review the ethical implications of both therapeutic (i.e. clinical) and non-therapeutic (i.e. social science) research involving those to whom the NHS has a duty of care (Department of Health, 1991). What follows is a review of these four stages of ethics and governance approval.

The initial phase of the ethics review process was obtaining institutional ethics approval. As the research was conducted as part of an educational programme, this review was conducted at the departmental level, with a report being relayed to the University ethics committee. In order to obtain approval at this stage, a standardised form was submitted along with the recruitment literature. If the research had not involved NHS participants, ethics approval at this phase would have been sufficient. However, because the research involved NHS staff members, the project was required to be reviewed at three further phases.

The first phase of obtaining NHS ethics approval involves researchers filling out an extensive online form which is submitted, along with all of the documents that will be taken 'into the field', to an 18-person REC. This documentation included;

- Initial recruitment e-mail
- Follow-up e-mail sent two weeks later if no response was received
- Project information document attached to these recruitment e-mails
- E-mail sent a week before the date of the interview to confirm details
- Participant Information sheets for each group attached to this confirmation e-mail and given to participants before the interview (i.e. because the practice groups were targeted for different reasons, each needed a different Participant Information sheet)
- Interview topic guides for each group of participants (i.e. because the practice groups had different professional backgrounds, the questions that they were asked varied and different interview topic guides had to be developed for each)
- Consent form

In addition to this 'field' documentation, the REC also required the following documentation;

- Departmental ethics approval confirmation
- Funding information
- A covering letter outlining the project
- A project protocol

- Transcriber's Confidentiality Agreement
- CV for the Chief Investigator

Given the need for large volumes of documentation, and for this documentation to be presented in a standardised way, preparation of the REC application took around one month. Following the submission of the application, researchers are then invited to attend a local REC meeting where they have the opportunity to discuss their research with the committee members and clarify any issues which arise, but which do not necessitate a substantial amendment to the online form (for example, spelling mistakes, inconsistencies within participant numbers and clarification of medical definitions). Following this meeting, RECs then offer a favourable, provisional or unfavourable opinion to the researcher (O'Reilly *et al.*, 2009). This project was subject to review by the South Yorkshire REC in February 2011, following which a favourable opinion with conditions (to alter the name of the REC and clarify participant numbers) was obtained. This alteration was made and a final favourable opinion was obtained on 4th March 2011. In the period between submitting the documentation to the REC and attending the REC meeting (approximately one month), the relevant information for obtaining an RP was compiled ready for the second stage of the NHS ethics and governance process.

RPs were introduced in 2009 as a 'bureaucracy buster' and way of streamlining the ethics approval process and reducing the amount of duplication that applications had previously required (Kielmann *et al.*, 2007: 237). They are necessary for researchers who do not have a contractual relationship with the NHS and circumvent the need for researchers to obtain separate honorary contracts at each individual research site. The RP form details each individual NHS Trust in which research will take place and the numbers of staff that will be recruited from each Trust. This form, along with confirmation of a favourable outcome from the REC, a Criminal Records Bureau certificate, a signed and dated CV and an occupational health certificate, is submitted to the lead R&D department for the study, which is usually the NHS Trust in which the majority of the fieldwork will be conducted. For this project, obtaining Criminal Records Bureau and occupation health certificates was not necessary due to the fact that the research mobilised an interview methodology and did not recruit patients. Once a valid Research Passport has been

issued, this can then be used to apply for governance approval at each NHS Trust in which the research will take place. The lead R&D department to which the relevant documents were submitted was York Hospital NHS Trust and a Research Passport was issued on 24th February 2011.

The process of applying for governance approval involves filling in relatively short Site Specific Information (SSI) and lengthier R&D forms for each NHS Trust from which participants are recruited. The former is necessary to review the financial and practical demands being placed on specific NHS sites to assess whether the site is capable of hosting the research (Smajdor *et al.*, 2009). Some of the R&D form is automatically populated from the REC form with details pertaining to the specific Trust being changed. Once these forms have been signed by the relevant people (the signatory for each Trust varies according to individual Trust governance requirements), they are submitted, along with supporting documentation to the relevant R&D department. Here, the documentation required is, usually;

- Completed R&D form
- SSI form
- All documents submitted to, and approved by the REC
- All correspondence with the REC
- REC approval letter
- RP
- Financial assessment of the research
- An indemnity statement
- Letter from the research sponsor confirming the institution and governance frameworks to which the researcher is bound

Due to the lack of standardisation across different Trusts, the process of applying for governance approval at numerous sites is extremely challenging. For the present study, nine NHS Trusts were identified as potential sites of research activities. Whilst some of these sites requested unsigned SSI forms where signatures would be collected by the R&D department, others required signatures to be obtained from clinical leads of each specified department, which was cumbersome and time-consuming. Governance applications were submitted to, and received from,

nine NHS Trusts. Given the lack of standardisation of governance application timeframes, the time taken for these governance approvals to be obtained varied widely from 3 days to 6 months. Moreover, given that research participants cannot be contacted prior to governance approval being granted, two of these governance applications were submitted somewhat needlessly since the Trusts to which they were submitted yielded no respondents.

5.5.1 Reflections on the NHS Ethics and R&D Approval Process

Although the process of obtaining NHS ethics and governance approvals is underpinned by rhetorics of risk protection and research rigour, the process has been widely critiqued by both clinical and social researchers. For social science research, the process has been critiqued for being bureaucratic, time consuming (Reed, 2007), 'unethical' (Dingwall, 2006) and focusing too heavily on scientific, rather than ethical, issues (Angell *et al.*, 2008). Moreover, the process has been identified as being too heavily biased towards clinical research methodologies, which means that NHS institutions, as research sites, are heavily gate-kept by NHS personnel, which places social researchers at a disadvantage due to their 'outsider' status (Reed, 2007; Richardson and McMullan, 2007). As such, there seems to be a disjuncture between the positivist, linear nature of the application process and the interpretivist, serendipitous nature of social research. Moreover, the 18-member REC is primarily constituted by individuals drawn from the clinical and biomedical community (Dyer, 2004; Gauld, 1999; Reed, 2007) whose lack of qualitative and social research expertise can lead to questions being raised which are less centred on ethics and more concerned with methodological or analytical issues. In a similar vein, Richards and Schwartz (2002) argue that debates about the ethics of social research may be inaccessible for healthcare professionals who receive little training in this area, which can lead to RECs being perceived as missing the point, crossing the boundary into the assessment of academic rigour and distrusting qualitative research, all of which further compound the notion that the NHS ethics process is biased against social research.

Although there is a significant amount of social science literature addressing the purpose, nature, challenges and benefits of the NHS ethics and governance

approval process, little attention is given to the degrees of expertise and experience of researchers going through the process. As such, a senior academic is likely to have a different experience of the process than a junior PhD researcher. Based on the experience in this particular project, for early careers researchers, the need for NHS ethics and governance approvals presents three primary problems.

Firstly, these processes require researchers to identify their sample members (or at least the NHS Trusts from which they will be drawn) and specific research questions early on so that the recruitment literature and interview topic guides can be submitted to the REC and the relevant information be filled in on the SSI and R&D forms. This early confirmation, however, sits in opposition to the nature of a PhD which is primarily an educational undertaking during which research questions and theoretical perspectives develop rather than being set from the beginning.

Secondly, the entire NHS ethics and governance approval process tends to take around six months (Reed, 2007), although as demonstrated in the present project, this can take as long as nine months (also see McDonach, 2009). Given that PhD researchers who are required to undergo NHS ethics and governance review are not provided with extra time in which to conduct their research, these extra months have to be factored into the project time line. This means that because PhD researchers can spend around one sixth of their research project time involved in these processes rather than conducting fieldwork, the breadth and quality of the empirical research may be hampered.

Finally, despite attempts to streamline and standardise the REC system, the process of obtaining governance approval remains extremely 'cumbersome' (Al-Shahi, 2005: 445) due to the different requirements of different Trusts' R&D departments. In some instances, these departments require substantial administration fees or remuneration for staff time given over to non-NHS research activities, neither of which is factored into PhD budgets. However, the most significant challenge raised by this lack of governance application standardisation is the different requirements for obtaining authorisation. In some instances, this is obtained by the R&D department on behalf of the researcher but in instances where the researcher has to approach clinical leads for signatures, this can present a number of challenges

for junior researchers in particular. Given that most clinicians will be relatively unfamiliar with social research, the request for a signature for authorisation for a qualitative interview study can be somewhat unclear. In this instance, researchers have to work hard to demonstrate the importance of their study, which is difficult given their lack of experience, networks and publications (what one may call *academic capital*). As such, this process of obtaining signatures from individuals who are largely unconnected with the research can be extremely time-consuming for junior researchers.

In 2010 the ESRC published its Framework for Research Ethics which generated some debate within the social science literature as to the necessity and place of NHS-style RECs in social research. In November of 2010, the journal *Sociological Review Online* published a special 'Debate' section on this framework within which Hammersley (2010) analysed the Framework as an indication of 'ethics creep' into the governance of social research whilst Reed (2010) imagined social researchers as having 'nowhere left to hide'.

In contrast to these somewhat bleak reflections on the NHS ethics and governance process, Adam Hedgecoe (2008b) drew on observations of RECs and interviews with their members to argue that these perspectives on RECs' expertise have over-emphasized the difference between social and biomedical research. Whilst traditional understandings of RECs' lack of social science expertise have constructed RECs as hindering social research, Hedgecoe argues that REC members in fact see their role as facilitating and supporting social research. Although Hedgecoe's empirically-informed conclusions provide a valuable antithesis to these traditional understandings, the latter remains the dominant voice in this field and is, perhaps, more commonly applicable to researchers' experiences of the NHS ethics and governance process than Hedgecoe's. Moreover, Hedgecoe's paper is only concerned with social scientists' experiences of the REC application process, which as is shown, is only the first phase of the journey towards full ethics and governance approval and eventual fieldwork.

Notwithstanding these debates, the process of obtaining ethics and governance approval for this project took around nine months and placed a large

administrative burden on the fieldwork phase of the research. Figure 2 highlights the complexities of this process.

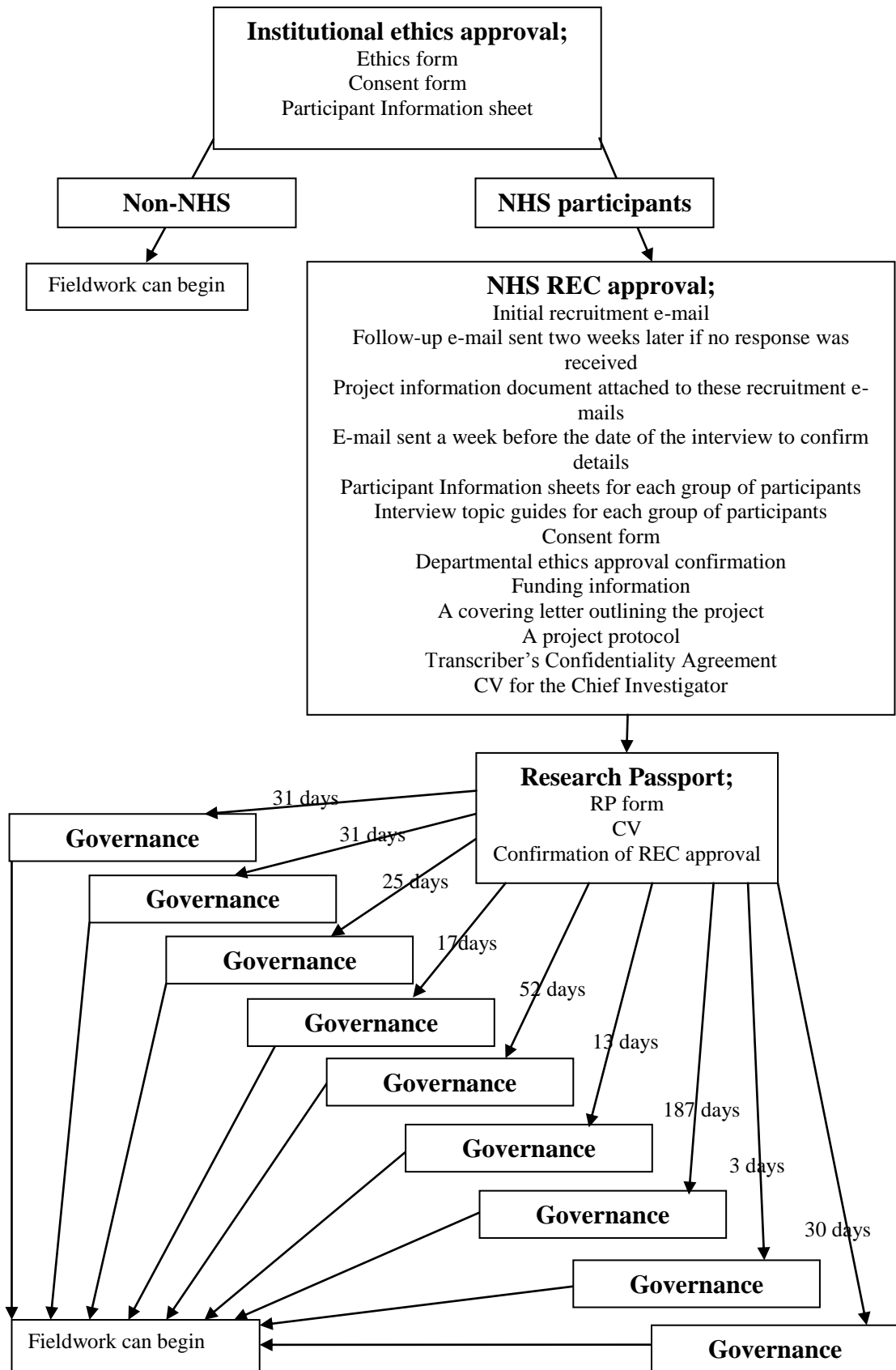


Figure 2: The ethics and governance approval process with time taken for governance approvals

5.6 Recruiting and Interviewing a Sample

Due to the need for NHS REC approval of recruitment literature, the recruitment process and its literature were standardised for all participants in the study. In total, thirty eight interviews were carried out.

In the case of participants who were NHS employees, the process of recruitment could only begin once the relevant ethics and governance approvals had been finalised. Once these approvals were in place and the names and contact details of all potential participants had been identified, an invitation e-mail or letter, for participants whose e-mail addresses were not available online, with a project summary was sent (see Appendices A and B). In cases where no response was received, a follow-up e-mail or letter was sent two weeks later (Appendix C). This follow-up correspondence was sent based on the assumption that a lack of response did not necessarily indicate an unwillingness to participate in the project. As the research was conducted with busy healthcare professionals, allowances for correspondence being lost or delayed response were made. In instances where no response was received following this second correspondence, it was assumed that the potential participant did not wish to take part in the study and so no further action was taken.

Where responses and expressions of interest in participation were received, details of the interview time and place were arranged over the telephone or by e-mail. One week before the interview was scheduled to take place, the participants were sent an e-mail confirming the interview (Appendix D) with a Participant Information document containing details of project funding, research objectives, the motivations for their inclusion in the study and details of the ethical considerations of the project (Appendix E).

This recruitment process followed the same time scale and used the same literature for all participants who were NHS employees. For those that were recruited from outside of the NHS, the recruitment process was less standardised and the content of the recruitment literature varied depending on how the individual was recruited. As such, the non-NHS participants who were recruited through

snowballing techniques were contacted in a more informal manner which diverged from the recruitment literature used for NHS employees given the different circumstances.

As mentioned, the divergent structures of everyday work across the practice groups from which the sample was drawn necessitated different approaches to recruitment and conducting interviews. In conducting interviews with practitioners from different professional fields, divergent interview topic guides were developed to reflect the divergent nature of practices and to answer the research questions outlined at the end of Chapter Four. These divergent topic guides can be found in Appendices F-K.

In all of the interviews, however, informed consent (Appendix L) was obtained prior to conducting the interview and each interview was recorded digitally. The following sections present an overview of the particularities of recruiting and interviewing participants from these practice groups.

5.6.1 Pharmacogeneticists

Pharmacogeneticists are defined here as scientists who are currently investigating the relationships between genetics and drug response/metabolism and/or developing technologies which may be implemented into PGx practice in the future. This group of participants are usually academics who run research groups and collaborate widely with healthcare practitioners from various fields. Due to their position at the forefront of the technological development of PGx, their perspectives on its current advancement and potential future implementation were of central importance to the research questions.

This group of actors were selected as an appropriate sample of key participants with whom to conduct pilot interviews given that they would be likely to be able to provide something of an ‘overview’ of the PGx story from the lab bench to the patient bedside. For these pilot interviews, seven pharmacogeneticists were identified through internet searches of current and previous UK PGx research projects. These pharmacogeneticists were contacted by e-mail for inclusion in the

study. Of the seven identified and contacted as potential pilot study participants, five were interviewed, one recommended a more appropriate colleague and one stated that they did not have time to participate. Six pharmacogeneticists, then, were interviewed during the pilot stage of the fieldwork (an overview of pilot studies is detailed below).

During these pilot interviews, four more pharmacogeneticists were identified by participants as potential interviewees and were subsequently contacted for participation once the rest of the recruitment and fieldwork was started. Two of these pharmacogeneticists did not respond to being contacted about participation. The other two agreed to participate and one of these recommended two of their research group members for participation, who were also then interviewed via telephone.

In total, then, ten pharmacogeneticists were interviewed. Six of these were interviewed for pilot research and four were interviewed subsequently as part of the main body of fieldwork. Seven of these interviews took place face-to-face in the university offices of these participants whilst four took place over the telephone. Each interview lasted between thirty and sixty minutes. Two of the pharmacogeneticists were female and two were in the process of researching as part of a PhD. Table 4 presents a breakdown of pharmacogeneticist participants.

	Anonymised Pseudonym	Gender	Specialist Job Role (if applicable)	Sampling Technique	Interview Method and Location
1	PGx 1	F		Purposive sampling (Pilot)	Face-to-face, university
2	PGx 2	M		Purposive sampling (Pilot)	Face-to-face, university
3	PGx 3	M		Purposive sampling (Pilot)	Face-to-face, university
4	PGx 4	M		Purposive sampling (Pilot)	Face-to-face, university
5	PGx 5	M		Purposive sampling (Pilot)	Face-to-face, university
6	PGx 6	F		Purposive sampling	Telephone
7	PGx 7	M		Snowballed (from PGx 6)	Telephone
8	PGx 8	M		Snowballed (from PGx 6)	Telephone
9	PGx 9	F		Purposive sampling (Pilot)	Face-to-face, university
10	MTC 1	M	Medical Technology Consultant, previously a community and hospital pharmacist	Purposive sampling	Telephone

Table 4: Breakdown of pharmacogeneticist participants

5.6.2 Oncologists

During the pilot interviews, the centrality of Oncology to the development of PGx in drug development and clinical practice was a recurring theme. It was identified that Oncology is the area of medicine where PGx is likely to have the largest and most imminent impact and, elsewhere, Oncology has been identified as a ‘promising’ field for PGx (Houtsma *et al.*, 2010). Moreover, the provision of some PGx testing for all cancer patients (for example, HER2 testing in breast cancer) means that PGx technologies and approaches seem to be becoming fairly well ‘normalised’ within Oncology practice. It was, therefore, imperative that the perspectives of Oncologists were reflected in the study.

Whilst field of Oncology is not homogenous and so is, instead, constituted by different specialisms dealing with different areas of the body (for example, breast, colorectal, gynaecological) and different treatment pathways (medical Oncology,

surgical Oncology and radiation Oncology), these nuances were not thought to have any significant bearing on the present research. As such, it was thought that all oncologists would have a sufficient knowledge and, potentially, experience of PGx to be able to offer their perspectives.

Six oncologists were targeted for inclusion in the study based on their position within some of the pharmacogeneticists' network maps and the feasibility of face-to-face interviews. Of these six, no responses were received from two potential participants following both initial and follow-up recruitment materials being sent and one felt that his inclusion would not be appropriate given his employment status as semi-retired. Of the three that agreed to be interviewed, correspondence with one was lost whilst interviews went ahead with the remaining two. Hence, two male oncologists were interviewed at the hospitals where they were employed. These interviews lasted between forty five and sixty minutes. Table 5 presents a breakdown of oncology participants.

	Anonymised Pseudonym	Gender	Specialist Job Role (if applicable)	Sampling Technique	Interview Method and Location
1	O 1	M		Purposive sampling	Face-to-face, hospital
2	O 2	M		Purposive sampling	Face-to-face, hospital

Table 5: Breakdown of oncologist participants

5.6.3 General Practitioners

As key actors in primary healthcare, GPs will have a central role in PGx in community settings. Within this, they may undertake testing within consultations or their prescription decisions may be negotiated with other healthcare practitioners (for example pharmacists) in light of PGx data (see Jamie, 2011). The delivery of PGx medicine in primary care settings will, then, involve GPs becoming more familiar with the principles of this technology and may necessitate increased collaboration and communication between themselves and community pharmacists. Given this, obtaining the perspectives of GPs was important to (i) understand the working relationship that pharmacists and GPs have at the moment, (ii) how this may change and (iii) what roles GPs see for themselves in delivering PGx medicine. Moreover,

the introduction of GP commissioning may impact on the way in which PGx technology is implemented into primary care practice in the future. Hence, the perspectives of GPs about their professional relationship with other healthcare practitioners, the introduction of GP commissioning and the potential future of PGx in primary healthcare were central to the research questions.

GPs were contacted by post given that few had their e-mail addresses published online. Twenty two GPs within York were contacted about their potential inclusion in the study via letter. Of these three responses were received and two subsequent interviews were carried out whilst correspondence with the other potential participant was lost. In addition, a GP from another city was contacted by e-mail on account of his previous involvement with a PGx research project. Although this GP was willing to participate, the practice manager at the surgery where he was employed did not give permission for access as is required by the NHS governance process. As such, this GP could not be interviewed.

In total, then, one male and one female GP were interviewed. These interviews were conducted in their consultation rooms during the participants' lunch breaks and lasted around thirty minutes. Table 6 presents a breakdown of GP participants.

	Anonymised Pseudonym	Gender	Specialist Job Role (if applicable)	Sampling Technique	Interview Method and Location
1	GP 1	F		York GP sampling frame	Face-to-face, GP surgery
2	GP 2	M		York GP sampling frame	Face-to-face, GP surgery

Table 6: Breakdown of GP participants

5.6.4 Pharmacy Stakeholders

What are being called 'pharmacy stakeholders' here are defined as individuals who are involved with the profession of pharmacy beyond being practicing pharmacists. This includes a diversity of policy makers, those involved with the development of pharmacy education, and chair people of various pharmacy practice groups. It was important to capture the perspectives of these stakeholders as (i) they were thought

to have an extensive overview of structure of the contemporary pharmacy, (ii) they may be positioned as central decision makers in processes of integrating PGx into pharmacy practice and (iii) they may be central actors in the ways in which PGx is understood and represented to pharmacists.

One potential participant was identified within correspondence with the Pharmacy Practice Research Trust as being potentially important for pilot work in order in order to understand PGx and pharmacy and the nature of contemporary everyday practice. Hence, during the pilot fieldwork whilst six pharmacogeneticists provided reflections on PGx from the lab bench side of the story, this pharmacy stakeholder provided reflections on the nature of contemporary pharmacy practice and the potential location of PGx within it from the patient bedside side. During the main phase of the fieldwork, five chair people of pharmacy professional groups were contacted as potential participants. One response was received to this recruitment correspondence and this stakeholder was subsequently interviewed. A further two academic pharmacy stakeholders were identified due to their research interests in ADRs and genetics education in pharmacy. Both of these stakeholders were interviewed.

In total, then, four interviews were carried out with what are being called here ‘pharmacy stakeholders’. Three of these participants were male and one was female. Three of these interviews were conducted in the participants’ office and one was conducted over the telephone and they lasted between thirty and sixty minutes. Table 7 presents a breakdown of pharmacy stakeholder participants.

	Anonymised Pseudonym	Gender	Specialist Job Role (if applicable)	Sampling Technique	Interview Method and Location
1	PS 1	F	Previously a hospital pharmacist	Purposive sampling (Pilot)	Telephone
2	PS 2	M	Professional group chairman	Purposive sampling	Face-to-face, university
3	PS 3	M	ADRs in pharmacy practice	Purposive sampling	Face-to-face, university
4	PS 4	M	Pharmacy genetics education	Purposive sampling	Telephone

Table 7: Breakdown of pharmacy stakeholder participants

5.6.5 Hospital Pharmacists

Previous research into PGx and pharmacy have focused almost exclusively on community pharmacy, which excludes a vast portion of the pharmacist population and those that are likely to have the most experience of the technology. This research, in contrast, focuses on the entire field of pharmacy and, as such, the perspectives of hospital pharmacists are central in answering the research questions. At present, PGx is more commonly practised in hospital, rather than community, settings and so it was assumed that hospital pharmacists would have a fairly high degree of familiarity with this paradigm of practice even if they did not use PGx technologies within their individual everyday practice. As such hospital pharmacists were included because of their current, as well as potential future, engagement with PGx. Additionally, their perspectives on the structure of contemporary pharmacy were also sought in order to map the hospital pharmacy practice landscape into which PGx will be integrated.

Hospital pharmacists were recruited through both individual purposive sampling and snowballing techniques. Three hospital pharmacists were identified as potential participants due to their occupational role as directors of hospital pharmacy services. Of these, two agreed to be included and were subsequently interviewed. Two other hospital pharmacists were identified as potential participants due to their specialism in Oncology and their location within the research networks of other participants. Both of these Oncology pharmacists agreed to be interviewed. Finally, a hospital pharmacist who was also a health economist with a particular interest in PGx and had previously collaborated with a number of other participants was also specifically targeted and interviewed. In total, then, five hospital pharmacists were recruited through this purposive sampling method. Four other hospital pharmacists were snowballed through one of the pharmacy directors and a final hospital pharmacist was snowballed through one of the community pharmacists.

In total, six female and four male hospital pharmacists were interviewed. In the majority of cases, these interviews were carried out during pharmacists' breaks in hospitals. In the case of the health economist, however, the interview was carried out in her university office whilst the hospital pharmacist snowballed through a

community pharmacist participated in a focus group with five community pharmacists. Each of these interviews lasted between forty and ninety minutes. Table 8 presents a breakdown of hospital pharmacy participants.

	Anonymised Pseudonym	Gender	Specialist Job Role (if applicable)	Sampling Technique	Interview Method and Location
1	HP 1	M	Chief Pharmacist	Purposive sampling	Face-to-face, hospital
2	HP 2	F		Snowballed (HP 1)	Face-to-face, hospital
3	HP 3	F	Oncology Pharmacist	Purposive sampling	Face-to-face, hospital
4	HP 4	F		Snowballed (HP 1)	Face-to-face, hospital
5	HP 5	M		Snowballed (CP 2)	Face-to-face, hospital
6	HP 6	M	Pharmacy Director	Purposive sampling	Face-to-face, hospital
7	HP 7	F		Snowballed (HP 1)	Face-to-face, hospital
8	HP 8	M		Snowballed (HP 1)	Face-to-face, hospital
9	HP 9	F	Oncology Pharmacist	Purposive sampling	Face-to-face, hospital
10	HE 1	F	Health Economist (previously a hospital pharmacist)	Purposive sampling	Face-to-face, university

Table 8: Breakdown of hospital pharmacist participants

5.6.6 Community Pharmacists

The perspectives of community pharmacists were important for an understanding of the potential future of PGx in pharmacy and for an overview of the contemporary structure of pharmacy practice. Compared with potential participants from the other five categories detailed above, recruiting community pharmacists presented a number of unique challenges.

In papers where interviews with pharmacists have been conducted, very little attention is given to the recruitment process, although this is an aspect of research that would benefit from a deeper exploration and analysis. Community pharmacists were very difficult to establish contact with as they rarely have personal e-mail

addresses available online; tend to only respond to medical or general queries (for example, questions about opening times or the availability of testing services) through their practice e-mail addresses; and receive a large volume of post which means that non-essential postal correspondence is usually discarded. Professional bodies such as Local Practice Forums offer a potential way of accessing a sample of pharmacists but these were unresponsive to correspondence in the case of this project. Given this, the most effective and appropriate methods for establishing contact with pharmacists proved to be through informal gatekeepers and snowballing.

Unlike the other categories of respondents, it was difficult to identify individual pharmacists to target for participation. Two pharmacists were purposively sampled because of their previous involvement with Warfarin projects. One of these agreed to be interviewed and subsequently acted as a gatekeeper for six of the other community pharmacists interviewed, five of whom were interviewed in a focus group (along with one hospital pharmacist). These informal networks were also used to recruit two other community pharmacists who were acquaintances of colleagues. Alongside these recruitment methods, a sampling frame of local pharmacies in York was constructed and letters sent out for attention of the proprietor. Of the seven pharmacies contacted in this way, no responses were received to the first invitation letter and subsequent follow-up correspondence yielded only one participant. Given the high number of participants accessed through informal networks and snowballing techniques, this lack of responses to the York letter drop was not problematic in this instance.

In total, ten community pharmacists were interviewed. Two of these were interviewed on the telephone, three were interviewed face-to-face and five were interviewed as part of a focus group. Each interview lasted between forty five and ninety minutes and the focus group lasted two hours. Table 9 presents a breakdown on the community pharmacy participants.

	Anonymised Pseudonym	Gender	Specialist Job Role (if applicable)	Sampling Technique	Interview Method and Location
1	CP 1	M		Snowballed (from colleague)	Telephone
2	CP 2	F	Warfarin practice	Purposive sampling	Face-to-face, cafe
3	CP 3	M		Snowballed (from colleague)	Telephone
4	CP 4	F		York pharmacy sampling frame	Face-to-face, cafe
5	CP 5	M		Snowballed (from CP 2)	Focus group, restaurant
6	CP 6	F		Snowballed (from CP 2)	Focus group, restaurant
7	CP 7	F		Snowballed (from CP 2)	Focus group, restaurant
8	CP 8	F		Snowballed (from CP 2)	Focus group, restaurant
9	CP 9	F		Snowballed (from CP 2)	Focus group, restaurant
10	CP 10	M		Snowballed (from CP 2)	Face-to-face, cafe

Table 9: Breakdown of community pharmacist participants

5.7 Pilot Fieldwork

Pilot fieldwork is useful for social scientists to test their research methods, questions and participants prior to beginning the main bulk of the fieldwork (Bryman, 2008). Maxwell (1996: 75) argues that conducting pilot interviews in qualitative research studies is important for refining interview questions to gauge ‘how people will understand them and how they are likely to respond’. Pilot interviews are also useful for identifying areas of importance which may have been missed out on the original interview guide.

For the present project, most of the pilot interviews were undertaken with pharmacogeneticists. They were identified as an appropriate group within the sample with whom to conduct pilot interviews because (i) it was felt that it was important for the project to ‘map’ out the current state of PGx technology in order to place the study findings within the context of the scientific development of this field; (ii) those developing the technology are likely to have well-informed insights into how it will come to be delivered in medical practice; and (iii) pharmacogeneticists work in

collaborative teams, which sometimes include pharmacists. The pilot interviews with pharmacogeneticists also served to establish where the original interview guide had omitted important topics relevant to the research. In total, six pilot interviews with pharmacogeneticists were conducted.

Necessarily, the pilot interviews with pharmacogeneticists focused primarily on the nature and development of the technologies of personalised medicine with the implications for pharmacy practice being the secondary topic of the interview. For the hospital and community pharmacists that were interviewed for the project, the primary focus was pharmacy practice and the implications of new technologies for it. Therefore, a pharmacy stakeholder was identified in collaboration with the Pharmacy Practice Research Trust as an appropriate participant with whom to test questions about pharmacy practice and the positioning of PGx within it.

The pilot fieldwork was useful for the subsequent fieldwork as it identified a number of areas of interest which were absent on the original interview topic guides. Following this fieldwork, then, the interview topic guides were amended to include these topics (see Appendices F-K). This was particularly helpful with respect to the NHS ethics and governance approval process where final versions of documentation such as interview topic guides are required before fieldwork begins. In conducting pilot interviews with non-NHS staff, these interview topic guides could, thus, be finalised before they were submitted for NHS approval.

5.8 Data Analysis

Following the data collection, the interviews were transcribed by a contracted transcriber. It should be noted that this transcriber signed a Confidentiality Agreement (see Appendix M) in order to protect the confidentiality of research participants, although the audio files were anonymised prior to being e-mailed to the transcriber. The data was transcribed verbatim but without conversational details such as pauses and hesitations as these were not crucial to the research questions and would have limited the readability of the transcripts (Potter and Wetherell, 1987).

As the interviews were transcribed by a contracted transcriber, the process of reading and re-reading them was particularly crucial. Undertaking their own transcription is acknowledged as a key way in which researchers become immersed in the data and come to construct themes arising from it (Bird, 2005). As such, in instances where this transcription has been sub-contracted, a period of the research should be wholly dedicated to familiarising oneself with the content of the interview transcripts. In this case, a month was taken solely to read through the data.

Data analysis took the form of a thematic analysis which was approached in a 'bottom-up' fashion whereby analytical frameworks were not imposed on the data but the data was allowed to speak for itself. This is not to say that the data analysis took a wholly grounded theory approach as the theoretical frameworks identified in the preceding chapters were used as sensitising tools to make sense of and explain the data (Murray *et al.*, 2010). This thematic analysis was a two level analysis. Firstly, the data pertaining to three broad categories of interest was identified; the structure of contemporary pharmacy practice, technologies and pharmacy, and PGx and pharmacy. A secondary analysis of the themes intersecting these categories was then carried out. It was within this secondary analysis that the empirical frameworks used in the following empirical chapters were identified. Within this, then, medicines management practices were identified as a key feature of pharmacy which intersected both hospital and community settings and was central to the understandings of new technologies in pharmacy. Within this, it was identified that pharmacists undertake something of a dual approach to medicines management where formalised, codified practices are undertaken concurrently to more negotiated practices which are argued to be enacted through what has been called here the 'pharmacy gaze'. This Foucauldian framework provided a way through which the construction of patient bodies within pharmacy could be analysed. It also provided a framework through which to analyse the effects of new technologies (specifically PGx) on everyday pharmacy practice.

The next three chapters present findings from this thematic analysis of the data. These chapters are structured around three broad topic areas of (i) the structure of contemporary pharmacy practice, (ii) technologies and pharmacy and (iii) PGx

and pharmacy with the themes of dual medicines management, risk and toxicity, and patient bodies constructed through the 'pharmacy gaze' cutting across each.

Chapter Six: Conceptualising Contemporary Pharmacy Practice

6.1 Introduction

This chapter draws on empirical data to present a sociological conceptualisation of contemporary pharmacy practice through the analysis of what I propose to call the ‘pharmacy gaze’. This pharmacy gaze takes Foucault’s notion of the ‘clinical gaze’ as its point of departure and argues that pharmacists construct patients in a distinct way, as at-risk medications users. The chapter argues that the management of medicines is undertaken within a dual process where a codified, formalised approach is enacted simultaneously with a less formalised, more negotiated process. The pharmacy gaze, then, is shown to be central to this more negotiated practice.

In order to understand this engagement with these dual medicines management processes, it is important to present an empirically-informed overview of the roles and statuses found within the contemporary pharmacy practice landscape. Mapping such a landscape will also be of benefit in framing the professional environment into which PGx technology may be implemented, discussed more fully in Chapter Seven and Chapter Eight. To begin with, then, this chapter outlines the status of contemporary pharmacy using the contrasting concepts of ‘medical technocracies’ (Serra, 2010) and ‘bioclinical collectives’ (Bourret, 2005; Rabearisoa and Bourret, 2009) as frames of reference for understanding the way in which pharmacy is practised in different medical settings. This analysis is intended as an empirically-informed adjunct to the theoretical issues explored in Chapter Two and, together with an elucidation of the pharmacy gaze, presents an outline of the practice environment into which new technologies are implemented. Through constructing this conceptual map of contemporary pharmacy practice, the key analytical elements of this chapter can be employed to understand the way in which new technologies generally, and PGx more specifically, are engaged with by pharmacists.

6.2 Status of Pharmacy Profession

As Chapter Two showed, the relative status of pharmacy as a healthcare profession has been continually debated in the academic literature. In the South African context, Masongo (2005) asks whether pharmacists should be seen as healthcare professionals or shopkeepers as the retail pressures on pharmacists have tended to inform understandings of the sector as less service oriented and, thus, less ‘professional’ than practitioners in other healthcare sectors (see Harding and Taylor, 1997). Despite Evetts’ (2003) assertion that professionals can have a ‘dual character’ which allows them to mobilise services for economic benefit, the discussion around the professional status of pharmacy continues.

A thematic coding of fieldwork data suggests that the professional status of pharmacy is highly aligned with the relevant practice sector, whose regimes govern the extent of collaborative working and the pattern of interaction with technologies. As such, there is a fairly clear status difference between community and hospital pharmacists which is mediated by the model of practice in each setting where community pharmacists practice in relative isolation and subordination (Cooper *et al.*, 2009) whilst hospital pharmacists engage in much more collaborative working with other health professionals. In order to contextualise the analysis of the pharmacy gaze later in the chapter, an analysis of these two practice models is now provided using the contrasting notions of medical technocracy (Serra, 2010) and bioclinical collective (Bourret, 2005; Rabeharisoa and Bourret, 2009) as frames of reference.

6.2.1 Community Practice: A Medical Technocracy

Community pharmacy practice traditionally involved compounding and dispensing medications that had been prescribed by other healthcare professionals, namely GPs. As demonstrated in Chapter Two, expansion of the role of community pharmacists over the past two decades has increased the clinical responsibilities of pharmacists and reconstituted the pharmacy space as an area for clinical consultations, public health information and direct drug purchasing (Taylor *et al.*, 2003). Despite this increased clinical role, the retail focus of community pharmacy, which has been

conceptualised elsewhere as ‘role strain’ (Harding and Taylor, 1997), remains central to debates as to the professional status of pharmacy in comparison to that of general medical practice.

In the main, the data presents an implicit assumption that community pharmacy practice occupies a lower status position in the primary care division of labour than general medical practice. Here, the retail aspects of the community pharmacy role are central to perceptions of its status, as Community Pharmacist 3 notes:

“they still prefer to go to GPs...that’s a perception that a lot of patients have about pharmacies. We are still the glorified shopkeepers” (CP 3)

Although Community Pharmacist 3 talks specifically about patients’ perceptions of community pharmacy’s status, the data suggests that GP’s limited understanding of the work of community pharmacists leads to assumptions about a lack of clinical focus and a potential “*conflict of interest*” (GP 2) due to the retail role of community pharmacists. These assumptions made by GPs reinforce the hierarchical division of primary care labour. Given this, the primary care practitioners interviewed reflected that most interaction between GPs and community pharmacists tends to be centred on ‘retail’ issues such as stock availability, rather than clinical collaboration, although more collaborative practices are thought to emerge when GPs have a greater understanding of pharmacists’ work (see below).

Given this apparent conflict of interest between GPs and community pharmacists and the hierarchical primary care model that emerges from it, GPs often assume that they should be the practitioners who set the agenda for practice in the community setting, as General Practitioner 2 highlights:

“I’m personally okay to make use of that [pharmacy clinical services] provided it’s within the spirit of the practice and within

the professional boundaries or expectations we need to fulfil” (GP 2)

Such boundary work rigidly demarcates the practices of pharmacy and general medicine and creates a technocratic hierarchy where the expertise and practice technologies of GPs are perceived as being higher in status compared with those of pharmacists. Within this, as the above quote from General Practitioner 2 highlights, GPs become gatekeepers not only for certain medicines through prescribing activities (see Busfield, 2010), but also for clinical services provided by the pharmacy. As such, these pharmacy-based clinical services will only be discussed with, or recommended to, patients when they fit within the terms of the GP’s technocracy. As such, pharmacists’ autonomy over their own clinical activities is somewhat limited by the rigid hierarchy in primary care practice.

This hierarchical technocracy, however, is not a universal community pharmacy experience and is, instead, dependent on the location of pharmacy practice and the level, and form, of GP and community pharmacist interaction. The differences between rural and urban pharmacy practice and the, generally, higher levels of inter-professional collaboration in the former have been examined elsewhere (Ranelli and Coward, 1996; Rogers *et al.*, 1998). The data collected here concur with previous findings and suggest that this technocratic hierarchy is less dominant in rural pharmacy settings where GPs and community pharmacists work more closely than those in more urban settings, as Community Pharmacist 2 (a rural community pharmacist) observes:

“I think because we were in a village and we had really strong links with our GP practice”

“Maybe for more town centre pharmacies it’s harder because they don’t always see the same patients all the time as you do if you’ve got more of a village or that kind of setting” (CP 2)

Serra’s (2010: 170) notion of a medical technocracy in liver transplantation medicine suggests a highly contested process of establishing practice boundaries in

which ‘each of these groups [of practitioners] seeks to conquer the areas dominated by the other group, controlling new practices’. The present data pertaining to community practice suggest that the boundary work undertaken by GPs and community pharmacists is done so through a relatively consensual (rather than conflictual) process. Within this, the differential status of GPs and pharmacists is accepted by the latter as an inevitable, and not necessarily undesirable, aspect of practising pharmacy. Hence, the boundaries between general medical and pharmacy practice are, generally, informally negotiated owing to the different expertise and job role of each occupation;

“doctors are up here and pharmacists are down here... we do a good job but we don’t do a doctor’s job” (CP 2).

In a number of cases, community pharmacist respondents had experience of providing clinical services in collaboration with GPs. Where community pharmacists have engaged in such practices, they note that they were able to demonstrate their ability to engage with clinically-focused activities and thereby question assumptions about their heavy retail focus. Such collaborative working is perceived as an opportunity for community pharmacy to integrate into the primary healthcare team and increase the trust that other practitioners have in the sector (see Chen and de Almeida Neto, 2007). Whilst a lack of trust was not made explicit during the interviews, GP’s lack of knowledge around the expertise and work of pharmacists can mean that the former are reluctant to hand over too many clinical services that have traditionally been the domain of general medical practice. When community pharmacists and GPs work closely together, however, this reluctance is often overcome by an acknowledgement of pharmacists’ capabilities of undertaking such roles, as Community Pharmacist 10 highlights:

*“Once they [GPs] know you can be clinical then they’re happy to hand over some work or smoking cessation or diabetes clinics”
(CP 10)*

The above quote demonstrates that this relatively consensual boundary work is, nonetheless, hierarchically managed whereby GPs hand over work to pharmacists only when the latter have demonstrated their clinical abilities and so weakened notions of their being simply ‘shopkeepers’ (Masongo, 2005). The data highlighting this consensual boundary work sits in opposition to Eaton and Webb’s (1979) assertion that the increase in clinical responsibility of pharmacists might be experienced by medical practitioners as ‘boundary encroachment’. They argue that given the potential for these new pharmacy roles to increase the status of pharmacy, acquire resources otherwise invested in medical practice and affect the ‘informal ranking of specialities’ (p.82), the boundaries around medical practice need to be re-asserted to confirm the autonomy of the medical profession and guard against boundary encroachment by these new clinical practitioners. The data, however, suggest that GPs are willing to re-negotiate boundaries around some clinical work where local pharmacists are able to provide services. Much of this willingness is rooted in GP’s experiences of other boundary shifts and changes to their working practices, such as increased bureaucracy, increased research burden and extended opening hours.

6.2.2 Hospital Practice: A Bioclinical Collective

Reflecting on her own experiences practising as both a community and hospital pharmacist, Heena Bhakta (2010), notes that there are substantial differences between these practice sectors with the latter being more ‘interdisciplinary’ and specialised. As such, in accordance with the Audit Commission’s (2001) recommendations, hospital pharmacists are more integrated into the medical practice team in comparison to those practising in the community who tend to be more ‘isolated’ (Cooper *et al.*, 2009). Moreover, hospital pharmacy is typified by disciplinary specialisation in which pharmacists opt for a particular area of medicine to specialise in, such as Oncology or Paediatrics. This specialisation in hospital pharmacy practice means that hospital pharmacists cultivate a set of expertise and skills based around one substantive area of medical practice and the medications associated with it. In doing so, hospital pharmacists play a significant role in assisting physicians with prescription and treatment decisions, in contrast to their community-based colleagues (Taylor *et al.*, 2003: 22).

This more collaborative model of practice in hospital settings can be analysed through the use of Bourret's (2005) and, latterly, Rabeharisoa and Bourret's (2009) notion of a 'bioclinical collective'. This model of practice is centred on clinicians and researchers working collaboratively to decide on the best course of treatment for a patient given the increased complexity of disease in the post-genomic era. Although much of hospital pharmacy practice is not routinely engaging with genomic techniques or information, the collaborative principles underpinning bioclinical collective practice are central to hospital pharmacy practice, as Hospital Pharmacist 4 notes:

"I work pretty closely with them [consultants] and the other specialist nurses and the whole team really" (HP 4)

Given this, the division of labour in hospitals is not hierarchically based on occupational categories but based on particular specialist fields where numerous practitioners from one specialism share their diverse expertise with others in order to identify the best course of action for the patient. In this way, the bioclinical collective practices that characterise professional relationships in hospitals tend to ascribe equal value to the expertise and work of practitioners from across occupational areas. This bioclinical collective model is particularly typical of specialist fields which require careful medicines management due to the increased risk of toxicity of the medications used in that field. Oncology is a particularly notable example of such a practice model where multi-disciplinary teams are a routine feature of practice due to the complexity of disease in this area and the increased risk of medications, as Hospital Pharmacist 3 (an Oncology pharmacist) and Oncologist 1 highlight below. Ideas around this understanding and framing of toxicity are discussed further below.

"You'll have the junior doctors and the nurses and pharmacy... so there is certainly collaboration" (HP 3- Oncology)

“The multidisciplinary team is the surgeon...the pathologist...the oncologist...the specialist nurse...usually somebody from radiology...sometimes you’ll have somebody from palliative care”
(O 1)

The relative lack of hierarchical divisions of labour between hospital pharmacists and other hospital practitioners means that hospital pharmacists are often perceived as higher in status or more ‘professional’ than those practising in the community (Elvey *et al.*, 2011). Here the absence of professional role strain or commercial pressures is central to patient and practitioner perceptions of hospital pharmacists as clinical practitioners, rather than just dispensers (see Rapport *et al.*, 2010). Moreover, this elevated professional status of hospital pharmacy through a central role in bioclinical collective working practices is mediated through the technological interventions which hospital pharmacists mobilise in their routine work. Through an analysis of EPS technologies, Petrakaki *et al.* (2012) argue that pharmacists’ engagement with innovative technologies can increase their professional status by expanding their professional jurisdictions; engaging them in clinical judgements through an increased information pool; strengthening inter-professional trust; and rendering them part of the ‘NHS family’ (Petrakaki *et al.*, 2012). This analysis of EPS demonstrates the ways in which the professional status of pharmacy can be influenced by engagement with technology. As hospital pharmacy practice engages with various diagnostic, ICT and medical technologies at the centre of its practice, this may go some way to understanding the disparity between the status of hospital and community pharmacists. This can be particularly witnessed in the case of patient medical records, as is touched upon below and discussed more fully in Chapter Seven.

Although previous commentaries (Basse, 2011) and research (Rapport *et al.*, 2010) have focused on the practice and status differences between community and hospital pharmacy, this binaried representation of pharmacy practice ignores the diversity found within each sector. The empirical data upon which this chapter is based suggests that the diverse contexts in which pharmacy is practised mean that those practising within the same sector (i.e. hospital or community) do not

necessarily share similar experiences. In the case of community pharmacy, for example, the experiences of owner-occupiers, large or small multiple employees and urban or rural practitioners can differ greatly because of this diversity of practice settings.

Nonetheless, the safe and effective dispensing and administration of medications is a central principle underpinning all forms of pharmacy practice. Hence, although their experiences of everyday practice routines may vary greatly, the philosophy of good pharmaceutical care and medicines management is a central foundation in all practice contexts. The remainder of this chapter offers a sociological analysis of the everyday practices of pharmacists through their engagement with pharmaceutical care and the medicines management processes. The chapter presents a dual approach to these processes by arguing that alongside pharmacists' engagement with formalised, bureaucratic pharmaceutical care and medicines management we find a more negotiated form of care and management, which co-constructs both medications and patients. Here, this is conceptualised as the 'pharmacy gaze'. To place this notion in context, the chapter first outlines the formalised processes of medicines management and pharmaceutical care.

6.3 Pharmaceutical Care and Medicines Management

There are philosophical distinctions between the practices of pharmaceutical care and medicines management. Pharmaceutical care entered the medical and pharmacy vocabulary in the 1990s with Hepler and Strand's (1990: 533) assertion that pharmacy practice ought to move beyond simply dispensing the correct medications towards 'the greater social good' of patient-centred care vis-a-vis pharmaceutical products. This patient-centred philosophy locates the minimisation of ADRs and the improvement of patient experience of medications at the centre of pharmaceutical care. As Chapter Two highlighted, this pharmaceutical care approach has recently discursively shifted to a focus on medicines optimisation in which the care of patients, as medications users, is increasingly centralised in pharmacy practice. As such, pharmaceutical care and, more recently medicines optimisation, are models of practice through which medicines are managed to be most effective for the patient.

Within this, the relationship between the patient and the pharmacist becomes defined as a covenant, although Barber (2001) argues that this framing of the relationship is somewhat insufficient in capturing the other commitments of the pharmacist (such as to the health of the population as a whole).

In contrast to the patient-centred practice of pharmaceutical care, medicines management is rooted in organisational interests to make medicines more effective and efficient for the organisation, rather than the individual patient (ibid.). Hence, medicines management is largely practised within the hospital and pharmacists play a central role in its delivery according to centralised directives. This aspect of hospital pharmacy practice is highly routinised and bureaucratised where decisions around patient medication are made with financial implications and local policy in mind. Here, the management of risk vis-a-vis potential ADRs is located within legal and corporate responsibility, as Hospital Pharmacist 1 (a chief pharmacist) points out:

“You have corporate responsibility for medicines management in the Trust...If something goes wrong with medicines within the Trust it’s the Chief Executive and myself who are ultimately responsible. We are the ones who end up in court and ultimately in prison” (HP 1- Chief Pharmacist).

Stowasser *et al.* (2004) argue that there are nine steps in what they term the ‘medicines management pathway’ with the role of the hospital pharmacist being well-defined at each. These steps are;

- (i) deciding to treat and prescribe; once a clinician has ascertained that treatment is necessary, the bioclinical collective team negotiate the most appropriate and cost-effective route to take.
- (ii) recording medicines order; once a medication has been decided on, this decisions needs to be carefully and accurately recorded.
- (iii) reviewing medicines order; the medicine is then reviewed for issues such as funding challenges, drug-drug interactions and ease of compliance.

- (iv) issuing medicine; once a medication is verified as being safe and appropriate, it is manufactured or issued from the producer (this may have already been undertaken and be in storage)
- (v) providing medicines information; the producer should also provide sufficient information on how to take/prepare the medicine and its potential toxicity.
- (vi) distributing and storing medicine; once issued, a medication is delivered to the care space (e.g. wards) and stored appropriately.
- (vii) administering medicine; this involves assessing when and how a medication should be administered (e.g. pain relief medication)
- (viii) monitoring for response; on-going monitoring of patients also includes monitoring for ill effects from medications.
- (ix) transferring verified information; information about the steps above needs to be communicated effectively with other health care professionals (typically via the patient medical record) to affect future medications decisions.

The centrality of the hospital pharmacist to this medicines management pathway establishes patient medications, as opposed to patient diagnosis, as their field of expertise within the bioclinical collective practice team. It is through this pathway of medicines management that pharmacists enact a central role in their practice, which is the symbolic transformation of inert chemical compounds into socially meaningful medicines (see Dingwall and Wilson, 1995; Harding and Taylor, 1997). In this sense a chemical compound becomes a social object central to the patient illness experience through its operationalisation through the medicines management pathway as, for example, the most appropriate, the easiest to comply with or the most cost-effective.

Since the vast majority of this medicines management pathway occurs within the hospital space, medicines management becomes central to hospital (pharmacy) practice. Stowasser *et al.* (2004) argue, however, that the medicines management pathway will play an increasingly important role in community pharmacy as more services are offered through community pharmacy and, in the UK, as more patients move on to 'shared care' programmes.

Generally in the community setting medicines management is not as prominent as in hospitals and a potential explanatory factor here is the co-location of numerous healthcare practices in the latter setting. Hence, whilst community pharmacists are involved in certain steps in the pathway described above, the structure of community pharmacy in the UK (for example not being co-located with other health care professionals and not being extended access to patient medical records) means that they cannot easily be involved in all of the steps owing to the spatial separation between them and their other primary care colleagues. However, the importance of community pharmacists to effective pharmaceutical care has been identified elsewhere (Farris *et al.*, 2005; Grainger-Rousseau *et al.*, 1997; Scottish Executive, 2006). Arguably the most salient example of pharmaceutical care in community practice is the undertaking of medicines use reviews (MURs). MURs were introduced as an Advanced pharmacy service in 2005 as a way for polypharmacy patients to make sense of their medications and voice any concerns with them (Latif and Boardman, 2008). Copies of the report generated from the MUR are given to patients and, if necessary, forwarded to the GP. Despite MURs being central to the pharmacy contract and pharmaceutical care, numerous challenges for pharmacists performing MURs have been identified such as low levels of patient engagement and lack of access to enough information to complete a comprehensive review (*ibid.*).

This means that although community pharmacists are increasingly involved in a community-based version of pharmaceutical care and medicines management, these practices remain closely linked with hospital practitioners and are facilitated by the hospital structure. As is shown below, the ontology of primary care drugs as being less complex and risky than hospital drugs may be significant in understanding why the labour of medicines management is apportioned in this way.

The data demonstrate that pharmacists practice a dual process in pharmaceutical care and medicines management. That is, their engagement with codified and formalised policy-based processes is enacted simultaneously with a more negotiated and informal pharmaceutical care and medicines management process, which here is conceptualised as the 'pharmacy gaze'. This pharmacy gaze

operates to co-construct medications as socially meaningful, risky objects and patients as at-risk medications users. Within this, the risk to patients is rooted in both the potential presence of ADRs and the potential absence of therapeutic benefit. As such, the notion of toxicity cannot easily be separated from efficacy, which points to the relational nature of drug toxicity and risk where the absence or presence of clinical benefits plays a role in constructing the pharmacological risk to the patient. In other words, risk and toxicity can be discursively constructed as the absence of therapeutic benefit as much as the presence of adverse reactions. Moreover, it should also be noted that toxicity may also occur simultaneously with efficacy, for example in cytotoxic medicine. The point is, then, that what constitutes toxicity should not be simplified as just a presence of adverse effects with little or no drug efficacy. In a short reflection on pharmacy's history, Barber (2005) notes that pharmacists have cultivated a 'pharmaceutical gaze', which he conceptualises as an 'ability to see into the properties of medicines and predict their effects'. He notes that this pharmaceutical gaze enables pharmacists to create a common language and to differentiate themselves from other healthcare practitioners.

Barber's concept is a useful starting point for a more detailed sociological conceptualisation of pharmacy practice. Hence, whilst Barber's *pharmaceutical gaze* gives some indications as to the ways in which pharmacists 'know' medicines, the *pharmacy gaze* outlined here conceptualises the way in which pharmacists also 'know' their patients and their patients' bodies, capturing the increased centrality of clinical practice to pharmacy. In doing so, the *pharmacy gaze* relates this co-construction of medicines and patients through understanding the ontology of a drug in terms of its relationship with the patient body. The chapter now turns to an overview of the Foucauldian principles underpinning the *pharmacy gaze*, before drawing on the interview data to expound the particular features of it.

6.4 The Pharmacy Gaze

6.4.1 Introduction

The notion of the *pharmacy gaze* takes Michel Foucault's notion of the 'clinical gaze' and Barber's 'pharmaceutical gaze' as its points of departure.

Foucault coined the term ‘clinical gaze’ to describe the way in which medical practitioners in the eighteenth and nineteenth centuries became increasingly focused on clinical observations of patients which reduced the patient body to a system of observable symptoms and signs. Through this reductionist approach, medical practitioners were able to gain power over their patients through their cultivation of an ‘expert’ discourse of disease and illness. This reductionist understanding of the patient body further served to construct a mind-body dualism whereby the sick body (and the particular disease pathology within it) became discursively detached from the human patient occupying it (Armstrong, 1997).

Foucault’s notion of a ‘clinical gaze’ has been employed subsequently in sociological studies of health and illness and applied across disease areas and patient populations. Despite pharmacy practitioners playing a key role in patient experiences of health care, the ‘gaze’ through which pharmacists view and interact with patients and their drugs is under-analysed in the sociological literature (see Ryan *et al.*, 2004). The pharmacy gaze departs from the clinical gaze in the sense that the latter is concerned with reducing patients to a series of signs and symptoms which medical practitioners mobilise to arrive at the ‘truth’ about a patients’ illness. In contrast, the pharmacy gaze is relatively unconcerned with diagnosis of illness and is, instead, centred on the construction of the patient as a user of these medicines and the reduction in the risk of toxicity arising from the relationship between these two elements. Hospital Pharmacist 5 highlights this division of expertise and labour:

“I speak to patients about their medicines. It tends to be very based around the medicines that they’re currently on rather than generalities” (HP 5)

It is through the co-construction and configuration of these elements that pharmacists are able to enact a central role in their practice, which is the ascription of social meanings to ‘stuff’ (Barber, 2005: 78), such as chemicals and formulas, that are at the core of pharmacy principles. It is through this enactment that such ‘stuff’ takes on the status of a socially meaningful object in a patient’s experience.

6.4.2 Making Medicines Meaningful

Dingwall and Wilson (1995) draw on Becker's (1967) work on the social construction of illicit drugs to argue that pharmacists occupy the role of symbolically and culturally transforming inert chemical compounds (Barber's 'stuff') into socially meaningful medications. This is done through their mobilisation of knowledge of the patient; advice on use of medications; and drug interactions expertise. In doing so, medications become social objects within the patient's wider 'lifeworld' and are imbued with connotations and meanings through the pharmacist's dispensing and counselling activities. One such example of the way in which medicines can take on social meanings is highlighted by Cribb *et al.* (2011). In their exploration of shared decision making in diabetes treatment, they note that being prescribed insulin can be understood by patients as indicative of their 'failure' (p. 38) to effectively manage their condition through dietary regimes.

Although Dingwall and Wilson's perspective is a useful analysis of the social role of pharmacy and feeds into understandings of the pharmacy gaze, their insights do not acknowledge the extent to which medications and patients are co-constructed by pharmacists. In this way, Dingwall and Wilson's (1995) perspective is limited in much the same way as Barber's (2005) pharmaceutical gaze in that they focus solely on medicines and do not examine pharmacists' construction and understandings of patients. The data collected here, however, show that pharmacists cultivate a particular way of knowing and understanding patients through this construction of medicines as socially meaningful objects. Hence, whilst chemical compounds are symbolically transformed into social objects, patients are simultaneously symbolically transformed into medications users around whom a discourse of toxicity and risk is constructed based on their individual patient journey and therapy regime.

This discourse of toxicity sits at the centre of the pharmacy gaze and relates to pharmacists mobilising their expertise in pharmacology to verify the 'proper' use of the 'best' medication (Dingwall and Wilson, 1995: 120). The construction of a discourse of toxicity is particularly applicable to hospital pharmacists whose gaze

extends beyond the one-off dispensing encounter to one prolonged for the duration of the patients' stay in hospital.

6.4.3 Constructing a Discourse of Toxicity

Central to the nature of social meanings afforded to medications is the ascription of their relative risk and toxicity. This is a key aspect of Barber's pharmaceutical gaze whereby pharmacists are able 'to see' into the properties of medicines and predict their potential effects. Barber's conceptualisation does not, however, place an emphasis on the specificities of the individual patient body through which, and within which, these potential effects occur. Although he notes that pharmacokinetics historically enabled hospital pharmacists to control risk, he suggests that pharmacy practice 'is not based on parts of the body...manipulating, cutting or caring for the body' (Barber, 2005). Ryan *et al.* (2004) argue in contrast that an analysis of the body in pharmacy is needed and the data presented here suggest that the potential (adverse) effects of drugs cannot be so easily separated from the biological patient body upon which they are acting. Hence, through the process of making medicines meaningful, pharmacists also make the patient body pharmacologically meaningful by constructing them, and in so doing gazing at them, as at-risk medications users. This co-construction of medications and patient bodies creates a need for medications and at-risk medications users to be expertly managed by the pharmacist through the employment of a discourse of toxicity.

This discourse of toxicity is centred on the way in which potential drug toxicity is communicated to patients and managed through the characteristics of pharmacy practice. The data suggest that there are two key ways in which this discourse of toxicity is manifested in routine pharmacy practice; through the *timing* and *location* of drug dispensing and administration.

The timing of medicinal interventions is central to pharmacy's management of toxicity and ensuring drug effectiveness. This timing is practised in a sequential and cyclical model whereby medications administration is located at a specific point within a sequence of clinical interventions in order to offer maximum effectiveness, as Hospital Pharmacist 9 (an Oncology pharmacist) says:

“Because there is a risk of anaphylaxis with it and the risk is reduced over time so if patients are okay after the first three cycles or whatever then they should be reasonably okay after that” (HP9-Oncology)

In communicating the importance of drug timing to patients through the discourse of toxicity, pharmacists ascribe sociality to medications by locating them within the patient’s ‘lifeworld’. In doing so, medicines become meaningful through the management of the risks associated with them by becoming a part of the patient’s wider social and cultural practices, such as being re-configured as part of meals or an evening regime. Through this reconfiguration as social objects, it is thought that increased adherence to medications regimes can be achieved. Adherence to medications regimes has been highlighted elsewhere as being a particular challenge for pharmacists and other healthcare professionals (Farmer, 2010). Farmer (2010) notes that a lack of adherence with medications can be due to a medication regime being understood by patients as sitting outside of their normal lifeworld. This is central to the discursive shift towards medicines optimisation where patient involvement in medications decisions is centralised as a way in which the use and management of medicines can be optimised through increased patient engagement (Cutler, 2011; Stephens, 2011). Given this, by mobilising practices which counsel patients extensively and locate therapy regimes within a patient’s normal routine, pharmacists are able to contribute to the improvement of adherence and, subsequently, patient outcomes, as Hospital Pharmacist 1 highlights:

“They’ve divided up into time periods to help them take their medicines at the right time” (HP 1- Chief Pharmacist)

This management of medicines timing is particularly important and highly centralised in the discourse of toxicity where the risk of ADRs is particularly high. Here, the dispensing of Oncology drugs is accompanied by relatively extensive counselling practices, as Hospital Pharmacist 3 (an Oncology pharmacist) notes:

“So the pharmacy staff, when they’re handing over prescriptions, will be doing a certain amount of patient counselling about how many tablets to take, how to take them, should they be taking them with food, after food” (HP 3- Oncology)

Hospital Pharmacist 3’s comment here, and much of the focus on timing in the discourse of toxicity, is located around discharge practices. Hence, much of the focus is on the effective timing of taking hospital drugs in community settings. The data also show that the location in which drugs are dispensed and administered is central to their ontological status. Here, the discourse of toxicity creates a distinction between primary and secondary care drugs vis-a-vis their potential toxicity and the expertise necessary to manage this toxicity.

In this distinction, primary care drugs, and the healthcare practitioners that routinely practise with them, become associated with what are perceived to be simple, common ailments that can be effectively managed with minimal risk of toxicity. Secondary care drugs, on the other hand, are ontologically associated with complex diseases and polypharmacy regimes which mobilise comparably toxic medicinal interventions.

Such toxicity of secondary care drugs is managed in the hospital setting by being contained within the physical boundaries of the hospital and the co-location of different practices within it. This is in contrast to the primary care setting where such toxicity cannot be easily contained within one environment as practitioners (most notably GPs and pharmacists) are geographically dispersed and do not practice as bioclinical collectives as do those in hospital-base settings.

Given this ontological and discursive binary between primary and secondary care drugs, healthcare practitioners working within each sector cultivate a particular set of expertise around the diseases and medications that they routinely encounter. In this way, boundaries are drawn between the knowledge and work of GPs and hospital doctors and community and hospital pharmacists, as the quotes below demonstrate.

“Community pharmacists don’t even deal very much with cancer drugs. That’s still secondary care” (CP 8)

“GPs are not happy about sharing responsibility for prescribing and monitoring these patients. They want to stick with what they know - diabetes, hypertension. They don’t want to see patients, generally I’m talking and there will be the occasional GP who might be happy but by and large they perceive oncology as being high-tech, complex, complicated” (HP 9-Oncology)

“There is quite a big gap at the moment but we shouldn’t forget that these patients are not only treated for the condition that they get all singing all dancing medicines for they’ve also got general medical conditions... And they will be getting treated by their GP and getting their medicines from the community pharmacy for a whole wide range of things as well as specialist care” (HP 6-Director of Pharmacy)

This discursive binary between hospital and community medical and pharmacy practices around the notion of complexity (both disease and drug) is, arguably, increasingly blurred as more patients are managed through shared care arrangements and hospital drugs are increasingly administered in community settings. One particular example here is the breast cancer drug Herceptin¹⁴ which is increasingly prescribed in hospitals but administered in patient’s homes in the community. Nevertheless, Herceptin is prescribed for a relatively complex disease and, due to it often being used as an adjunct therapy with traditional chemotherapy, reflects this complexity in regard to its potential toxicity and managing adverse effects. Given this, timing remains integral to the management of toxicity that surrounds this therapy, as Hospital Pharmacist 9 (an Oncology pharmacist) highlights below.

¹⁴ This drug is described by Hedgecoe (2004) as the first example of a pharmacogenetic drug in routine clinical practice. In the present discussion, however, the pharmacogenetic status of Herceptin is purely coincidental and not related to the argument at hand.

“Those drugs [Herceptin] were then made up by the third party supplier and then they were transported by the nurse to the patient’s home at a predetermined time, predetermined date” (HP 9-Oncology)

Moreover, this quote demonstrates that although the binary between hospital and community medicine is somewhat blurred, there is still a degree of boundary work being carried out around the management of Herceptin’s toxicity. As such, only practitioners with expertise in this area (in this case a specialist oncology nurse) are able to interact with this medication and the patient as a user of it. Such expertise moves beyond the confines of the hospital into the wider community setting, accompanying and enabling the movement of the drug. This suggests that the hospital regime for toxicity management is embedded within the drug itself. As a result, when the drug moves to the community setting, it carries the medicines management regime of the hospital with it, which brings secondary care drug ontology and primary care cultural practices together into the patient experience of drug taking.

These anxieties, grounded in discourses of complexity, and the boundary work they necessitate provide a useful framework for analysing the potential implementation of PGx technologies. As Community Pharmacist 6 highlights, at present there is an alignment between PGx principles and practices with highly specialised hospital-based fields which are routinely utilising relatively complex medications:

“I think there’s an assumption that it’s [pharmacogenetic medicine] very much secondary care led therefore you wouldn’t necessarily see that in the community and an assumption that it’s very specialist” (CP 6).

The role of disease and drug complexity in affecting the implementation of pharmacogenetics in hospital and community pharmacy practice is discussed in more detail Chapter Eight.

6.4.4 Gazing at the Patient Body

Central to this primary/secondary care binary within the discourse of toxicity is the patient body as this is the site through which the discourse of toxicity is enacted and within which the ontological status of drugs comes into being. In other words, the discourse of toxicity cannot exist without the presence of the patient body as it is the patient body within which adverse reactions take place and, thus, through which understandings of drugs as potentially toxic are developed. The data suggest that pharmacists have a particular way of constructing and knowing the patient body through this discourse of toxicity. As such, central to the pharmacy gaze is a co-construction of medications as risky pharmacological interventions and patient bodies as a site of complexity and risk brought about by the pharmacological action of these medications. Given their expert knowledge of pharmacology, the pharmacy gaze claims the management of these dual elements as pharmacists' field of practice and expertise.

The traditional role of pharmacists as compounders and dispensers meant that the majority of their time was spent in the dispensary with limited contact with patients. As such, the patient body *only* became apparent to the pharmacist through adverse reactions and toxicity.

Although the increased clinical role of pharmacists has created new ways through which pharmacists interact with patient bodies (see below), the patient body is still primarily apparent to pharmacists within, and through, the discourse of toxicity. Within this, the patient body is constructed as a complex site of potential risk brought about by the actions of medications working within it, which pharmacists claim as their field of expertise. As such, particularly in the hospital setting where prescription decisions are arrived at through a highly collaborative process of negotiation, pharmacists bear a degree of responsibility for ensuring the maximum efficacy and minimal toxicity on the patient body of therapy regimes, as Hospital Pharmacist 3 highlights:

“The body is very complex so how does it handle the drugs? Effects from the tumour, effects from the patient’s body, the rate of liver metabolism” (HP 3- Oncology)

This quote demonstrates the need to effectively manage the complex and risk-laden patient body vis-a-vis drug action and potential side effects. Particularly in the hospital setting and in fields with highly toxic medications, this is done through the reduction of the ill body into a series of criteria and algorithms through which prescription decisions are made, as Hospital Pharmacist 9 (an Oncology pharmacist) and Hospital Pharmacist 4 highlight:

“In order to screen a prescription for chemotherapy you would need to check certain aspects of the patient” (HP 9-Oncology)

“You’re going to have to check that those criteria have been met before the drugs actually released or dispensed” (HP 4)

In addition to determining these characteristics of the patient body, a key driving factor for these prescription decisions is also the cost of the medications. Hence, the ill body is understood as a potentially expensive body. Particularly in the hospital setting, where high-tech, innovative and comparatively expensive therapies are more likely to be prescribed, treatment decisions are often mediated by the potential financial implications.

“There were these new treatment options coming onboard all the time and yet we were told to save money all the time” (HE 1- also previous a HP)

This centrality of financial implications to therapy decisions also provides another way through which the implementation of PGx into routine practice can be analysed. Elsewhere pre-prescription PGx testing has been regarded as a way through which traditional ‘trial and error’ prescription models can be improved (Martin *et al.*, 2006). This improvement, however, relies on these tests being

relatively cheap (in contrast to trial and error approaches) and providing reliable results on which prescription decisions can be made. Here, again the differences between primary and secondary practices and medications become important. Hence, in primary care settings the relatively cheap price and low toxicity of medications is understood to make the ‘trial and error’ prescription model relatively unproblematic, as Community Pharmacist 6 notes:

“It will depend very much on the cost because if we look at things like Codeine, you could just try it and if it don’t work you try something else because it’s so cheap to try” (CP 6)

In contrast, in secondary care where there is an increased risk of toxicity and higher financial burden of ineffective medications, pre-prescription PGx test results are understood as constituting another ‘aspect’ (to use Hospital Pharmacist 3’s term) of the patient body through which prescription decisions are made. Hence, pre-prescription PGx testing in hospital settings is a potential way for the ill patient body to become a less expensive body.

As mentioned above, pharmacists’ interactions with the patient body are increasingly enacted through pharmacy’s clinical role. In the community setting in particular, these clinically-based interactions often occur through testing services that are part of the extended role. Through this aspect of practice, the patient body becomes a biological entity about which ‘truths’ can be ascertained through the results of black-boxed tests, as Community Pharmacist 3 demonstrates:

“I was offering cholesterol testing as well as CVD [Cardiovascular Disease] calculations. So that was cholesterol, blood pressure test, heart monitoring and in that respect calculating patients’ CVD risk” (CP 3)

Unlike in hospitals, however, the results of these tests do not necessarily serve to construct the patient body as a series of criteria or algorithms or feed into prescription decisions. Instead, these tests provide patients with access to

biomedical knowledge about their own bodies. At the same time, the patient as a lay manager of medicines is increasingly an object for community pharmacy as part of the move by government to better medicines management in the community (Department of Health, 2000; Department of Health, 2003b). This is further reflected in the recent discursive policy shift away from medicines ‘management’ and towards medicines ‘optimisation’ which places an increased focus on the ways in which medicines are used by patients (see Colquhoun, 2012). Within this, community pharmacy services such as the New Medicines Service¹⁵ (NMS), are posited as examples of this ‘policy in action’ which locate the community pharmacist as a central practitioner in this optimisation process. This reconfiguration of the pharmacist as a healthcare practitioner has necessitated the incorporation of a divergent skill set around increasingly physical interactions with the patient body into routine practice; as Community Pharmacist 2 notes, this was something unlikely to happen in the past:

“We’ve never actually touched patients before, you know, you do the medication for them, you stick it in a bag and you hand it over. Pharmacists are generally not used to touching patients. Communication skill as well is not something that pharmacists in the past have needed” (CP 2)

The pharmacist/patient relationship is also configured around the status of the patient body as being chronically or acutely ill. Here, the acutely ill patient body is present for a relative short period of time and, generally, represents fewer complexities or risks vis-a-vis toxicity and adverse reactions. It is through interactions with this sort of patient body that pharmacists are most likely to enact a ‘shopkeeper’ role (Masongo, 2005) and experience the role strain and status issues associate with it. In contrast, chronically ill bodies tend to be more complex and risky due to the increased chance of polypharmacy regimes. As such, pharmacists’ interactions with them tend to be lengthier, more sustained and more akin to that of

¹⁵ The New Medicines Service was introduced as an advanced service in the community pharmacy contract in October 2011. It is focused on supporting patients with long-term conditions to comply with new medications that they have been prescribed (Buxton, 2011).

other healthcare professionals. The quote below highlights the central role pharmacists can play in the experience of chronically ill patients;

“People who were post-bone marrow transplantation and they’d be on quite extensive drug regimens... I’d go through their medications with them and help them about how to organise their 25 medicines they were taking a day” (HE 1- also previous a HP)

This difference between pharmacy/patient interactions with acutely and chronically ill patient bodies may also be a central factor in understanding the status differences between community and hospital pharmacists outlined at the beginning of this chapter.

6.4.5 The Bioclinical Collective Gaze

Another key difference between hospital and community pharmacists’ interactions with the patient body is the status of the hospital pharmacy gaze as one of many practitioner gazes which the patient body is subject to given the number of practitioners who become involved in the patient’s care. Here, then, the pharmacy gaze which constructs the patient as a medications-user is one of a number of perspectives through which the ill body is narrated by the bioclinical collective. Unlike in community settings, where practice co-location and collaboration are much more limited, these varying gazes are not deployed in isolation but instead, as May (1992) suggests, work interactionally to construct a narrative of the patient body which is aligned with hospital expertise, knowledge and policy.

As an example of such divergent gazes at work in the hospital setting, May highlights the particular way in which nurses utilise the structure of their practice (i.e. being based on wards and having more time to speak with patients) and position within the hospital division of labour to cultivate both a foreground and background knowledge of patients. Hence, nurses gaze at patients both as a particular, clinically-defined set of care requirements (foreground knowledge obtained through a clinical

gaze which seeks ‘truths’ about the patient body) and as idiosyncratic and private subjects (background knowledge obtained through a more nursing-specific gaze).

The exploration of different gazes in the hospital setting is useful in understanding the different ways in which patients are constructed by different health care professionals and for placing the pharmacy gaze within wider understandings of patients. Much of the work in this area, however, treats different clinical gazes or ways of knowing patients as discrete and related solely to that particular field of practice. The data, however, show that through bioclinical collective practices, pharmacists engage with and negotiate ‘gazes’ other than that of their own profession, particularly around the time of discharge.

This multi-gaze that the patient body is subject to in hospital settings is facilitated through hospital policy generally allowing all health care professionals that interact with patients to have access to patient medical records. Berg and Bowker (1997) have analysed patient medical records from a Foucauldian perspective and argue that patient medical records produce a history, geography and memory of the patient through verified (i.e. tested) ‘truths’ about the patient body. Moreover, they argue that patient medical records are fundamental to the everyday production of the patient body and to the production of the organisations that enact and treat it. Hence, the relations in the hospital (between actors in the bioclinical collective and between patients and practitioners) are mediated through the medical record.

The data here confirm this general argument that access to patient medical records is of central importance to hospital and community pharmacy practice. In hospitals, allowing multiple and diverse practice populations to access, and contribute to, patient medical records collates multiple practitioner gazes in one documentary space. This documentary space serves to construct a history, geography and memory of a multi-faceted patient body through the mobilisation of various fields of expertise, as Hospital Pharmacist 6 shows;

“So it’s not just pharmacy but OTs and physios and all sorts of people who have access... all write in the patient’s notes” (HP 6-Director of Pharmacy)

In the community setting, the boundaries of expertise that are drawn around GPs create an intellectual and practice hierarchy between GPs and pharmacists which is manifested in the restriction of medical record access to the GP and, potentially, staff working in the GP surgery. As such, pharmacists practising in community settings are not granted the power to see patient records, or enter onto them observations based on pharmacy expertise. As such, the record is an important ‘inscription device’ that acts to confirm diagnostic power and expertise. This limitation of the gazes through which community pharmacists see patients was understood by respondents as being restrictive for practice as the complexities of the ill body, and their potential impact on the pharmacological action of therapies, could not be effectively managed by the community pharmacist in the same way as in hospitals, as Community Pharmacist 8 demonstrates;

“How community pharmacists are supposed to make sure that the patient is moving on with the correct medication- it’s virtually impossible without records” (CP8)

In their analysis of EPS, Petrakaki *et al.* (2012) unsurprisingly argue that increased pharmacist access to patient medical records would enhance community pharmacy’s status in terms of increased capacity for decision-making; expanding their professional jurisdictions; engaging them in clinical judgements through an increased information pool; strengthening inter-professional trust; and rendering them part of the ‘NHS family’. Moreover, as the quote above highlights, resetting the boundaries of medical record access may also be beneficial for patients through improved counselling practices and adherence. This extension of access to patient medical records, however, presents a number of practical and ethical challenges. Hobson *et al.* (2010) note, for example, that patients are reluctant for pharmacists to access sensitive, and what is largely perceived to be irrelevant, medical information such as sexual health issues. This perspective is reflected in an earlier Patients’

Association (2008) report where the practical issues of limiting medical record access to pharmacists alone (rather than all staff working in pharmacies) was also centralised. Additionally, extending medical record access undermines a central feature of the medical technocracy that exists in primary care practice. Hence, the potential for community pharmacists to interact with patient bodies through a biomedical gaze is primarily limited by the restrictions placed on medical record access in routine primary care practice. However, the increasingly clinical future of pharmacy (detailed below) means that such debates around record access will become more common.

6.4.6 Future Pharmacy Gazes

An analysis of the present character of any field of practice somewhat necessarily invites a reflection on its future. The data demonstrate three broad directions in which it is thought the pharmacy gaze may travel; an increasingly clinical gaze, which is highly aligned with an increasingly public health-oriented gaze and an increasingly molecularised gaze. Each of these is taken in turn.

The traditional role of pharmacists as primarily medicines compounders, manufacturers and dispensers located their practice within the dispensary with minimal patient contact. The ubiquity of pre-packaged medicines and extended role of pharmacy in the post World War Two era, however, increasingly located pharmacy practice outside of the dispensary and entailed increased patient contact in both the hospital and community setting.

The data show that the pharmacy gaze is increasingly focused on medicines-centred clinical activities. Hence, somewhat in opposition to the clinical gaze forwarded by Foucault, the pharmacy gaze has shifted from viewing the patient from within the dispensary as a set of medications requirements disconnected from the patient body to seeing patients in a more multi-faceted way through increased clinical contact. This is particularly true in the hospital setting where pharmacists spend large amounts of time in face-to-face contact with patients on wards. In the community setting, the pharmacy gaze was understood to become increasingly focused on clinical and public health activities. Within this, the respondents noted

concerns around funding for pharmacy, particularly in light of GP commissioning practices, as being particularly prominent for community pharmacists. Given this, the future of community pharmacy was thought to lie in a diversified practice which aligns with current public health concerns, as Community Pharmacist 2 outlines;

“I think community pharmacy can only increase its public health profile really. Get more involved in screening for things like sexual health...get more involved in some of the issues we’ve got around obesity, weight management problems” (CP 2).

This view of the future role of community pharmacy aligns with Taylor’s (2005) conceptualisation of community pharmacy’s future, which he envisages as being centred around increased co-location with clinical practice and a reconfiguration of community pharmacists as ‘the people’s doctors’ (p. 292) owing to their increased prescribing abilities and public health advisory role.

In the hospital setting, this increased clinical focus is understood as the most effective method through which drug toxicity can be managed. Hence, the discourse of toxicity is increasingly communicated to patients by active face-to-face counselling by the pharmacist rather than through passive patient information leaflets. This method of managing toxicity is thought to encourage adherence, improve patients’ experiences of their illness and medicines and reduce the financial burden of drug-related readmissions (for example Bajramovic *et al.*, 2004). This sense of the effectiveness of face-to-face clinical work and counselling is encapsulated by Hospital Pharmacist 1 (a chief pharmacist);

“It’s all about asset stripping staff out of the dispensary and getting them to be able to work on the ward...you cannot do effective medicines management in the dispensary” (HP 1- Chief Pharmacist)

Another broad area of development for the pharmacy gaze was conceptualised as being in increased molecularisation. With developments in testing

technologies (both DNA-based and otherwise), the data show that hospital pharmacists are interacting with patients framed as molecular subjects at the diagnostic and prescription phases of the patient's journey. Within this, monoclonal antibodies (mAbs) and PGx were identified as particularly central to this molecularised gaze, which can be understood in line with Clarke *et al.*'s (2003) biomedicalisation thesis. As such, it might be argued that the patient body in pharmacy is being increasingly biomedicalised through the integration of new molecular genomic technologies.

The implementation of these technologies into routine clinical practice was posited within the discourse of toxicity as offering effective ways to reduce the toxicity of (particularly Oncology) therapies. As such, they were not understood to represent a paradigmatic shift in pharmacy practice but, instead, to introduce new methods of practising the core principles of pharmacy. To demonstrate, in the case of PGx, there was an understanding that personalised principles were already at the centre of pharmacy practice as the discourse of toxicity relies on the idiosyncrasies of the patient body to determine drug response predictions. Implementing PGx testing into routine practice was thought to molecularise this personalised approach, as Hospital Pharmacist 1 (a chief pharmacist) shows;

“Tailor made therapy - yeah, I suppose we can all argue that we tailor make people's therapy but not on a genetic basis. I don't think we've got down to the molecular level yet as pharmacists”
(HP 1- Chief Pharmacist).

6.5. Conclusion

The pharmacy gaze provides a useful way of sociologically conceptualising contemporary pharmacy practice. This chapter provides an overview of the roles and statuses found within the contemporary pharmacy practice landscape and, in turn, provides a framework through which the implementation of innovative technologies into pharmacy practice can be analysed. Using empirical data, this chapter has demonstrated the way in which working practices in community and hospital pharmacy can be understood in line with Serra's (2010) and Rabeharisoa and

Bourret's (2009) notions of medical technocracies and bioclinical collectives. In this way, the demarcation of roles in community practice can be understood as maintaining hierarchical relationships between GPs and community pharmacists and feeding into perceptions of the latter as primarily retail focused. Within this, the relatively rigid boundaries that are drawn around the work of GPs and their capability to define the terms of practice in primary care are legitimated. In contrast, the data demonstrate a more bioclinical collectivity in hospital practice where the absence of retail identities and role strain contribute to the attribution of higher status to hospital pharmacists than those working in community.

The chapter argues that central to both hospital and community pharmacy is good medicines management and pharmaceutical care practices. Here, the pharmacy gaze is a useful tool for analysing the ways in which formalised, bureaucratic medicines management and pharmaceutical care policies operate concurrently with more negotiated processes. The pharmacy gaze, then, is centred on the co-construction of chemical compounds as risky medications and patients as at-risk medications users around whom a discourse of toxicity and risk is constructed based on their individual patient journey and therapy regime. The pharmacy gaze makes a novel Foucauldian contribution to sociological understandings of pharmacy practice in that it centralises the patient and their body as the site within which ADRs occur and, thus, through which discourses of toxicity are created. Moreover, this positioning of the patient body as a site of complexity and management makes medicines meaningful through locating them within patients' wider lifeworld. This process of making medicines meaningful further indicates differing practice and expertise in hospital and community pharmacy. As the chapter demonstrates, the location in which drugs are dispensed and administered is central to and a reflection of their attributed ontological status as being more or less toxic. Within this, relatively complex secondary care diseases and their comparatively toxic medications require a particular set of pharmacy expertise and practices which are divergent from those in primary care that are mainly associated with relatively simple diseases and therapies.

This notion of divergent status and working practices in primary and secondary care pharmacy is a central feature of the following chapters. Through the

use of the dual medicines management process and the pharmacy gaze as a conceptual framework, these chapters demonstrate that engagement with new medical technologies in general, and PGx specifically, is mediated through the practice relationships and environments into which they are implemented. This is a particularly pertinent issue to address given the contemporary policy focus on GP commissioning, which may alter the relationship between GPs and community pharmacists and the way in which pharmacy services are provided in primary care. As such, the following chapters make use of May and Finch's (2009) NPT as a point of reference to show the ways in which the differential structures and practices of hospital and community pharmacy necessitate the mobilisation of different forms of work in order to implement new technologies into routine practice. In addition, by returning to the notions of medical technocracy and bioclinical collective, the following chapters demonstrate the ways in which the implementation of innovative technologies into different pharmacy practice settings can re-configure them vis-à-vis their roles and status.

Chapter Seven: Technology in Pharmacy

7.1 Introduction

Pharmacists interact with technologies in their everyday practice as part of their engagement with medicines and their associated ‘stuff’ (Barber, 2005). Particularly in community pharmacy, the extended clinical role has necessitated pharmacists’ increasing use of a variety of diagnostic devices such as carbon monoxide monitors, blood glucose tests and pregnancy testing kits. This chapter draws on empirical data to argue that pharmacists’ engagement with these clinical devices enables the pharmacy gaze to move beyond a focus solely on medicines to one which incorporates the patient body, as outlined in Chapter Six. Hence, the outputs from these devices provide a means through which the patient body becomes known as a site of complexity and risk. Pharmacists’ engagement with such technological devices is, then, central to the practice of a pharmacy, rather than *pharmaceutical* gaze (Barber, 2005).

In the hospital setting, technologies that have impacted on pharmacy have, for the most part tended to be less clinical and more operational. As such, innovative technologies in hospital pharmacy practice have tended to be centred around dispensing practices rather than testing and monitoring devices. Dispensing robots, electronic prescribing systems and computerised medical records are clear examples of this. These technologies fit within the corporate responsibility framework of hospital pharmacy by assisting with audit activities, streamlining processes and reducing dispensing errors. This focus on reducing errors also resonates with the implementation of technology within community pharmacy where technologies are operationalised as a means of improving patient safety through both improving general health and managing medicines’ toxicity.

Innovative technologies in pharmacy can act to reconfigure the occupational role and identity of the profession. This process of defining professional boundaries and jurisdictions of various practices through innovations has been explored elsewhere (Korica and Molloy, 2010; Mclaughlin and Webster, 1998; Zetka, 2001). The implementation and effects of technology in pharmacy have not, however, been

extensively analysed. The research that does exist in this area tends to focus on the macro-level of the pharmacy sector in its entirety rather than the micro-level work which is carried out to integrate technologies, and their effects, into practice. This reflects a wider paucity of attention given to how technology features in the routine practice of medical professionals, through which Heath *et al.* (2003:1881) argue technology ‘gains its significance’.

Given this, this chapter examines the ways in which new technologies are configured into everyday pharmacy working practices. The chapter draws on the dual medicines management model described in Chapter Six to argue that innovative technologies in pharmacy are operationalised and configured in two ways: through their positioning within codified formalised, organisational medicines management processes and through their centrality to the pharmacy gaze as a more individualised, negotiated method of medicines management in everyday practice.

May and Finch’s (2009) NPT provides useful insights for conceptualising the ways in which new technologies are integrated into everyday pharmacy work as the components of NPT resonate with much of the data collected here. Given this, these components are used here as reference points for understanding the work that pharmacists undertake with respect to embedding new technologies. As Chapter Five (Methodology) notes, NPT is not methodologically deployed as an analytical framework for the thesis overall, rather some of its components are drawn on heuristically to help understand how innovative technologies and practices are taken up. Together, the dual medicines management approach and elements of NPT provide a general framework through which the implementation of technologies into hospital and community pharmacy can be analysed.

7.2 Drug Technologies

Much of the emphasis on new technologies in pharmacy is centred around devices and black-boxed artefacts which are most commonly mobilised as part of pharmacists’ clinical practice.

Much of the data collected here which focuses on new technologies in pharmacy is concerned with new drug technologies, which is to say new pharmaceutical products that reorganise or reconfigure pharmacy work. Within this, the discourse of toxicity around these new drug technologies is central to their reorganisational capacity. As such, these new drugs represent new ways of constructing and managing toxicity. The most pertinent example of this to be highlighted in the interview data is monoclonal antibody (mAb) technology. This field of drug technology specifically targets areas of single proteins (epitopes) which are over-expressed as a result of disease. Hence, mAb drugs do not rely on the ‘shotgun’ approach of, for example, cytotoxic medications and, as a result, are less likely to cause adverse effects (Keller, 2009).

They are also important because they are seen to enable more targeted, personalised treatment regimes. This is reflected in the way that mAbs are most commonly prescribed to cancer patients whose bodies are constructed within the pharmacy gaze as particularly complex and risk-laden in terms of their morbidity, but made more so given the effects of traditional chemotherapy regimes. Pharmacogeneticist 9 (who has a particular interest in Oncology) highlights this;

“We give them enough drugs to just not quite kill them but actually sometimes it’s the drugs that kill you and not the cancer so we need to try and get away from that because there’s more morbidity associated with the drugs” (PGx 9)

Hence, the prescription of mAbs is understood as a positive step in cancer care given their reduced toxicity, as Hospital Pharmacist 8 highlights;

“I know that you’ve got your monoclonal antibodies now and they are not without their side effects but they are in many ways superior in terms of side effect profiles to conventional chemotherapy” (HP 8)

This perceived superiority to traditional cytotoxic medications is discursively aligned with increasingly targeted prescription behaviour patterns where a

‘molecular gaze’ is adopted by prescribers in making therapy decisions. Rose (2007) argues that this molecular gaze sits within a more general molecular ‘style of thought’ (see Fleck, 1979) that underpins contemporary medical practice. Given this ‘style of thought’ in treatment decisions, the pharmacy gaze has also become increasingly molecularised with the pharmacological action of drugs, and their potential toxicities, being understood at the molecular level. Hence, the discourse of toxicity around mAbs is created based on the molecular characteristics of the patient body, which are identified through testing for specific biomarkers, as in the case of pre-prescription HER2 testing for Herceptin regimes. Hospital Pharmacist 9 (Oncology pharmacist) demonstrates this well;

“MAbs where you are focusing on markers and testing. For the conventional chemo type drugs there’s no way of predicting which patients are going to do well with this treatment and so you end up giving it to everybody” (HP 9- Oncology)

This quote also highlights the paradigmatic shift in Oncology practice from “willy-nilly” (HP 9- Oncology) universal chemotherapy regimens to increasingly molecularised and personalised courses of therapy. While, at first sight, more personalised treatment regimes might be presumed to be expensive, from the perspective of formalised medicines management, such an approach reduces cost because of the reduction of adverse drug effects:

“So it’s all now about targeted therapies...And it’s good because it means that you don’t over treat patients. You’re not treating patients willy-nilly. I think it’s good because it’s a lot more individualised now in terms of making sure that patients get the treatments that are best for them” (HP 9- Oncology)

Given this decreased propensity for toxicity, mAbs can potentially reconfigure the everyday work of pharmacy by refocusing work away from the management of adverse drug effects which has previously been central to Oncology pharmacy practice. Moreover, this decreased toxicity and the potential for mAbs to be administered to patients orally means that there is a drive towards relocating

Oncology medication administration away from the hospital (So, 2010). In moving towards the administration of relatively low toxicity medications outside of the hospital setting, these drugs are made meaningful to patients through their existence within their wider 'lifeworld'. So (2010: 35) also highlights the way in which this relocation of medications is defined through formal medicines management policies and organisational interests as a 'more cost effective way' of treating Oncology patients.

7.3 Medicines Management and Pharmaceutical Care Technologies

Defining new technologies in pharmacy is central to their configuration as useful or otherwise for everyday working practices. The specificities of this 'coherence' work (see May and Finch, 2009) depend upon the sector of pharmacy into which these technologies are being implemented. As such, the 'scope' of the technology in question (i.e. whether it focuses on chronically or acutely ill patient bodies or low or high risk medications) affects the process of defining the utility of technologies in different pharmacy settings. Here, again, the differences between hospital and community pharmacy practice become apparent through this process of defining the innovation. Within this, the meaning of the new technology is linked with the particular nature of toxicity management being undertaken in that location. As such, the practices and discourses of medicines management and pharmaceutical care are central to this process of defining new technologies in hospital and community pharmacy respectively.

New technologies are, then, located within formal, codified and bureaucratic strategies of improving pharmaceutical care and medicines management at local and national levels (see Audit Commission, 2001). Chapter Six demonstrated an epistemic distinction between hospital and community pharmacy practice around the notions of medicines management and pharmaceutical care with medicines management being related to an understanding of organisational interests in improved medicines efficacy and pharmaceutical care being more focused on individualised patient-centric efficacy and risk.

Within this, medicines management in hospital pharmacy is grounded in organisational interests in medicines efficacy, where therapy decisions are based around local policies and financial implications. Moreover, risk management in this practice model is located within legal and corporate responsibilities. In this vein, the implementation of innovative practice technologies in hospital pharmacy is understood as a way of both streamlining dispensing practices in order to improve overall pharmacy efficiency and improving and monitoring dispensing quality, as Hospital Pharmacist 6 says;

“The computer does all that [inputs prescription details such as dates and signatures] for you which means that we’ve been able to focus the pharmacist resource more on safety and appropriateness of drug treatment.” (HP 6- Director of Pharmacy)

“And the way the information can be used in terms of we can do audits that were impossible to do previously” (HP 6- Director of Pharmacy)

Here, the electronic patient record and the computer system on which it depends are defined through bureaucratic policy rhetorics as technological instruments which can make more efficient use of staff resources and assist with better quality audit activities. On the less formalised, more negotiated level of everyday practice, these technologies are central to the discourse of toxicity generated through the hospital pharmacy gaze. In this, toxicity is managed through the application and mobilisation of these technologies, as Hospital Pharmacist 6 highlights in reference to electronic prescribing systems:

“Under electronic prescriptions and administration records... And that’s made a massive difference in terms of the information you can present to prescribers at the point their doing prescriptions about interactions and allergies and all sorts of other things” (HP 6- Director of Pharmacy)

Another example of this is computerised labelling where medicines are made meaningful and located within a patients' wider lifeworld through the information (for example, dosage and administration details) provided on these labels. Shrank *et al.* (2007b) note that effective labelling is central to toxicity management as, in contrast to Patient Information Leaflets, medication labels are part of the medication itself given that labels cannot as easily be separated from medications. Although this labelling work has always been a central feature of pharmacy practice, its computerisation represents a new paradigm of medicines management where computer-generated (rather than hand-written) labels are thought to be clearer, thus making medicines easier for patients to engage with and adhere to (Shrank *et al.*, 2007a). The comment from Hospital Pharmacist 4 highlights the impact of electronic medication labelling;

“When I started we had typewriters. From that point of view technology has really improved in terms of...patient labelling”
(HP 4)

The implementation of technologies into community pharmacy is centred around two primary concerns: the pharmaceutical care of individual patients vis-à-vis potential drug reactions, and the increase in clinical practice, the latter of which is explored in more detail below.

The discourses and practices of pharmaceutical care are central to the process of defining new technologies in community pharmacy. Similar to the medicines management discourses mobilised in hospital pharmacy, pharmaceutical care processes are central to the operationalisation of new technologies in everyday community practice. As such, the community pharmacy computer is understood as a means to improve pharmaceutical care, patient adherence and outcomes and reduce toxicity through various functions and packages. The data suggests that the most pertinent example of this is the implementation of computer systems into everyday pharmacy work.

The arrival of computer systems in community pharmacy represents a significant departure from traditional experiences of pharmacy work, in which

manual documentation and procedures played a central role and underpinned much of the GP/pharmacist communication (Motulsky *et al.*, 2008). Writing some years ago, Foster (1992) noted that producing labels, storing patient prescription information, producing patient safety documentation and managing stock were the key areas that applications of computer technology addressed in pharmacy; the data collected here suggest that these work activities are still the primary applications of computer technology in community pharmacy.

Making sense of the meaning and significance of computerisation of community pharmacy is strongly linked with pharmaceutical care processes and discourses through the use of computers to identify potential toxicity. Within this, the pharmacy computer is framed as advantageous in its capacity to store patient medication records and algorithmic information which can help identify potential drug interactions. In doing so, the community pharmacy computer is understood as a way to improve pharmaceutical care by increasing patient and practitioner awareness of potential toxicity (Abarca *et al.*, 2006). This is in addition to the capacity for electronically producing labels and safety information, which is central to patient adherence and outcomes policies.

At the less formalised, policy-bound level of everyday pharmacy practice, the community pharmacy computer is seen to enhance rather than undermine the pharmacy gaze. Patient information on the computer acts as a documentary space for the recording and management of toxicity which at the same time brings the patient body to life through its presence within this toxicity documentary. The community pharmacy computer, then, is used to store patient drug histories which construct a discourse of toxicity through the identification of potential risk-laden drug interactions. Within the documentary space of this drug history the patient body is configured as a complex site of potential toxicity to be managed by the community pharmacist through labelling, advice and counselling. Community Pharmacist 2 highlights the centrality of the computer to toxicity management in contemporary community pharmacy practice;

“I think the computer coming into the pharmacy opened so many doors really. Prior to that we didn’t even have a record of what

patients had ever had. We'd nothing to help us with drug interactions. We'd no computer to flash up warnings. I mean, I often think - well I worry, to be honest - how much harm we did to patients because of drug interactions that we never even - we may have known about but not to the extent that we do today. And we had nothing to remind us of them at all. We didn't put particular patient warnings on labels" (CP 2)

Defining the utility and meaning of new technologies in pharmacy is a process which sits within both formalised, codified pharmaceutical care and medicines management practices and less formalised, more negotiated everyday work practices which are enacted through the pharmacy gaze. Within bureaucratic medicines management and pharmaceutical care rhetoric and practices, the integration of new technologies into pharmacy is operationalised as a way to improve the safety and efficacy of pharmacy dispensing. At a more negotiated, pharmacy gaze level, new technologies act as inscription devices to configure the patient body as a set of particular risks and toxicities which are then observed through the pharmacy gaze and managed through the discourse of toxicity. Moreover, in community pharmacy new technologies can also act to configure a more clinically-focused pharmacy gaze. It is to this application of technology that the chapter now turns.

7.4 Clinical Roles and Technologies

This chapter is concerned with the ways in which new technologies shape and reorganise everyday pharmacy work and relations. The changes that have occurred, and continue to occur, in everyday pharmacy work are multi-dimensional and arise from both macro and micro policies and strategies such as the Department of Health and RPSGB's extended role (see Chapter Two). One key way in which pharmacy work and relations have been reorganised in the last three decades is in its more clinical focus, in which new technologies have played a central role.

New technologies are central to this more clinical reorganisation of pharmacy in two key ways. In one way, new technologies which are central to clinical activities

have become increasingly present in (particularly community) pharmacy. These are defined here as technologies *of* clinical work. In another way, technologies such as electronic prescribing and pharmacy robots are conceptualised as central actors in the process of reorganising pharmacy work. As such, new innovations are understood as reorganising pharmacy work towards an increased clinical focus by removing pharmacists from the dispensary and what Hospital Pharmacist 6 (Director of Pharmacy) describes as “*traffic warden duties*” and increasing their clinical workload. These are defined here as technologies *enabling* clinical work. Each of these is taken in turn.

7.4.1 Technologies of Clinical Work: Configuring the Individual and Public Health Body

New technologies are central to much of the clinical work that pharmacists, particularly in the community setting, now undertake as part of their everyday practice. These black-boxed devices, such as blood glucose and carbon monoxide monitors, act as new ways of knowing the patient body. Moreover, given their association with the maintenance of health and wellbeing, they also act to reconfigure the pharmacist as a health promotion or public health practitioner. Through this reconfiguration, pharmacy practice becomes less spatially-bound to the dispensary and is increasingly practised in the consultation room (in the case of community pharmacy) and at the patient bedside (in the case of hospital pharmacy).

Chapter Six noted that the clinical role of community pharmacists has created new ways through which pharmacists interact with, and come to know, patient bodies. The outputs from black-boxed clinical devices, such as those mentioned above, provide patients and pharmacists with access to biomedical knowledge about patient bodies. Unlike in hospital pharmacy and GP work, this knowledge does not necessarily feed into prescription decisions but instead becomes central to the individual patient health project and risk profile. In this way, the clinical monitoring work that is undertaken by community pharmacists can be understood as sitting within a health promotion and surveillance medicine approach where the ‘extracorporeal space’, otherwise referred to as ‘lifestyle’ (Armstrong, 1995:401), becomes important in the pharmacists’ configuration of, and interaction with, the

patient body. Through testing and monitoring individual patient bodies, the scope of the pharmacy gaze is modified to focus on what is described here as the collective ‘public health body’. Within this, the health profile of individual patient bodies contributes to the configuration of a ‘public health body’ which is located within wider public health discourses and foci.

This clinical dimension represents a significant shift in the pharmacy gaze beyond the medication needs of patients, which is highly spatially-bound to the dispensary, to one that incorporates the wider ‘lifeworld’ of patients and the impact this has on health. Such an example of this is provided by Community Pharmacist 2 who ran a health promotion clinic which mobilised a number of devices to provide patients with knowledge about their own bodies, which was then used for health advice. In this monitoring clinic, blood pressure, blood glucose and cholesterol monitoring kits and scales were used to configure the patient as a set of health risks and behaviours which could be managed by the pharmacist;

“Just come along, get your blood pressure taken, get your blood glucose/cholesterol done and we’ll give you a bit of healthy lifestyle advice, etc.... We did it for about eight or nine months and it was really popular. We got husbands and wives coming together in the evening, which was great. Because we used to say, well, your cholesterol may be up, do you eat a lot of cheese? The husband would say no and the wife would say yes you do...this is something new for pharmacy” (CP 2)

This quote demonstrates that monitoring devices and the ‘extracorporeal space’ (in this case regarding eating habits) are central to the clinical community pharmacy gaze and the public health body it constructs. Moreover, Community Pharmacist 2’s reflection suggests a significant practice shift from the traditional role of pharmacists to this more public health or health promotion oriented focus, through which individual patient’s health profiles and what we can call a collective public health body are brought into being. Elsewhere, the relationships between public health and medical practice more generally (Armstrong, 1995) and public health and pharmacy (Anderson, 2007; Department of Health, 2005a) have been explored. In

the case of public health and pharmacy, however, there is a marked absence of the patient body through which public health discourses are enacted in the pharmacy setting. In much the same way as Chapter Six argues that an analysis of medicines management is limited without the presence of a medications using body, neither can public health practice be fully analysed without a body, or collective of bodies, discursively constructed by public health concerns.

Whereas the traditional pharmacy gaze centres on individual patient bodies as sites of medications use and potential toxicity, the public health and health promotion focus of the pharmacy gaze is centred on multiple bodies and their collective relationship with wider public health foci. As such, the testing and monitoring technologies that are central to the performance of clinical pharmacy activities configure both individual health and risk profiles and a collective public health and risk profile which feeds into macro- and meso- level public health strategies. The following quote from Community Pharmacist 2 demonstrates the way in which the individual health profile and what we can call a collective public health body are created through testing and monitoring activities;

“so they [patients] just used to go away with their own results. We kept a copy of the results because we had to give that anonymised information to the PCT” (CP 2)

This type of clinical work in community pharmacy has previously fed into questions around boundary encroachment (Eaton and Webb, 1979; Edmunds and Calnan, 2001) and the General Pharmaceutical Council recently argued that pharmacists are not competent to ‘undertake a physical examination which includes the touching of a patient’s body’ (General Pharmaceutical Council, 2012: 122). These concerns are located within a relatively rigid model of primary care practice where the medical technocracy in which GPs retain power is seen as at risk from disadvantageous jurisdictional realignments. Contrary to this, however, Community Pharmacist 2 notes that pharmacists’ relative professional status can be advantageous for engaging patients in public health and health promotion activities, in which technological devices play a key role:

“And people do sometimes feel less worried about coming into that kind of environment than going to the GP practice... Pharmacy can actually play a part in health promotion like that if people are more willing to come and see it as less official than going to the doctors’ practices I think” (CP 2)

This notion was also suggested by Community Pharmacist 1 who notes that pharmacists utilising flu vaccination technologies enabled a wider population to have the vaccine than would have done if this remained a GP activity. Through administering vaccinations, the activities of pharmacists are placed within the boundaries of public health practices and their role in configuring, and managing the public health body is assured. This also supports Taylor’s (2005: 292) vision of the community pharmacist as ‘the people’s doctor’ and, elsewhere, the benefits of pharmacists’ involvement with vaccination programmes and technologies have also been noted (Steyer *et al.*, 2004);

“Some of the larger Boots stores have got involved in administering flu vaccines...the flu vaccinations enabled a few more people to get vaccinated who wouldn’t otherwise have been able to” (CP 1)

Clinical devices are central to the construction of the collective public health body through the community pharmacy gaze. Within this, potential toxicity is understood as a risk not just of medications and the body’s relationship to them but through the body’s characteristics which are defined within public health and health promotion norms and discourses. These characteristics, such as weight, body mass index and cholesterol levels, are then made socially meaningful as characteristics of a public health body through these clinical devices. In other words, the public health body comes into being through the outputs from clinical devices and the relationship of these outputs with wider public health foci. Whereas the complexity of the body in the traditional pharmacy gaze is rooted in the body as a site of medications use (see Chapter Six), the clinical pharmacy gaze operationalises the complexity of the public health body as being rooted in the body’s characteristics and the health risks that they present. As such, bodily characteristics such as blood pressure or weight are

central to the clinical pharmacy gaze and organise public health interventions in community pharmacy.

In this sense, the clinical community pharmacy gaze is strongly linked with the wider pharmacy gaze outlined in Chapter Six in that it is, at the base level, concerned with toxicity. The departure comes from the clinical community pharmacy gaze's relationship with the patient body through a surveillance approach with understands health risks as being more generally linked to the 'extracorporal space' rather than just medications. May and Finch (2009) note that a central part of coherence work is defining innovations by their differences from existing practices. In this case, the reconfiguration of pharmacy work to focus on the public health body is defined by its difference from the traditional pharmacy gaze, which focuses on medications and their local toxicities alone. This reshaping of pharmacy's focus is aligned with macro-level policies, such as the provision of Essential services through the extended role, and micro-level work activities, such as providing specialist clinics.

7.4.2 Technologies Enabling Clinical Work: Practising Away From the Dispensary

Chapter Six noted that one of the most significant shifts in both hospital and community pharmacy work is the relocation of pharmacy practice, and practitioners, away from the dispensary. Increased patient contact was presented in this chapter as being an effective medicines management (or more recently, medicines optimisation) strategy. This relocation of pharmacists away from the dispensary is primarily facilitated through the integration of new technologies, such as dispensing robots and electronic prescribing and labelling services, which perform a number of the functions previously undertaken by dispensary-bound pharmacists.

Such technologies are more commonly associated with hospital pharmacy and sit within formal medicines management policies. The integration of such technologies reconfigures the role and position of pharmacists within the hospital practice structure given their increased integration into the bioclinical collective (Rabeharisoa and Bourret, 2009). Given this, the use of such technologies in

pharmacy can be understood in line with the collective action aspect of NPT (May and Finch, 2009). According to May and Finch (2009:544) when new technologies are integrated into everyday practices, work is undertaken to ‘reorganize relationships’ which ‘involves collective purposive action aimed at some goal’. In this case, the goal is the increased pharmacy clinical work and patient contact where relationships are reorganised around the integration of pharmacists within the bioclinical collective practice team. Given this, the ‘relational integration’ of these new technologies is mediated by an understanding of their being necessary for improved medicines management within clinical pharmacy.

Hospital Pharmacist 1 (a chief pharmacist) demonstrates the way in which the local relationships (between pharmacists and other healthcare practitioners and between pharmacists and patients) are reconfigured by the presence of technologies:

“So we’re investing quite heavily in technology. We’ve got very sensible computer systems to support the dispensing processes. We’ll be getting a robot in the next few months to make sure that that’s all automated. It’s all about asset stripping staff out of the dispensary and getting them to be able to work on the wards” (HP 1- Chief Pharmacist)

The integration of these technologies has also altered the sorts of everyday activities that hospital pharmacists undertake. Hospital Pharmacist 6 (Director of Pharmacy) notes that the entrance of the computer into hospital pharmacy has shifted the focus of pharmacists’ work away from somewhat mundane activities which can now be effectively enacted by technological devices. Hospital Pharmacist 6 locates these activities within the pharmacists’ ‘checking’ role as *“traffic warden duties”* and defines the use of a computer for them as beneficial for medicines management and safety processes:

“It’s what I describe as prescribing traffic warden duties, if you like. It’s everything written in block capitals, can you read it, has the doctor signed it, has it got a date on it, are the doctor’s intentions clear?...the computer does all that for you which means

that we've been able to focus the pharmacist resource more on safety and appropriateness of drug treatment rather than dotting i's and crossing t's and writing the print names in block capitals like we used to do." (HP 6- Director of Pharmacy)

In this quote, the clinical work of pharmacists is privileged over dispensary-bound checking duties where the former is understood as a more effective use of pharmacy resources. These sentiments are echoed by Hospital Pharmacist 4 vis-a-vis dispensing robots;

"From the point of view of [the] department probably yes. Releasing staff to other duties I think it's probably going to be beneficial" (HP 4)

Pharmacy robots have received some attention in the academic literature. In their study of hospital pharmacy robots in two UK hospital pharmacies, Barrett *et al.* (2011) note that pharmacy robots reorganise professional relationships throughout the hospital structure. In this way, pharmacists became further integrated into medical teams and increase their 'institutional legitimacy within the hospital' (p, 13) whilst pharmacy assistants expanded their jurisdiction into knowledge of robotics. Hence, the collective action involved in integrating pharmacy robots into everyday work is far-reaching yet ubiquitously underpinned by the need to reduce prescribing errors and improve medicines management in accordance with local and national policies (see Audit Commission, 2001).

The implementation of dispensing robots, as well as other technologies, in routine pharmacy practice could be analysed from an actor-network theory (ANT) perspective. Briefly, ANT is premised on the notion that the social world and social relations within it are constituted by networks of heterogeneous actants. These actants can be either human or nonhuman since it is the capacity for enabling action which is central to the actant's existence within the network (Latour, 2007). Hence, reflexivity and intentionality are not essential characteristics of actants, which means that anything can be an actant provided it 'is granted to be the source of action' (Latour, cited in Cerulo, 2009: 534). In an analysis of metered dosage inhalers

(MDIs), Prout (1996: 210) notes that the MDI network is constituted by a complex set of associations between a large number of human and nonhuman actants which are 'mutually configured in the process'. As such, the MDI network is constituted by designers, clinicians, patients, patients' families, nurses, pharmacists, MDIs, monitoring devices and instructional documentation, the qualities of all of which are configured through, and within, this network. Pharmacy robots could be analysed from an ANT perspective and understood as actants within the hospital network given their centrality to everyday pharmacy work and processes. Hence, pharmacy robots, and other technologies, could further be understood as actors, or participants, in the bioclinical collective which Chapter Six argues typifies hospital practice.

However, constructivist perspectives, such as ANT, have been subject to critique for their understanding of artefacts as nothing more than a sum of the interpretations and negotiations which happen around them. Hutchby (2003) draws on the field of the psychology of perceptions to offer a middle ground theory between realism and constructivism in the understanding of technologies. In a direct critique of Grint and Woolgar's (1997) 'technologies as text' perspective (i.e. where technologies ought to be understood as texts written by producers and read by consumers), he argues that the constructivist understanding of technologies as *tabulae rasa* is limited through its failure to acknowledge that technologies possess properties outside of the interpretations of them. As Rappert, (2003: 566), in his response to Hutchby, points out 'interpretations of technology are still interpretations of something and what that 'something' is must be acknowledged'. However, while not proposing a return to determinist understanding of technology, Hutchby suggests that technologies possess different 'affordances' (that is to say possibilities for action and use) which frame, but do not determine, action related to them.

Hutchby's middle ground perspective offers a more useful way to approach an analysis of technologies in pharmacy as the data resonate with the idea that technologies offer different affordances to different actors in different contexts. As such, when technologies are located within bureaucratic medicines management arenas by those with increased, and corporate, medicines management responsibilities (i.e. chief pharmacists and hospital chief executives), they afford the possibility of improving organisational medicines management processes and

efficiency throughout the pharmacy department. In another arena, the location of technologies in everyday practice of pharmacy affords the possibility of shifting the location, and nature, of everyday pharmacy work away from dispensary-based activities to more clinical patient engagement. In this way, a technology such as a pharmacy robot may be seen by different actors as affording different actions; whilst the chief pharmacist might see the possibility of reducing drug-related morbidity statistics, the pharmacists might see the possibility of an increased clinical workload, and the pharmacy technician might see the possibility of becoming a skilled robotics engineer.

Technological innovation, then, is a key element in changing pharmacy practice and is central to the reorganisation of pharmacy work and relationships around a more clinical focus. Technology has, in the main, reshaped technology around this clinical focus in two key ways: in providing clinical devices through which clinical monitoring is enabled and providing technologies, such as computers and robots, to perform more mundane pharmacy work activities which allows for the relocation of pharmacists away from the dispensary. The chapter now turns to an analysis of the evaluation of these reorganising capacities of innovations in pharmacy.

7.5 Reflexive Monitoring and Integration of New Technologies

May and Finch (2009) argue that ‘reflexive monitoring’ is the process through which technological innovations are both formally and informally evaluated. Within this, judgements are made as to the effectiveness and utility of a new practice, based on ‘socially patterned and institutionally shared beliefs’ (May and Finch, 2009: 545) This process, therefore, offers a framework for understanding why some technologies are integrated into everyday practice (or ‘normalised’) and others are not. According to May and Finch, this reflexive monitoring process is undertaken through both communal and individual appraisal techniques, which can be understood as mapping onto the formalised and more negotiated medicines management processes outlined in the thesis so far. Hence, communal appraisal involves assessment within an organisational context and mobilises formalised ‘mechanisms of institutional knowledge production’ whilst individual appraisal

involves informalised judgements about the value and outcomes of an innovation which are rooted in individual practices (May and Finch, 2009: 546). Here, then the communal appraisal process can be understood as sitting within formal, organisational medicines management policy whilst individual appraisal can be related to informal medicines management processes enacted through the pharmacy gaze and the discourse of toxicity.

The data from the fieldwork demonstrate that pharmacists undertake reflexive monitoring through both communal and individual appraisal in their everyday interactions with new technologies. As a result of this reflexive monitoring process, some innovations fail to be normalised in everyday practice. Two examples of this were highlighted by Community Pharmacist 1 in discussing the drugs Zocor (to treat cholesterol and coronary heart disease) and Clamelle (to treat Chlamydia). In both of these instances, pre-prescription testing is undertaken to determine the appropriateness of the drug. In the case of Zocor, which was declassified to an over-the-counter medication in 2004, this is done by the pharmacist constructing a patient risk profile through a pre-prescription consultation. In the case of Clamelle, this is testing done by the patient following the purchase of a testing kit from the pharmacy. In cases where the patient tests positive for Chlamydia, they can then return to the pharmacy to purchase the necessary antibiotics. In both of these cases, Community Pharmacist 1 notes that these “*didn’t really take off*” and “*didn’t make a massive impact*”.

This lack of normalisation can be understood as related to the professional jurisdictions that are relatively rigidly enacted in the community setting. In this division of labour, pre-prescription testing is a work activity most commonly associated with GPs and located within particular healthcare settings. The reallocation of testing activities to pharmacists and patients for these particular innovations can be understood as a potential barrier to their normalisation;

“It [Zocor] was something they could get with less hassle from the doctors and the doctor was able to arrange the necessary blood tests to do this” (CP 1)

This quote highlights the inconvenience and limited capacity of pharmacy testing as factors explaining Zocor's lack of normalisation. This can be analysed within May and Finch's (2009: 545) notion of 'contextual integration' whereby innovations are incorporated into a social context where new work is linked with existing structures and procedures. In this case, the declassification of Zocor did not incorporate pre-prescription blood testing into pharmacy practice. Given this, Community Pharmacist 1 highlights the comparative ease with which Zocor, and similar medicines, can be accessed through practitioners whose everyday work already incorporates such pre-prescription testing activities.

Moreover, these examples demonstrate the issues that can occur when work activities necessitated by an innovation (in this case pre-prescription testing) are outside of a traditional professional jurisdiction. As such, the location of pre-prescription testing work within the professional boundaries of general medical practice suggests that the requirement for pre-prescription consultations in the community pharmacy and Clamelle's requirement for patients to self-test at home represent too much of a divergence from the community division of labour in which pre-prescription testing is carried out by the GP. Community Pharmacist 10 also highlights this issue of innovations representing a practice outside of the traditional division of labour;

"You have to question whether patients would come to the pharmacy to get a test done when they could get it done at the doctors" (CP 10)

Reflexive monitoring in hospital pharmacy highlights the individual appraisal process which is carried out in conjunction with more communal evaluations of the value of new innovations. In their study of hospital pharmacy robots, Barrett *et al.* (2011) juxtapose the communal appraisal of robotic innovations, which are grounded in government priorities for reducing dispensing errors and improving pharmacy efficiency, with individual appraisals grounded in the routine work of dispensing, loading the robot and dealing with malfunctions. Although this study does not employ an NPT framework of analysis, the interplay of communal and individual appraisal processes can, nonetheless, be seen.

The data here present a similar story. As such, innovations are communally appraised through the rhetoric of codified formalised policies as beneficial for medicines management, staff resourcing and pharmacy efficiency, as the above quote from Hospital Pharmacist 1 (a chief pharmacist) highlights.

Running concurrently to this communal appraisal is a more individual process of evaluation where innovations are judged against wider expectations of the professional practice of pharmacy and the management of everyday work activities.

As described above, the implementation of technology into pharmacy practice is central to the increased clinical role of the sector. It is also through defining this increased clinical work as a central feature of contemporary pharmacy practice that appraisals of the value of new innovations are enabled. In other words, as the boundaries of pharmacy practice shift to incorporate increased clinical work the value of new innovations is measured against expectations about what pharmacy is, or should be given this restructured division of labour. As an example, Community Pharmacist 2 discusses computer technology as an aid to clinical work and states that *“It’s basically unrecognisable from how pharmacy used to be, which is brilliant”* (CP2). Within this appraisal, the implementation of computer technology is understood to have had a key role in shifting the boundaries of what constitutes pharmacy practice. This strategy in pharmacy is described by Birenbaum (1990) as a ‘collective mobility project’.

In other instances, however, this collective mobility towards clinical practice, facilitated by technological innovations, can have a more negative register and be associated with deskilling. As such, technology in pharmacy is evaluated as artefacts through, and within, which ideas about what pharmacy practices is, and should be, are positioned too far from pharmacy’s core focus on medications and their ‘stuff’. Hospital Pharmacist 4 demonstrates this;

“We don’t actually practice making medicines in the department anymore...that’s a bit of a negative... It’s become more patient-focused. So actually out there on the wards working with patients

rather than in the department. And we've actually deskilled, which I'm not so sure is a good thing" (HP 4)

Within this comment, the implementation of technology into hospital pharmacy is seen as a way in which the sector has been deskilled vis-a-vis medicines manufacturing. Within this, innovations which enable clinical work are regarded as ways in which the activities of pharmacy have been reconfigured away from the central focus on medicines production, which characterised traditional pharmacy practice. This evaluation of innovation is made despite the involvement of pharmacists in producing medicines through their involvement with clinical trials. Hence, although the work involved in making medicines has been modified (which is the root of Hospital Pharmacist 4's concern about deskilling), pharmacists involvement in clinical trials can be understood as their continued involvement in medicines manufacturing.

Hospital Pharmacist 4's evaluation of technology in hospital pharmacy resonates with Novek's (2000) study of automated dispensing technology in three Canadian hospital pharmacies. In these three hospitals this technology, which was implemented in line with local medicines management and safety policies, is appraised as a means through which medications dispensing, as the core interest and work of pharmacy, is routinised in order to be delegated to pharmacy technical staff. In doing so, technology can act to shift the professional boundaries of pharmacy and pharmacy technician work and, as a result, was resisted by Novek's respondents.

Individual appraisal processes also involve locating the additional labour necessary for implementing innovations within wider occupational demands and workloads. In their work on pharmacy robots, Barrett *et al.* (2011: 10) note that 'new routines in pharmacy work' had to be developed in order to overcome technical and mechanical difficulties with the technology. In this case, this new work was most frequently undertaken by pharmacy assistants in order to minimise the impact on pharmacists' core activities. In other cases, however, new technologies which necessitate a restructuring of everyday workloads are a central feature of the work of pharmacists and are, thus, appraised within the context of pharmacists' (as opposed to their support staff's) everyday activities. An example of this is provided by

Hospital Pharmacist 4 who evaluated the value of email technology in the context of pharmacists' everyday workload:

“One of the downsides is, I think, we’re all burdened by email now. At one point you used to pick up the phone to communicate with somebody. Now, for example on Monday I was off and I came in one Tuesday to over 200 emails. And you can’t actually manage to keep up with them” (HP 4)

This comment locates individual appraisal activities within workload management concerns. Here, the implementation of e-mail technology into everyday pharmacy work is understood to include increased labour which cannot easily be configured into everyday activities and which adds no apparent value. This individual appraisal sits somewhat in opposition to more communal appraisals of communication technologies in pharmacy which email is assessed as a useful technology for pharmacy practice vis-à-vis patient safety and bioclinical collective communication (see Pohjanoksa-Mäntylä *et al.*, 2008).

This issue of communication is also central to the above quote. The integration of email technology (as a means to communicate with other healthcare practitioners and patients) into everyday practice is regarded as a disruption of traditional communication methods.

7.6 Summary and Discussion

This chapter shows how new technologies reorganise everyday pharmacy work and relations in various ways. The specific sector of pharmacy within which innovations are implemented is key to the ways in which innovations may come to reorganise everyday work and relationships. This reflects both the professional relationships which characterise work in these settings (i.e. bioclinical collective or medical technocratic practices) and the framing of patient bodies and medications which organise this work. As such, the prevalence of acutely ill patient bodies and higher toxicity medications in the hospital setting means that the focus of hospital pharmacy is different from that in the community setting which is geared towards chronically

ill bodies and relatively low toxicity medication. The scope and nature of the technology which is introduced into pharmacy, and the perceived utility of technology as more or less useful is shaped by these discrete settings. For example, a technology designed to enable weight monitoring in otherwise healthy patient bodies is useful for the community pharmacy focus on the public health body but may not be as useful for hospital pharmacy's focus on highly toxic medications and acutely ill patient bodies.

In addition, the chapter highlights the importance of the dual medicines management model to the implementation and evaluation of new technologies in hospital and community pharmacy. Whereas the formalised and bureaucratic medicines management policies focus on the institutional operationalisation of new technologies, the less formalised medicines management practices which are enacted through the pharmacy gaze are more focused around individual patient bodies and the reorganisation of everyday work activities. This chapter shows the way in which new technologies are defined and evaluated within both of these medicines management approaches in both hospital and community pharmacy.

In analysing the implementation of new technologies into pharmacy practice, then, three related themes are shown here to be important- the relationship between the scope of the new innovation and the sector of pharmacy into which the innovation is being implemented; the bureaucratic medicines management policies which define and evaluate the innovation vis-à-vis organisational interests; and the everyday practice enacted through the pharmacy gaze. In order to demonstrate the way in which these three themes are important in understanding new technologies in pharmacy, Table 10 uses examples of pharmacy technologies discussed here to show how these technologies relate to pharmacy sectors, the codified medicines management process and everyday working practices.

For example, Table 10 shows that the scope of mAbs is centred on the acutely ill bodies of cancer patients, highly toxic cancer medications and targeted approaches to therapy. This scope, then, binds mAbs to hospital pharmacy practice. Within this setting, mAbs are operationalised through formal bureaucratic medicines management policies as a way to reduce the financial burden of adverse drug effects

and to improve patients' experiences of their medications regimes. Moreover, as So's (2010) paper suggests, the move towards the administration of some Oncology treatments in patient homes also means that mAbs are operationalised in line with organisational interests as a way to reduce drug dispensing and administration costs and make pharmacy departments more efficient. Table 10 shows that running concurrently to this operationalisation of mAbs is the construction of mAbs in everyday practice through the pharmacy gaze. Within this, mAbs are understood as central to the treatment of cancer patient bodies, which are constructed through the pharmacy gaze as particularly complex bodies. Given this complexity, the pharmacy gaze tends to construct cancer patient bodies at a more molecular level where prescription decisions are made based on the outcomes from pre-prescription testing activities. In addition, Chapters Two and Six highlighted the cultural construction of medications and their location with patients' wider lifeworlds as central to the pharmacy professional identity and pharmacy gaze. Table 10 highlights that in the case of mAbs, this process of locating medications within the patients' wider lifeworld is undertaken through the increasing practice of administering medications in patients' homes (see So, 2010).

To take an example of a more community pharmacy based technology, Table 10 shows that the scope of testing and monitoring devices is centred on chronically ill bodies, public health discourses and low risk medications. As such, this form of technology is highly bound to community pharmacy practice. In this setting, testing and monitoring devices are operationalised through formalised bureaucratic medicines management and pharmaceutical care policies as a way to improve public health and position the pharmacist within public health practices (see Department of Health, 2005a). At the less formalised level of everyday practice, the modified pharmacy gaze brings the patient body into being through the results of these testing activities. In doing so, the pharmacy gaze is modified to focus on what is being called here a collective public health body. As the chapter describes, the community pharmacy gaze is modified to include public health concerns (such as blood pressure and weight) as well as being focused on individual patient bodies, medications and their potential toxicities. As such, the patient body is configured as a site for public health discourses and interventions. This testing and monitoring work, then,

relocates some of the everyday community pharmacy work away from the dispensary into the more clinical setting of the pharmacy consulting room.

To summarise, Table 10 demonstrates the ways in which the key issues in analysing technologies in pharmacy highlighted by this thesis relate to each other in specific hospital and community examples. This Table is further expanded in Chapter 8 to highlight the ways in which the three broad concerns come into play in understanding pharmacogenetics in pharmacy practice.

Technology	Relationship between pharmacy sector and technology scope	Formalised Codified Process	Everyday Practices (Enacted Through the Pharmacy Gaze)
Monoclonal antibodies	Sector: Hospital pharmacy Scope: Acutely ill bodies; high toxicity medications; targeted therapies	-Decreased capacity for toxicity -Reduce burden of ADRs -Improve patient medication experience -Administration outside of the hospital: reduces cost	-Oncology patients; complex bodies -Molecularised gaze and therapies -Administration outside of the hospital: places medicines in the 'lifeworld'
Pharmacy robotics	Sector: Hospital pharmacy Scope: Large pharmacy departments; high stock levels; high patient numbers; complex regimen; high toxicity medications	-Reduces dispensing errors -Improves pharmacy efficiency -Enables clinical practice; time on wards	-Capacity for human error in stocking machine and data input -Increases pharmacists 'legitimacy' within the bioclinical collective (Barrett, 2011)
Electronic patient record	Sector: Hospital pharmacy Scope; Bioclinical collective gazes; complex illness; complex regimen; high toxicity medications	-Improves audit processes -Improves medicines management	-Removes pharmacists from " <i>traffic warden duties</i> " (HP6) -Brings the patient body into being -Constructs a discourse of toxicity around the patient body
Pharmacy computer- labelling practices	Sector: Hospital and community pharmacy Scope: Complex regimen (H); high toxicity medications (H); chronically ill bodies (C)	-Improves audit processes -Improves patient adherence: reduces toxicity	-Symbolic transformation of medicines into social objects -Places medicines in the 'lifeworld' -Shifts GP/pharmacist communications
Testing and monitoring devices	Sector: Community pharmacy Scope: Chronically ill bodies; low risk medications; public health focus	-Improves public health -Reconfigures pharmacists as public health professionals	-Constructs a collective public health body -Brings the patient body into being -Moves practice away from the dispensary

Table 10: Technologies in pharmacy. Exploring the relationship between technology, pharmacy sector, bureaucratic policies and everyday practice

7.7 Conclusion

An analysis of the implementation of technologies in pharmacy practice is a useful way of contextualising the ways in which the everyday work of pharmacists has changed. This chapter uses the dual medicines management framework described in Chapter Six and some concepts arising from May and Finch's NPT to argue that the work undertaken to embed innovations within everyday pharmacy work is enacted through both formal medicines management and pharmaceutical care policies and through the more negotiated pharmacy gaze. In this way, new technologies become defined as useful or otherwise based on their relationship with corporate and audit activities and toxicity management of individual patients. The chapter also follows on from Chapter Six's conceptualisation of hospital and community pharmacy practice and argues that whilst the definition of new technologies in hospital pharmacy is undertaken within organisational interests in medicines efficacy, their operationalisation in community pharmacy is focused around the discourse of toxicity for individual patients and their drug regimen.

The chapter notes that technologies introduced into everyday practice have shaped pharmacy practice to make it more clinically focused. This chapter argues that there are two key ways in which technology has reconfigured pharmacy practice in this way: through technologies which are central to clinical work activities and through technologies which make pharmacists less spatially-bound to the dispensary to enable a more clinically focused engagement with patients. Technologies which are central in clinical work activities, namely testing and monitoring devices, are argued to modify the pharmacy gaze away from one solely focused on medications and their potential risks, to one focused on patient health and risk profiles. In doing so, these technologies create a new dimension to the pharmacy gaze complementing that of the individual patient with one which configures patient bodies collectively as what I have called a 'public health body', which is managed in line with macro and meso public health discourses and strategies. Technologies of this sort are mainly associated with the reorganisation of community pharmacy work. In the hospital setting, technologies which facilitate the relocation of pharmacy practitioners away from the dispensary are argued to be a key way in which pharmacy work has been

reorganised. In this way, technologies such as dispensing robots are argued to occupy a central position within the bioclinical collective of the hospital.

Finally, the chapter mobilises May and Finch's notion of 'reflexive monitoring' to examine the ways in which new innovations are evaluated and integrated into everyday routine practice. Here, the processes of communally and individually appraising technologies are related to the formal medicines management process and the less formalised pharmacy gaze and the professional jurisdictions within the primary care medical technocracy. In this way, technologies which necessitate pharmacists undertaking work which is usually done by GPs fail to be normalised effectively owing to the divergence from routine practice patterns that they represent.

This chapter has drawn on a number of examples of technologies which have (and have not) become a routine part of pharmacy practice in both hospital and community settings to argue that technologies have the capacity to reorganise pharmacy work and inter-professional relationships. Continuing this analysis, Chapter Eight looks at PGx technology as a technological paradigm which has the potential to reconfigure pharmacy practice and modify the pharmacy gaze to one which is increasingly molecular. In doing so, Chapter Eight focuses on the operationalisation of PGx in both formalised medicines management policies and through the less formalised, more negotiated pharmacy gaze; the way in which PGx has reorganised practice roles in the field of Oncology; and the ways in which PGx may reshape hospital and community pharmacy practice vis-a-vis managing the toxicity of medications and the patient body.

Chapter Eight: Pharmacogenetics in Pharmacy

8.1 Introduction

Pharmacogenetics sits within a broad paradigm of genetics/genomics¹⁶-focused drug discovery and medical practice where genetics/genomics have become increasingly central to drug development processes and therapy decisions in some medical specialisms (Clarke *et al.*, 2003). This ‘geneticisation’ (Lippman, 1992) of drug development and medical practices is shifting definitions and understandings of diseases, the patient bodies in which they are manifested and the therapies which are appropriate to treat them. As an example, genomic information can be understood as broadening and adding complexity to definitions of breast cancer by reconfiguring it as a set of heterogeneous genetic conditions rather than one disease (see Curtis *et al.*, 2012), as Oncologist 1 points out;

“It’s not one disease it’s a family of diseases and now even things that we used to call breast cancer or lung cancer we’re chopping up into smaller and smaller sections” (O 1)

At the same time, therapy options for breast cancer have been narrowed by the increasing stratification of patient populations based on genetically-determined potential drug responses. This stratification is central to PGx which is premised on providing the right drug to the right patient in order to maximise therapeutic benefits and minimise adverse events.

At present, PGx in medical practice is limited to secondary care and, within this, to specialist areas which deal with particularly toxic therapies, most notably Oncology. In primary care, although putative links between genetically-determined drug responses and some primary care drugs have been identified (Grice *et al.*, 2006) the implementation of PGx into routine practice is less developed. Nonetheless, given the increasing genetics/genomics focus in drug development and some medical practices, it is likely that pharmacists in both hospital and community settings will become increasingly familiar with and well versed in applying the principles of PGx

¹⁶ Chapter Three elucidates the ontological differences between genomics and genetics in drug development and clinical settings.

to their everyday practice. Hence, pharmacists' expertise in medicines and their toxicities is likely to increasingly include genetic information.

Despite this, there is limited empirical research on the ways in which this shift in practice is likely to affect pharmacists in terms of their everyday work and professional status. Moreover, Ryan *et al.* (2004) argue that given that pharmacists are likely to be at the 'forefront' of PGx medicine, a sociological understanding of this is necessary. Given this, this chapter uses empirical interview data to build on the characterisation of contemporary pharmacy practice outlined in Chapter Six and the analysis of new innovations in pharmacy in Chapter Seven to explore the ways in which PGx is affecting, and may potentially affect, pharmacy practice in different settings. Given the different degrees of 'normalisation' of PGx in primary and secondary care settings, this chapter takes hospital and community pharmacy as two discrete landscapes vis-a-vis PGx innovation. Within this, the chapter discusses Oncology as an example of PGx practice being normalised in secondary care everyday practice.

The chapter, then, continues to mobilise the dual medicines management model that has previously been outlined to analyse the ways in which PGx is understood and framed by both codified, bureaucratic medicines management and pharmaceutical care policies and the more negotiated pharmacy gaze in everyday practice.

8.2. Defining PGx

As Chapter Seven demonstrated, the process of defining new technologies depends on their configuration as useful or otherwise for everyday practice. The evidence from the fieldwork indicates that this also involves a move away from media 'hype' to develop a "*realistic*" (PS 4) picture of PGx in practice:

"There's obviously been too much hype in terms of what we can do" (PS 4)

“What is very important... is to try and get across the concept that not everything that’s called a miracle cure is actually a miracle cure” (PS 4)

“The media hype it up every time there’s a study” (PS 3)

“Pharmacogenetics has been bigged up by the media” (PS 3)

“It’s quite hyped in the papers as well sometimes, which can do some harm” (PGx 2)

Within the coherence work of defining new technologies, Table 10 in Chapter Seven shows the ways in which new technologies in pharmacy are defined through both formalised, bureaucratic medicines management policies which are concerned with the organisational benefits of new technologies and in everyday practice through the pharmacy gaze and the discourse of toxicity. Defining PGx in pharmacy centres on coherence work around a number of tests, drugs and practices. As a result, whilst some uses of PGx may be defined (through both aspects of the dual medicines management model) as beneficial for pharmacy and patients and come to be normalised in everyday practice, others may be defined as less useful and fail to be integrated into everyday work. This differential coherence work is discussed by Hedgecoe (2008a) where he notes that whilst HER2 testing has become a regular feature of Oncology practice, APOE4 testing is defined as less clinically useful given its familial impacts (see Chapter Three).

Further, in defining the utility of PGx in practice it seems imperative to make the following distinction: *“pharmacogenetics as a technology versus pharmacogenetics as a service...those are two quite distinct entities” (HE 1- previously a HP)*. This quote highlights that defining the value of PGx in pharmacy practice depends on both the technological artefacts of the testing devices (for example, sample preparation and assay robustness) and the service structures around them (for example, the time taken for analysis and data output). This distinction can be understood in line with Damanpour’s (1996) model of ‘product’ and ‘process’ innovations. As Chapter Four argued, PGx can be understood as straddling these two

innovation categories as new technological products of PGx also necessitate new processes and services, as Health Economist 1 shows:

“There are more and more developments in terms of the technologies but there’s been virtually no work done in terms of how do you deliver the service?” (HE 1- previously a HP)

Oncologist 2 provides an example of this distinction with regards to the breast cancer drug Herceptin:

“We need to be doing it [routinely testing for HER2 over-expression in breast cancer patients]. Okay, how do we do it?... We don’t know” (O 2)

Within this quote, the distinction between the PGx product and the PGx service becomes apparent. Hence, whilst the technological product of the test is defined as beneficial (*“we need to be doing it”*), the service around providing this test is less clearly cohered with contemporary work structures. This distinction between technology (product) and service (process) can further be understood in line with the dual medicines management model described in Chapters Six and Seven. Here, it could be argued that whilst the technological products of PGx are defined through formalised, bureaucratic medicines management policies as beneficial for patients and organisations because of their ability to better target therapies, the service processes associated with delivering these PGx tests are defined and evaluated in terms of everyday practice and clinical gazes.

Moreover, as Chapter Seven highlighted, the discourses and practices which underpin hospital and community pharmacy practice (medicines management and pharmaceutical care respectively) are central to the coherence work around new innovations. In the case of PGx, there is a clear division between the coherence work undertaken by pharmacists working in these two sectors. Given this, this chapter treats hospital and community pharmacy practice vis-a-vis PGx as two distinct practice landscapes where the coherence, reflexive monitoring and integration work

around PGx are highly divergent. The chapter first turns to an analysis of PGx in hospital pharmacy.

8.3 PGx in Hospital Pharmacy Practice

The hospital pharmacists that were interviewed had a relatively high level of knowledge of PGx compared with those working in the community. Although the complexities of PGx were not common knowledge amongst all hospital pharmacists, there was a general awareness of this paradigm of practice amongst the population. Many of the hospital pharmacists, then, engaged with PGx in a similar way to Hospital Pharmacist 4;

“I’ve heard of it but I haven’t actually come across it in our own practice” (HP 4)

As this chapter highlights below, practitioners in the field of Oncology are those with the most knowledge and expertise around PGx. As such, the Oncology pharmacists that were interviewed (n=2) had high degrees of knowledge about PGx;

“KJ: Has genetic medicine made any other impacts on your practice since you qualified?

HP9: Oh, yeah, definitely...all the diagnostics have really come into their own now...We’ve got the KRAS testing for patients before they have Cetuximab, another one of the monoclonals. And now we’ve got the EGFR testing of course in non-small cell lung cancer before they start their Gefitinib” (HP 9- Oncology)

Given the co-location of Oncology pharmacists and those specialising in other clinical areas in one physical space (as opposed to community pharmacists who practice in relative isolation (Cooper *et al.*, 2009)), the bioclinical collective nature of hospital pharmacy practice means that the transfer of knowledge and expertise of PGx is relatively easy. Hence, through practising in a relatively collaborative environment and being in close proximity to practitioners who use PGx routinely, it is hardly surprising that hospital pharmacists’ knowledge of PGx is fairly high. This

is in contrast to community pharmacists who practise in isolation from each other and may find obtaining and sharing knowledge about PGx, or other innovations, more challenging.

8.4 Implementing PGx into Hospital Practice

At present, then, PGx is understood as sitting within the “*domain of the hospital pharmacists*” (PGx 5) owing to the disease areas and medications for which PGx testing is deemed appropriate. Within this, the epistemic differences between hospital and community pharmacy outlined in Chapters Six and Seven are central. Hence, whilst highly toxic medications are prescribed and administered to treat acutely ill patient bodies in the hospital setting, community practice tends to be more centred on less toxic medications and the chronically ill bodies to which they are administered. PGx, then, sits within the “*domain*” of hospital pharmacy given the comparatively toxic nature of medications and the ability of this paradigm of practice to predict and manage these relatively severe adverse events.

The implementation of PGx into routine hospital practice is represented in the interview data as being a journey which universally begins with PGx developments in Oncology. From here, PGx technologies are imagined to “*seep*” (PGx 3) into other clinical specialisms where ADRs are a notable issue, such as Cardiology and Paediatrics. This understanding of the implementation of PGx contrasts with traditional diffusion of innovation studies which represent diffusion and implementation as a top-down and linear process (see Rogers, 2003). The interview data, however, represent the implementation of PGx into routine practice as being more “*piecemeal*” (PGx 3; HE 1) and contingent upon the outcomes from private sector research, as Community Pharmacist 6 observes;

“It depends what the drugs are that come out” (CP 6)

Moreover, Rogers (2003) presents innovations as external artefacts which are implemented into a social system by innovators who exist outside of that given social system. Again, there can be seen to be a disjuncture here between traditional diffusion of innovation theory and the implementation of PGx into hospital practice.

As such, PGx innovations are not universally developed by external actors and agencies and subsequently introduced to the hospital. Instead, many hospital practitioners are also active researchers and play a central role in development of PGx technology in collaboration with both public and private actors and agencies. As such, the very meaning of innovation is constituted by bioclinical collectives that comprise both internal and external hospital actors;

“We have, here, a multi-disciplinary which comprises clinicians, nurses, geneticists, statisticians, cell biologists, pharmacologists and also includes people who are PhD students, MRES students, post-docs etc and clinical research fellows” (PGx 2)

“The pharmacy departments basically support the clinical trials. It will be the consultants will be wanted to take part in a clinical trial which may be either sponsored by the pharmaceutical industry or maybe by non-commercial research, so it’s the academics... it’s very collaborative” (HP 3- Oncology)

This model of PGx ‘seeping’ from Oncology into other clinical areas resonates with Jain’s (2009) assertion that PGx represents more of an evolution than a revolution in research and practice. Although popular media portrayals of PGx have constructed this paradigm of practice as somewhat revolutionary (Almomani and McElnay, 2012), the interview data suggest that practitioners envisage the development of PGx more in line with Jain’s evolutionary characterisation. Within this, the evolution of PGx technologies is understood as a series of small step-changes associated with the development of new genetic technologies such as PCR and ‘Next Generation’ sequencing. The following quotes highlight this well;

“The thing about genetics is that there is always kind of step changes. The Next Generation Sequencing is going to be another step change so it goes along and things are stable for a bit and then suddenly you’ll get a new discovery or technique and it will suddenly change what we do” (PGx 9).

“It’s just going to be a slow piecemeal change. I don’t think there’s going to be any revolution, I think there’s just going to be an evolution slowly over time as further information comes through” (PGx 3)

“There’s going to be certain examples where practice is going to change incrementally” (HE 1- previous a HP)

“It happens in a very piecemeal, very fragmented sort of way” (HP 1)

As Community Pharmacist 6 highlights above, much of the implementation story around PGx is linked with the outcomes and perspectives of private sector drug development. Chapter Three notes that PGx presents a potential way in which pharmaceutical companies’ R&D costs can be reduced, thus making this approach to drug development appealing. On the other hand, taking a stratified approach in drug development will ‘almost certainly reduce the number of patients who are likely to receive the drug...and perhaps end the era of blockbuster drugs’ (Pirmohamed and Lewis, 2004). Hospital Pharmacist 5 characterises this as follows;

“There seems to be two areas in new medicines. There’s stuff you can give to anyone; so you can give huge volumes at low cost. And there’s stuff that you give only to specific conditions; so high cost low volumes” (HP 5)

The data suggest that drug development companies may be somewhat reluctant to move away from the “*huge volumes at lost cost*” blockbuster model of drug production;

“I suspect that drug companies in general are not keen to have to have pharmacogenetic tests. They will tend to push the drugs that are suitable for everybody” (PGx 1)

“They don’t want to identify a sub-group and run the risk of getting a licence for a very narrow population of patients” (PGx 3)

“If they’re going to try and get marketing authorisation for a drug they want to make the money back. So they’re going to need high volume stuff and inevitably pharmacogenetics isn’t going to necessarily be high volume” (CP 9)

Pharmacogeneticist 9 notes that where pharmaceutical companies do have an interest in genetic stratification, they tend to still remain focused on therapies which may yield high returns rather than *“high cost low volumes” (HP 5)*;

“I think things like obesity and male pattern baldness are things that they’ll want to have a say in” (PGx 9)

However, Pharmacy Stakeholder 3’s comment that *“the blockbuster model is sort of drying up”* resonates with PricewaterhouseCoopers’ (2009) assertion that big pharmaceutical companies can no longer ‘profit alone’ within the blockbuster model. From this perspective, the implementation of stratified approaches to drug development is seen to be more likely;

“They’ve accepted that this is going to be the norm for the future. The ABPI (Association of the British Pharmaceutical Industry) has written a report on that saying that it’s really going to go towards a stratification of medicines” (PGx 2)

“They’re going to have to start looking at a different model of working. If you look at blockbusters there’s not that many come down the line in recent years...it makes sense to me that you would develop things that would reduce the risk of ADRs and boost efficacy and try and get a licence based on a genetic test” (PS 3)

“Slowly over the next twenty years, as new drugs come along, which are better than the current drugs, they will be developed in a stratified manner” (PGx 2)

“I think it will go down the individualised route” (HP 9- Oncology)

The data suggest, however, that traditional blockbuster and more stratified approaches are not mutually exclusive. Given this, it is suggested that drug development companies will continue to invest in the blockbuster model of practice whilst simultaneously developing drugs in a more stratified way. Moreover, this stratified approach may also be applied to making more effective use of existing medications;

“I think it’s probably both. I don’t think it will be one or the other. I think we’ll still be seeing chemotherapy come out. I’m still seeing new drugs come out which are chemotherapy and at the same time we are seeing more drugs which are monoclonals and therefore you can test. So I think it’s both. I think there will still be plenty of drugs that come out that are both” (HP 9- Oncology)

“The use of pharmacogenetics... will allow us to use existing medicine much better by stratifying patients based on their ability to handle a medicine” (MTC 1)

“In the case of existing drugs, it may be that we might start using patient genetic information to determine whether they’re suitable” (PGx 1)

Running concurrently to this increasing stratification in drug development, the data also present a potential expansion of the work of drug development companies to include diagnostic testing production. Pharmacogeneticists 1 and 4 demonstrate this well;

“They don’t necessarily have a big background or commitment to diagnostics...Companies like GSK and Astra Zeneca don’t, so,

potentially, offering diagnostic tests is diversification for them in a way and is going to make life quite difficult” (PGx 1)

“The only other way [for pharmaceutical companies to make profit outside of a blockbuster model] is that they buy into the technology for testing and screening and make their money with screening and make less on the drugs” (PGx 4)

These quotes suggest a conflation of the work of pharmaceutical companies, who have traditionally produced (blockbuster) drugs, and biotechnology companies, who have traditionally produced diagnostic tests. This movement into test production is understood as challenging for drug development companies given the potential for generic (pharmaco)genetic testing kits to be produced;

“That’s difficult to work as a business model I would think because the technologies for screening for particular genetic markers are generically available and are becoming increasingly cheap and will be available at point of care” (PGx 4)

Pharmacogeneticist 4’s assertion here that PGx testing will be “*available at point of care*” raises interesting questions about community pharmacists performing PGx testing, or supplying tests to be carried out by patients at home;

“It isn’t at all far-fetched to believe that you can go to Boot’s the pharmacy, or even to your GP and out the pin prick of blood on the machine and a rapid sequence PCR comes up and tells you your particular allele while you wait. I don’t think that’s remotely out of the question” (PGx 4)

“There will be people that would pay for that because there are some people who want to find out everything about themselves” (CP 2)

This is explored in more detail below. As mentioned above, however, the implementation of PGx into routine hospital practice is almost universally imagined as beginning in the specialist area of Oncology. Here, then, it is useful to present a brief overview of the nature of PGx in this area.

8.4.1 PGx and Oncology

Oncology is conceptualised as the medical specialism in which PGx has made, and will continue to make, the biggest impact on practice;

*“Cancer drugs is where there’s a lot of innovation at the moment”
(CP5)*

“There’s going to be certain examples where practice is going to change incrementally and by the introduction of new tests, particularly oncology” (HE 1- previously a HP)

“In terms of cancer drugs it’s probably going to be something that’s going to be much bigger in the future” (HP3- Oncology)

“It probably will in terms of cancer care certainly” (HP 4)

“If you do specialist wards like Oncology or Rheumatology, you get a lot more of it there” (HP 8)

“Clearly there are some examples of pharmacogenetic type tests being used in Oncology” (PGx 1)

“I think that it is going to come into certain areas quicker than others. For example, cancer is going to be one area where it is going to be very quick” (PGx 2)

“Where I think it’s even more useful is...in the context of anti-cancer drugs” (PS 4)

“I think it’s going to be mainly Oncology. That’s where I see it mostly” (PGx 9)

Elsewhere, Oncology has been identified as a ‘promising field’ for PGx given the severity of ADRs that frequently arise from cytotoxic medications (Houtsma *et al.*, 2010). The data suggest that these adverse drug reactions are understood at both levels of the medicines management model- through formalised policies and through the pharmacy gaze. At the level of formalised, bureaucratic medicines management, these adverse reactions to cytotoxic drugs are understood to place financial and resource strain on hospitals due to the number of beds and staff which are required to manage these adverse events;

“If you could filter off all those people [who are at increased risk of drug response] through pharmacogenetics and tailor therapy properly, it’s bound to have an impact on performance” (HP 1- Chief Pharmacist)

At the level of the pharmacy gaze, the cancer patient body is constructed as a site of particular complexity and risk. Given this, the cancer patient body is understood to require careful management through the bioclinical collective gaze of the multi-disciplinary team which typifies Oncology practice, as Oncologist 1 shows;

“Everything is done through what we call a multidisciplinary team ...The multidisciplinary team is the surgeon because they often make the diagnosis; the pathologist because they’re looking at the tissue and telling us what type of tumour it is; the oncologist who deals with the drug treatment and the radiotherapy side of things; specialist nurse; usually somebody from radiology to look at all the x-rays and scans. And then sometimes you’ll have somebody from palliative care, it depends on the tumour type, somebody from orthopaedics” (O 1)

Given the complexity of the cancer patient body, the disease within it and the medications used to treat it, the Oncology pharmacy gaze is highly specialised and linked with cutting edge research in the field. Within this, Oncology medications are discursively located within a particularly toxic patient experience arising from both the toxicity of disease and the toxicity of medications. As such, as Pharmacogeneticist 9 highlights, the toxicity of disease and the toxicity of therapy are inextricably linked;

“And that’s because we give them enough drugs to just not quite kill them but actually sometimes it’s the drugs that kill you and not the cancer” (PGx 9)

Given this, then, PGx is identified as a way in which highly toxic medications administered to Oncology patients can be more effectively managed. The data identify this as occurring on two levels; firstly through the increased stratification of patients in clinical trials and secondly through pre-prescription testing to stratify potential drug responses. These more stratified approaches to Oncology prescribing are understood to improve cancer patients’ experiences of their disease and medication regimes;

“When you compare the quality of life of patients who are on these targeted agents as opposed to cytotoxic medications you can’t really compare highly enough in terms of advantage, in terms of quality of life that it provides” (PS 4)

“We might look back in 20 years’ time and think back in the 90s wasn’t it so bad. What such a blunt approach to just chemotherapy” (HP3- Oncology)

Given the importance of PGx in the field of Oncology and its use in routine practice, it could be argued that PGx *as a style of thought* (Fleck, 1979) has become somewhat normalised in Oncology practice. Here, again the distinction between PGx *products* and other aspects of PGx practice are important. Hence, it is not that all available PGx *products* are normalised in Oncology, but rather that a

(pharmaco)genetic approach to disease, the body and medications is a part of routine practice. In other words a ‘molecular gaze’ (Rose, 2007) enacted through various molecular and genetic products has become normalised in Oncology practice. To demonstrate, Oncologist 1 notes that genetic approaches to diagnostic practises are well entrenched in Oncology;

“It’s routine in breast cancer to do oestrogen receptors and HER2...Everybody else [apart from people over the age of 80] is tested” (O1)

Moreover, Hospital Pharmacists 3 and 9 (both Oncology pharmacists) state that pre-prescription genetic testing is routine for those medications where a pre-prescription test is available;

“There will always be the KRAS question if you’ve got things like Cetuximab and Panitumumab in it... Breast cancer, there is a trial looking at this 70 gene signature so that’s at trial so we’ll wait to see the results of that. You obviously do the HER2 testing in breast cancer so that’s sort of routine” (HP 3- Oncology)

“All the diagnostics have really come into their own now I think. So besides the HER2 we’ve got the KRAS testing for patients before they have Cetuximab, another one of the monoclonals. And now we’ve got the EGFR testing of course in non-small cell lung cancer before they start their Gefitinib” (HP 9- Oncology)

Given this increase in stratified approaches to therapy in Oncology practice, the discourse of toxicity around medications in this area is shifting. Within this, the management of toxicity in cancer regimes is conceptualised as an exercise which could be effectively undertaken by practitioners in the community setting. Hence, given the reduction in adverse reactions which pre-prescription PGx testing promises, the need to administer medications and monitor patients within the hospital setting is less apparent.

Chapter Six briefly highlighted the case of Herceptin being administered in patients' homes. This practice is thought to improve patients' experiences of their medications by removing the need for them to visit the hospital for their therapy and improve the efficiency of pharmacy departments by reducing costs and waiting times;

“It avoids all the having to travel in and then having to travel back again after the treatment” (HP 9- Oncology)

This practice also redefines the nature of Oncology and its medications by making the area less spatially-bound to the hospital setting. In doing so, cancer becomes redefined as a more chronic condition which can be managed by primary care practitioners, as the following quotes point out;

“We’ve changed cancer from being a rapidly fatal disease to being more of a chronic disease” (O1)

“The longest standing drug is Imatinib in terms of an oral drug which is an ‘ib’.... I did think could we actually have this prescribed by GPs and have it supplied in the community” (HP9- Oncology)

“It’s [cancer] really a chronic disease now we’re talking about so it would make sense for the patients to actually be monitored more by the GP” (HP9- Oncology)

This shift in understanding cancer as a more chronic condition also impacts on the ways in which the toxicity of cancer medications is operationalised. As such, Phillips and Currow (2010) note that the management of toxicity of Oncology medications is increasingly focused on *other* chronic co-morbidities such as cardiac complications and decreased immune functionality rather than acute problems such as nausea and hair loss.

Analysing the implementation of PGx in Oncology practice provides a useful way of understanding the relationship between medicines management and the discourse of toxicity and PGx testing. Given the routine way in which (pharmaco)genetic principles are mobilised in Oncology, this field provides a potential framework for examining the implementation of PGx in other specialist fields and, potentially, generalist primary care. The chapter now turns to an examination of this process of defining PGx in more general terms.

8.5 Defining PGx in Hospital: Medicine Management

Within the hospital “domain” (PGx 5), the value of PGx is defined through both formalised, bureaucratic medicines management policies and at the more negotiated everyday level of the hospital pharmacy gaze and the discourse of toxicity. At the level of formalised medicines management policies, PGx technologies are located within corporate and organisational concerns about the time and financial burden of ADRs. Here, the promissory discourses surrounding PGx technologies are mobilised as part of this bureaucratised coherence work. Hospital Pharmacist 1 (a chief pharmacist) demonstrates this well;

“You’re going to reduce the number of hospital re-admissions due to medication failure or medicines related problems. You could potentially cut down the costs” (HP1- Chief Pharmacist)

Within this quote, pre-prescription PGx testing is seen as a way to reduce the number of patients attending hospital due to potentially preventable adverse drug events. As such, PGx is understood as a cost-saving technological paradigm which is beneficial for the organisation’s budget. These corporate discourses which characterise much of the formalised bureaucratic medicines management approach resonate with much of the promissory discourse around PGx which is developed by researchers in this area. In their paper examining the expectations created around the (then) emerging field of PGx, Hedgecoe and Martin (2003) argue that the creation of promises of improved drug efficacy and reduced financial burden of ADRs is central to the development of PGx. With regards to the above quote, it can be seen that the

cost saving ‘visions’ (ibid.) for PGx have come to underpin formalised, codified approaches to PGx.

Although these promissory discourses around pre-prescription PGx testing are fairly pervasive, the cost-effectiveness ‘vision’ of PGx is questioned by a number of respondents. For example, Health Economist 1 (previously a hospital pharmacist) questioned the robustness of the economic evaluations undertaken;

“I’m not convinced that all the evidence that says “yes, it’s cost effective” is actually true...So is it cost effective? The answer is we don’t really know” (HE 1- previously a HP)

Additionally, Pharmacogeneticist 4 questions who ought to pay for the pre-prescription testing in an era of increasingly challenging NHS budgets;

“The NHS is already under financial strain...It’s [pre-prescription testing] very expensive... who pays for it?” (PGx 4)

These promissory discourses of PGx tend to centre on PGx *products* rather than *processes*. As such, it is the pre-prescription testing artefacts and their outputs (i.e. data showing whether patients are likely to respond well to a medication) which are cohered as beneficial for the hospital organisation. Running concurrently to this formalised medicines management understanding of PGx *products* is a less formalised operationalisation of PGx *processes*. As Chapters Six and Seven demonstrated, this less formalised coherence work is less concerned with the impacts of innovation on the wider hospital structure than the reorganisation of everyday working activities which is necessitated by these innovative approaches. Again, here, Damanpour’s (1996) dual model of innovations becomes apparent where PGx *products* are cohered through bureaucratised medicines management policies whilst PGx *processes* and services are cohered at the level of everyday practice and the pharmacy gaze.

The provision of PGx testing is understood as reorganising pharmacy work around a new set of artefacts which configure an increasingly molecularised patient

body. Within this, practice boundaries within the hospital are routinely negotiated vis-a-vis PGx services, as Pharmacogeneticist 9 highlights;

“Consultants and specialists don’t understand it [genetic testing]...so we keep getting referrals and we keep having to bat them back and say ‘no this isn’t what we do, it’s not appropriate for us to see this patient’...we’re not paid to see those people...we do sometimes end up seeing the patient” (PGx 9)

Here, Pharmacogeneticist 9 demonstrates the way in which practice boundaries are constructed around new services associated with PGx testing. Results interpretation and patient counselling work is reassigned to clinical genetics departments due to consultants’ lack of expertise in the area of genetic testing and medicine. Although Pharmacogeneticist 9 demonstrates a level of resistance to this boundary crossing, her comment that *“we do sometimes end up seeing the patient”* hints at the flexibility of these boundaries and the renegotiation which occurs around PGx processes. Moreover, the flexibility of boundaries which she demonstrates in this comment gives further evidence to the claim that hospital practice is characterised by bioclinical collective models of practice where practice boundaries are subject to negotiation given the highly collaborative nature of work and outcomes. Additionally, the resistance demonstrated in this quote gives an insight into the ways in which the dual medicines management approaches intersect in everyday negotiated work. Within this, although the boundaries which are being constructed pertain to everyday work patterns and different clinical gazes (i.e. the less formalised medicines management process), the organisational budgetary concerns of formalised medicines management policies also come into play as an important feature in organising professional boundaries (*“we’re not paid to see those people”*).

8.6 Reconfiguring the Hospital Pharmacy Gaze

Within hospital pharmacy practice, PGx reorganises the pharmacy gaze and the discourse of toxicity which it generates. Chapter Six noted that the pharmacy gaze focuses on the patient body as a site of medications use and the discourse of toxicity

which is generated to manage this body is concerned with the potential adverse effects of medications which are administered to it. Hence, the body is constructed as being at-risk from adverse effects of the pharmacological composition and action of medications. Although the patient body and the medication are co-constructed within this pharmacy gaze, the model of ADRs is relatively linear and one-sided with drugs being the risky object and the patient body being the at-risk subject. PGx testing, however, reorganises this understanding of adverse drug events where the genetic composition of the body reconfigures it as a potentially risky object. Hence, within what might be called a ‘pharmacogenetics gaze’, the body is not an inactive subject within which adverse events occur but is, instead, an active biological object whose (genetic) composition can contribute to adverse events.

The discourse of toxicity, then, is reconfigured to take into account genetic information about the patient body, which is reconstructed at a more molecular level. PGx testing also constructs the patient body in an increasingly algorithmic way. Chapter Six highlights the way in which the acutely ill patient body is reduced to a series of criteria and algorithms through which prescription decisions are made in the hospital setting. This chapter noted that this is particularly the case in medical specialisms where highly toxic medications are routinely prescribed and the risk of adverse drug events is, thus, very high. The data suggest that PGx test results are used as part of this algorithmic construction of the patient body in hospital settings;

“You’re going to have to check that those criteria [of the patient body] have been met before the drugs actually released or dispensed. If you think about chemotherapy you have to meet certain criteria... so I can’t see that it [pharmacogenetic testing] will be any different” (HP 4)

“We have genetic predictors and we also have clinical predictors. We can put them together and devise a better dosing algorithm, which helps you to be better able to define what a patient’s dosing requirement will be” (PGx 2)

“Whether it’s other characteristics of the patient or their disease pharmacogenetics is just something else in a way that you put into the mix for deciding what is the best treatment for this individual patient” (HP 3- Oncology)

“It’s just another piece of information like a test for lithium level. It’s just another layer of information” (PS 3)

Hence, these test results are understood to add another, more genetic dimension, to clinicians’ prescription decisions and, subsequently, to the pharmacy gaze. Hence, test results are understood as an additional piece of information in therapy decisions;

“This [pharmacogenetic information] is another piece of information that can help you in terms of your medicines selection and also thinking about how the medicines are going to work when they’re being taken” (HE 1- previously a HP)

“It’s another test that leads you down a treatment pathway” (HP 6)

This additional information, then, also expands the pharmacy gaze to incorporate a focus on genetic information in medicines safety as Hospital Pharmacists 3 and 9 (both Oncology pharmacists) points out;

“The pharmacogenetics issue is just another one of those extra things about the patient’s whole medical history and ideally we want the lot to be able to do the best checks and give the best for that patient when we’re checking this prescription” (HP 3- Oncology)

“You do it [pharmacogenetic test] at the start of treatment and then you know, in terms of planning, whether the patients’ appropriate for treatment or not... And it’s good because it means

you don't over-treat patients...it's a lot more individualised now in terms of making sure that patients get the treatments that are best for them" (HP9- Oncology)

The quote from Hospital Pharmacist 9 also demonstrates the way in which medications are made meaningful to patients through the use of PGx testing. Chapter Six noted that a central part of pharmacy practice and the pharmacy gaze is the process of locating medications and their risks within the patients' wider lifeworld. In configuring chemical compounds as socially and culturally meaningful objects, medications become meaningful through their status as "appropriate" and "best" for patients. In the above quote, Hospital Pharmacist 9 demonstrates that way in which PGx information can be used to construct this appropriateness. In other instances, of course, PGx information is used to construct medications as inappropriate. Within this, PGx data underpins the discourse of toxicity created around a medication and configures it as inappropriate and toxic for the patient body.

Additionally, PGx information can act to culturally configure disease as well as the medication used to treat it. Within this, molecular information underpins the definition of the nature of disease and the prognosis arising from it. Oncologist 1 demonstrates the way in which a pre-prescription PGx test for Herceptin can make breast cancer meaningful through the prognosis which PGx data suggest;

"Women were quite disappointed if they couldn't have Herceptin...but what it does is it turns a very nasty cancer into one that's about the same as everybody else's. So actually not needing Herceptin is a positive thing. We have to say that so many times to patients, you know, you shouldn't be disappointed if you don't need Herceptin, that means your cancer is not as aggressive as some people's" (O1)

This practice of making medicines meaningful through PGx testing can also act to make genetic information culturally meaningful within a much wider scope. Hence, where a PGx test highlights the potential for other toxicities, this genetic information then becomes meaningful in the context of the patients' wider

'lifeworld'. As an example, Chapter Three highlights the wider implications of PGx testing for Tacrine response where this test also indicates Alzheimer's susceptibility. This concern about Tacrine therapy is highlighted by Pharmacogeneticists 5 and 8;

"There was a concern about APOE4 and about the use of that in a pharmacogenetic setting when it gives information about Alzheimer's disease" (PGx 5)

"There's a gene called APOE4 I think that predicts Alzheimer's but also predicts response to Tacrine" (PGx 8)

Other respondents also noted similar concerns about the meanings of PGx test results in patients' wider 'lifeworld';

"If they test somebody and it brings up issues related to family links or something like that, which potentially it could, it's potentially quite an emotive area" (PGx 4)

"Especially breast cancer patients, they worry about other people in their family. I think they're always really hopeful that there's going to be a genetic solution" (HP 2)

"Well, they assume that has implications for their family. Women worry obviously about hereditary breast cancer and will their daughters be at risk of breast cancer and so the genetics obviously has that connotation" (O 1)

So far this chapter has located PGx products and processes within hospital practice and, more specifically, within the specialist area of Oncology. It has been highlighted here that this is because of the ontological differences between primary and secondary care medications which is outlined in Chapter Six. Within this, the relatively high toxicity of secondary care medications makes the stratification of patient populations more of a priority in this setting. Despite this, putative links between primary care drugs and genetically-determined drug responses have been

identified. Moreover, the primary care drug Warfarin is one of the most commonly cited as a beneficiary of pre-prescription PGx testing (Wadelius and Pirmohamed, 2006). Hence, although PGx is primarily a hospital-based practice at present, an analysis of its implementation in the community setting is imperative. It is to this analysis that this chapter now turns.

8.7 PGx in Community Pharmacy Practice

In contrast to the picture in hospital pharmacy practice outlined above, the community pharmacists interviewed had a relatively limited knowledge of PGx. The knowledge which community pharmacists did have was, generally, unintentionally acquired through personal experience, meetings, practitioner publications and inclusion in the present research study;

“Really my only experience [of pharmacogenetics] was a quick browse on Wikipedia...but it was being mentioned in the pharmacy press” (CP 1)

“We’ve had one branch meeting that I remember and I don’t remember very much about it apart from the word ‘pharmacogenetics’” (CP 9)

In the same way that the relatively high levels of knowledge of hospital pharmacists can be understood within the bioclinical collective structure of their practice, the medical technocracy which characterises community practice can be understood as a factor in community pharmacists’ limited knowledge of PGx. As Cooper *et al.* (2009) highlight, community pharmacists practise in relative isolation which makes the informal transfer of knowledge between them more challenging than in the hospital setting.

Moreover, as is discussed below, the association of PGx testing with highly toxic medications means that this technological paradigm is uncommon in community practice where the potential for ADRs is reduced. Given this, the data

suggest that an ‘early days’ discourse is mobilised to make sense of the implementation of PGx in community pharmacy;

*“It’s very early days... Treatment I think will still be 10 years off”
(CP 8)*

“I think it’s about a future role rather than a role that’s likely to develop in the next two or three years” (PS 1- also a previous HP)

“I think it’s still too early to say how it will impact on patients and what role we can play with it” (HP 5)

“I think it’s too far down the line of the worry list of things they’ve going to be thinking about” (HE 1- also a previous HP)

“You never really know how things are going to go” (PGx 3)

This ‘early days’ discourse generates a number of highly speculative scenarios for how PGx might work in everyday community pharmacy practice. Elsewhere, this process of imaging future scenarios has been argued to be central to the construction and implementation of innovations (Bell, 1996; Rappert, 1999). In the hospital setting such future scenarios are highly rationalised and based on experiential knowledge of previous genetic or molecular innovations and services. In the community setting, however, given the lack of experience around the implementation of molecular innovations, these future scenarios tend to be more speculative. These potential ‘PGx futures’ in community pharmacy are outlined later in the chapter.

8.8 Implementing PGx into Community Practice

PGx has made a limited impact on community practice because the trial-and-error model of prescribing primary care drugs is less problematic in the community than in the hospital. Hence, the relatively low cost and toxicity of primary care medications

mean that non-responsiveness and ADRs are less problematic in this setting than in the hospital.

The data suggest that the implementation of PGx in the community setting is highly linked with the medical technocracy in which community pharmacy practice sits. Innovations in community pharmacy, then, are understood as being administered in a 'top-down' manner through governmental and professional bodies (for example the Department of Health and RPS) and GPs. Within this model of innovations in community pharmacy, links with traditional linear models of innovation diffusion can be seen where external actors (i.e. GPs or Department of Health personnel) are heavily involved in the implementation process.

This relatively linear model of implementation is linked with the nature of community pharmacy as "reactive" (HE 1- also a previous HP), which is, in turn, related to the retail focus of community pharmacy work which limits the autonomy of practitioners. In other words, given the corporate environment in which most community pharmacy work is undertaken, the ability of practitioners to proactively engage with innovative technologies and practices is limited. Community Pharmacist 1 highlights this well;

"Not everybody gets a good chance to sit down and inwardly digest. It's not so much a lack of interest but more a lack of time to learn and understand these things" (CP 1)

The data suggest that the implementation of PGx into community pharmacy practice is most likely to be administered through GPs where GPs are the most likely community practitioners to undertake PGx work (i.e. testing and results interpretation). This model of PGx practice in the community is most similar to the present model of primary care practice (see Jamie, 2011: 694) and, therefore, serves to compound the boundaries of practice which construct diagnosis and prescribing (and all of their associated tasks) as the role of the GP and the practice of dispensing as that of the pharmacist. Within this, the data present pharmacists as occupying something of an adjunct role supporting the work of GPs in this area, as the following quotes demonstrates;

“We’ve really got to be working towards showing how we can help and how it [pharmacogenetics] can be good for everybody. How it can free up what the GPs need to do. We can do some of this” (CP 2)

“As the technology becomes a lot more widespread then that’s something that could spill over into pharmacy to try and take the pressure off other primary healthcare providers...” (CP 1)

The above quote from Community Pharmacist 1 represents community pharmacists’ involvement in PGx as being necessary once this practice has become challenging for the structures of general practice. In this way, Community Pharmacist 1 represents the involvement of community pharmacists in PGx medicine as being similar to their involvement in flu vaccination work presented in Chapter Seven as he went on to say;

“... in the same way that those flu vaccinations played a very valuable role in taking a bit of the pressure off GPs for the flu vaccinations and enabled a few more people to get vaccinated who wouldn’t otherwise have been able to” (CP 1)

This potential model of PGx medical delivery draws parallels with Cooper *et al.*’s (2009) understanding of community pharmacists as subordinate ‘doctors’ tools’. In this way, the skills of pharmacists are only drawn upon when necessary to support the work of GPs, which also resonates with Harding and Taylor’s (2002: 442) observation that ‘pharmacists take their lead from physicians’.

8.9 Defining PGx in the Community: Pharmaceutical Care

Chapter Six noted the philosophical differences between medicines management and pharmaceutical care where the former relates the organisational and corporate interests in medicines efficacy and the latter is focused on medicines efficacy for the individual patient. In this thesis it is argued that medicines management pertains more to hospital pharmacy practice whilst pharmaceutical care more accurately

characterises community pharmacy practice. Given this, PGx in community pharmacy practice is defined and cohered through formalised, codified pharmaceutical care policies and practices and at the level of everyday practice through the pharmacy gaze and discourse of toxicity. At the level of formalised, codified pharmaceutical care, PGx is largely defined in much the same way it is in the hospital setting. As such, pre-prescription testing is understood as a way to stratify patient populations to reduce adverse drug events;

“Patients have a very variable response. We can get a little tiny frail old lady and a big strapping chap and there can be differences. There must be a reason for this...So pharmacogenetics is interesting for anticoagulation, very much so... I think in the future it would be fantastic” (CP 2)

Additionally, PGx in the community setting is also defined as a way in which medications adherence could be improved. In the community setting, patients are given a relatively high degree of agency over their medication regimes as, in contrast to in the hospital setting, these medications are not generally administered on a daily basis and patients are not monitored in their taking of these medicines. As such, the choice of whether to adhere to a medications regime lies almost entirely with the patient. In their review of studies around patient non-adherence, Vermeire *et al.* (2001) highlight that patient non-adherence to primary care drugs is a ‘major problem’ for the NHS and present a number of reasons for this such as poor practitioner-patient communication; complexity of therapy regimen; polypharmacy; the cost and frequency of dosing; and patients’ own beliefs about their illness and medicines (also see Webster *et al.*, 2009). Charland *et al* (2012) argue that patients having knowledge of the PGx reasoning behind their medication regime can encourage them to comply and this is echoed in the following quote from Pharmacogeneticist 2;

“One of the side benefits of pharmacogenetics is actually that they [patients] are going to have to make more of an effort to have an interest in what their disease is and an interest in the treatments that we’re using. Obviously everyone has an interest in the disease

they have but don't have much of an interest in the drugs they're taking and that leads to some problems with regards to compliance. Fifty percent of people or more than that don't take the drug regularly as they're supposed to. So if you have more of an interest in your disease and how it's being treated, then you're more likely to adhere to the therapies, so that's something that will be a side benefit" (PGx 2)

Similarly, Pharmacy Stakeholder 2 noted patients' increased receptivity to therapies with a personalised element;

"If you tell someone we're going to tailor the drug to reduce your chances of side effects, or increase the chances of it actually working, they should be hugely receptive to it...An awful large number of patients abandon their treatment because they've read the information leaflet or they've perceived a side effect; they'll take one tablet or they'll take none. So I think they would love it really to think that someone is tailoring a drug for them" (PS 2)

Although PGx has made a limited impact on primary care practice so far, the data show that it is defined as a paradigm of practice which pharmacists will need an awareness of given the increased presence of genetic/genomic techniques and stratification approaches in drug development. In other words, as Cryan (2004) and Alcalde and Rothstein (2002) note, future pharmacists will prescribe a greater range of drug regimen (i.e. different dosages, strengths and administration directions) based on genetic information and will, thus, need to have an awareness of the issues. As such, PGx is defined as an important future paradigm in pharmacy;

"I'm sure in the future it will be hugely useful" (CP 2)

"Community pharmacists will probably need an awareness" (CP 6)

“I can only see that their role is going to increase as the complexity of drugs and drug dosing and the spectrum of drugs available increases...we’re going to have to have the pharmacists taking a much more direct role in prescribing and monitoring” (PGx 4)

“I would hope that they would be really...prepared for the whole range I was imagining of scenarios” (GP 2)

Within this future, a number of potential roles for pharmacists are highlighted in the data. These are conceptualised here as ‘pharmacogenetic futures’ and are highly speculative given the limited impact of PGx in community practice to date.

8.10 Community Pharmacists’ PGx Futures

Within the adjunct role of community pharmacists presented above, the data present a number of options for work activities for community pharmacists in delivering PGx medicine. As mentioned above, these potential PGx futures are highly speculative given the limited impact of PGx in primary care and the ‘early days’ discourse which is thus developed. These future scenarios can, broadly, be divided into three categories of work; one around testing activities; one around results interpretation and patient counselling; and one around inter-professional collaboration and education.

Firstly, community pharmacists’ involvement in PGx testing is understood as an extension of the testing activities which they currently undertake in their clinical work;

“Well pharmacists already...do some levels of testing like pregnancy testing” (PS 2)

“Now, because most community pharmacies have a consultation area... there are pharmacies that are setup already to do that. So if it was things like taking a finger prick test or blood test I don’t see

why that couldn't be done in a pharmacy. I'd like to think that we could be somehow involved in it" (CP 4)

"Community pharmacists do testing for blood pressure or cholesterol testing so they could do genetic testing in the community pharmacy" (HP 5)

"Could [community] pharmacies do that [pharmacogenetic testing]? They do things like cholesterol testing and various other things so I don't see why not" (HP 3- Oncology)

"There may be some generic tests which come along a bit like cholesterol testing, which anyone can do, which may be a point-of-care diagnostic, which you could potentially do in a pharmacy" (PGx 2)

"As pharmacists can be involved in glucose testing and those sorts of things, in that setting, I think it would be entirely reasonable" (PGx 5)

Here, the black-boxed nature of PGx testing (e.g. a *"finger prick test"* (CP 4)) is central to the ability of community pharmacists to carry out this work as interpreting complex results is not easily harmonised with existing practises and structures in community pharmacy. Hence, the outcome from PGx testing products needs to be somewhat binaried in order for these outcomes to be useful in community pharmacy practice, as Pharmacy Stakeholder 4 shows;

"If it's a simple test where you do what we call an antibody test, like a colour test, that is doable" (PS 4)

Secondly, community pharmacists interpreting test results and providing information and counselling to patients has been suggested elsewhere (Clemerson *et al.*, 2006; Moffat and Dawson, 2001). The data here suggest that this role of

community pharmacists may be beneficial for patients by locating their PGx information within their wider ‘lifeworld’ and illness trajectory;

“They [community pharmacists] definitely have an advisory role to the patients in terms of I’ve had this test and what does it mean” (HE 1- also a previous HP)

“Who should explain the results of the test, who should discuss whether or not to have the test in the first place, what’d the turnaround time and what’s the effectiveness of the test, the ability of it to predict a particular side effect. And obviously when we’re talking about people who could either explain the results or think about the decision to have the test pharmacists are included as one of the option” (HE 1- also a previous HP)

“The people who actually understand medicines and their effect on the body are pharmacists. So if anybody is going to be able to explain in lay terms, pharmacists are the right persons” (MTC 1- also a previous HP and CP)

“They need to present themselves as the translator of information because I think that would strengthen the relationship between the patient and the healthcare professional” (MTC 1- also a previous HP and CP)

Finally, some of the data suggest that community pharmacists are in a central position to provide education about PGx to other healthcare practitioners and patients. It is suggested that as experts in medicines and their associated ‘stuff’ (Barber, 2005) pharmacists occupy an optimal position to disseminate PGx knowledge to other primary care practitioners and patients;

“As an education role, fine...I think that’s a very important part” (O 2)

“There has to be a big communication discussion between healthcare professionals and the wider world. And I happen to think that the best people, the best qualified people to do that are pharmacists...The people who actually understand medicines and their effect on the body are pharmacists. So if anybody is going to be able to explain in lay terms, pharmacists are the right persons”
(MTC 1- also a previous HP and CP)

This “*translational*” (MTC 1) role of pharmacists also offers a way through which pharmacists can demonstrate their expertise in the area of medicines and strengthen inter-professional communication and collaboration. Elsewhere Penick Brock *et al.* (2003) argue that this sort of ‘pharmacist educator’ role places community pharmacists in a prominent position to expand their professional jurisdiction by becoming involved in research which has not previously been part of community pharmacy work. This “*translational*” work, thus, presents a way in which PGx may undermine the relatively rigid hierarchical boundaries of the traditionally medically technocratic primary care structure and facilitate a more bioclinical collective model of practice.

As mentioned above, these imagined PGx futures in community pharmacy are highly speculative given the limited impact that this paradigm of practice has made on community pharmacy so far. Moreover, these three futures present PGx as a set of (testing) products which are present in every community pharmacy around which something of a standardised process is developed. The data, however, suggest that the PGx roles outlined here are more likely to be undertaken by specialist pharmacists. As such, in much the same way as hospital pharmacists specialise in an area of medical practice, the data present the most likely scenario as being one in which a small number of community pharmacists become accredited with specialist skills and expertise in the area of (pharmaco)genetic medicine;

“I could envisage this being more in a specialist clinic” (PS 2)

“At the moment pharmacists tend to be specialists around disease areas and specialities like that whereas maybe that

[pharmacogenetics] would be a specialist area that would cover lots of different disease specialities but it would be a specialist interest area” (HP 2)

“I don’t think all pharmacies will do this but there will be some specialist pharmacists, who will become specialised in the area; who will then be able to interpret and help with this process, as there will be specialised clinical pharmacologists and specialised physicians in this area. So it is going to be a specialist area.” (PGx 2)

“There would be quite a profound role. I think you’re getting into the realms here - beyond specialist pharmacists- you’re getting into a realm of consultant pharmacist and that’s the area and level of expertise and practice I would expect somebody to have before they started to dip their toe into the mucky areas of pharmacogenetics” (HP 1- Chief Pharmacist)

“I think it’s interesting whether the profession goes down the road where everybody needs to have those core competencies or whether you go down the line of your GPs with a special interest; so you get pharmacists with a special interest in pharmacogenetics...The profession is going down the consultancy, particularly in hospital pharmacy, route. So to me that seems a more logical approach” (HE 1- also a previous HP)

The data suggest that these PGx futures will impact on the ways in which pharmacists interact with patients, patient bodies and medications. As such, the community pharmacy gaze is reconfigured by pharmacists’ practice within these PGx futures.

8.11 Reconfiguring the Community Pharmacy Gaze

The limited presence of PGx in community pharmacy can be understood as relating to the nature of the pharmacy gaze and the discourse of toxicity which it generates in community practice. As Chapter Six noted, the pharmacy gaze and discourse of toxicity in community pharmacy practice are centred on relatively simple patient bodies to which fairly low toxicity medications are administered.

The implementation of PGx into community pharmacy may reconfigure the community pharmacy gaze in similar ways to that described above in the case of hospital practitioners. As such, the introduction of genetic information into community pharmacy may reconstruct the previously relatively simply patient body as a more complex, molecular entity and the previously fairly low-risk medications which are administered to it as toxic regimes in need of closer management. Through this, the traditional trial-and-error model of prescribing in primary care becomes redefined as inappropriate for failing to take into account the complexities of the molecular patient body and the potential toxicities which it presents. In this way, PGx can be understood as drawing parallels between the hospital and community pharmacy gazes where trial-and-error prescribing in the community is displaced by more systematic and complex prescribing and management practices as in the hospital.

Chapters Six and Seven highlighted increased clinical work as a key feature of the community pharmacy gaze. Chapter Seven argued that by mobilising various testing technologies, community pharmacists bring into being what is called here a collective ‘public health body’ which positions patients’ ‘extracorporeal space’ (Armstrong, 1995) and bodily characteristics (such as weight and cholesterol levels) as roots of toxicity and risk. The introduction of (pharmaco)genetic principles into community pharmacy may reshape this clinical community pharmacy gaze to incorporate a focus on the molecular aspects of this bodily toxicity. For example, community pharmacists have a strong involvement in delivering smoking cessation support services and providing medicinal materials, such as nicotine patches, which have a central role in this cessation process. Within pharmacy smoking cessation services, the public health body is brought into being through the relationship

between the at-risk smokers' body and national smoking cessation objectives. The role of the pharmacist in this smoking cessation process is enacted through their provision of support services and administration of medicinal products. Recent work in the area of the pharmacokinetics and pharmacodynamics of nicotine suggest that there may be a genetic basis to dependence mechanisms and that smoking cessation products may be more effectively used through an understanding of these genetic elements (see Kortmann *et al.*, 2010). In this way, PGx can be understood as reconfiguring the clinical pharmacy gaze to incorporate a more genetic element into the clinical services which community pharmacists provide.

Hence, whereas PGx is most commonly understood as a series of products and processes around prescribed medicines, its implications for community pharmacy may be more pervasive in centring on clinical, as well as dispensing, work. As such, the community pharmacy gaze may be reconfigured around both its medications and clinical foci.

Within this potential reconfiguration of the pharmacy gaze in community practice, the importance of algorithms is, once again, clear. Chapter Six noted the way in which the complexity of the ill patient body is managed through its construction in algorithmic terms. Additionally, it is argued above that PGx configures an algorithmic patient body in the hospital setting. The data here suggest that in the community setting, algorithms are of central importance in delivering PGx medicine in two key ways. In one way, there is an algorithmic construction of the patient body in much the same way as occurs in the hospital setting;

“The information would tell you more about whether they can have the drug. So as well as age, weight, other drugs I guess genetics would also be part of it” (CP 10)

“There are clinical algorithms which you can now put in-pharmacogenetic test result; patients' weight; age; health etc.- put that all into a programme and get the dose out. I think pharmacists will be open to that and will use that information as they would to

check if the patient had had any liver problems or kidney problems before prescribing them certain drugs” (PGx 5)

Within this, the complexity of the patient body is managed through its construction as a set of criteria which influence therapy decisions. In another way, the patient body is managed through algorithmic safety software which is stored on, and managed by, the pharmacy computer. This algorithmic software is similar to that which pharmacists currently use for indentifying potential drug-drug interactions as part of their “*checking*” (HP 6- Director of Pharmacy) role. The provision of PGx medicine is imagined to add a layer of complexity to this software by introducing gene-drug algorithms to the repertoire of information involved in this “*checking*” role;

“They do drug interactions now as a matter of course...I guess that will become more sophisticated and might include pharmacogenetics” (O 1)

Within this, the development of gene-drug reaction algorithms can be understood as bridging the gap between PGx products and processes. In other words, it is through such algorithms that the outputs from PGx products (i.e. test results) are translated into PGx processes through the therapy decisions that they enact. Here, then, algorithmic software which manages the body, its medications and the potentially toxic relationship between them can be understood as both a product and a process innovation.

As well as reconfiguring the ways in which community pharmacists gaze at their patients, the implementation of PGx into community practice may reconfigure the ways in which patients, and other practitioners, understand pharmacists as professionals. In other words, PGx may alter the professional identity of community pharmacists in a number of ways.

8.12 Reconfiguring the Professional Identity of Community Pharmacy

In their study of electronic prescribing systems (EPS) in community pharmacy, Petrakaki *et al.* (2012) note that the implementation of new technologies into pharmacy can change pharmacists work in the following areas: nature of work; professional values; roles; jurisdictions; boundaries and power. Within this, they argue that re-professionalisation and de-professionalisation of pharmacy occur simultaneously where pharmacists are increasingly provided with opportunities for challenging clinical work and decision-making and are more fully integrated into the NHS (re-professionalising activities) whilst concurrently their work is increasingly automated, controlled and rendered invisible (de-professionalisation). As such, through the implementation of EPS technology, the community pharmacy identity is shifted. The data suggest that a similar process may occur in the community setting through PGx technologies.

At present, the professional identity of community pharmacists is heavily linked with their retail role which leads to their characterisation by other healthcare practitioners and patients as “*glorified shopkeepers*” (CP 1). Their practice with relatively simple (in other words non-complex) bodies and medicines can also feed into their identity as ‘quasi’ professionals (Denzin and Mettlin, 1968). Additionally, community pharmacists’ practising in ‘isolation’ (Cooper *et al.*, 2009) is shown in Chapter Six to be central to their position in the primary care medical technocracy and, thus, their professional identity.

It has been suggested that the implementation of PGx into pharmacy could increase the inter-professional communication between pharmacists and other healthcare practitioners (Cryan, 2004) and thus, as Petrakaki *et al.* (2012) argue, ‘bring pharmacists into the NHS family’. These sentiments are supported in the data where PGx being part of routine community pharmacy practice is understood to necessitate the movement of community pharmacy practice away from a medical technocracy model to one of a more bioclinical collective nature;

“We’d need to be talking with GPs and nurses and all sorts of other people a lot more than we do currently” (CP 10)

In addition, the reconfiguration of the community pharmacy gaze outlined above may impact upon the professional identity of community pharmacy. Hence, where PGx reconfigures the primary care patient body as increasingly molecularised and complex, the identity of community pharmacy may become increasingly understood in terms of complexity; complexity of bodies and complexity of medications. Community Pharmacist 10 states that this would affect the way in which community pharmacy is perceived by patients and other healthcare practitioners;

“By doing genetics, we’re saying that we can be more high-tech than people think we are now” (CP 10)

Community Pharmacist 3 notes that the professional identity of community pharmacists is reconfigured by this added complexity;

“You automatically send a signal that we are here for health reasons as opposed to just dispensing the medication” (CP 3)

Resonances can be seen here with Pickstone’s (2000) ways of knowing, which was outlined in more detail in Chapter Two. Pickstone argues that there are five ways of knowing in science and medicine which have shaped medical practice throughout history. He argues that there are connections between these ways of knowing, the technologies that are used and the extent to which medicine (or certain branches of it) are understood as a ‘science’, which then impacts upon the professional identity of the practitioners involved. He presents the two most recent of these ways of knowing as ‘experimentalism’ and, more latterly, ‘technoscience’. Contemporary community pharmacy practice can be understood as sitting within an ‘experimentalism’ model given the ubiquity of the trial-and-error model of prescribing. In integrating PGx into community pharmacy, Community Pharmacist 3 suggests that the sector may be reconfigured to a more ‘technoscience’ way of knowing. In this way, PGx may help community pharmacy ‘transition into the future’ (Streetman, 2007: 2040) and may reconfigure community pharmacy as ‘less an art and more a science’ (Johnson *et al.*, 2002: 13S).

8.13 Reflexive Monitoring and Integration of PGx: Products and Processes

Chapter Seven highlighted May and Finch's (2009) notions of reflexive monitoring and integration as useful reference points for analysing the evaluation of new innovations in pharmacy practice. To reiterate, reflexive monitoring is the process through which new innovations are formally and informally evaluated through communal and individual appraisal techniques. In pharmacy practice, communal, formal evaluation is argued, in Chapter Seven, to map onto formalised, bureaucratic medicines management policies and processes whilst more negotiated, individual appraisal is related to medicines management processes enacted through the pharmacy gaze in everyday practice.

The data show that PGx is subject to reflexive monitoring in both the hospital and community setting. In some cases, this reflexive monitoring leads to the normalisation of PGx practice as in pre-prescription HER2 testing for breast cancer patients. In other instances, this evaluative work highlights problems with PGx products and processes which leads to a lack of integration. Although he does not employ the constructs of NPT specifically, parallels can be drawn here with Hedgecoe's (2008a) notion of clinical usefulness. Within this, he argues that whilst pre-prescription PGx tests may be defined as useful and integrated into some clinical contexts (for example, HER2 testing in Oncology), in other areas such as APOE4 testing for Tacrine, pre-prescription testing is defined as less useful and so fails to be normalised into everyday routine practice.

The reflexive monitoring of PGx is an evaluation of both PGx products and PGx processes (see Damanpour, 1996). The data suggest that most of the evaluative work around PGx *products* is done through national and regional communal appraisal practises. Within this, bodies and organisations such as NICE and the Cancer Network are central actors in this evaluative work and define whether, and how, PGx testing products are useful for practice. Oncologist 2 shows, for example, that the value of HER2 testing in breast cancer patients was "*sorted out at the national level*" by the Cancer Network.

Once this national level communal appraisal of PGx *products* is understood as somewhat completed (i.e. once, for example, a clinical trial has finished), evaluation then begins to centre on the micro-level integration of PGx *processes*. The following quote from Oncologist 2 demonstrates this in the case of HER2 testing for breast cancer patients;

“We need to be doing it [routinely testing for HER2 over-expression in breast cancer patients]. Okay, how do we do it?... We don’t know” (O 2)

Within this quote the evaluative work of the HER2 testing *products* by the Cancer Network has already taken place and, as an outcome, the routine testing of breast cancer patients for HER2 over-expression has been recommended. The quote shows that the appraisal work is then centred on the integration of these testing *processes* in everyday practice.

In the hospital setting much of this integration work around PGx processes is undertaken through national directives where the bodies which undertake much of the communal appraisal work then set national frameworks for implementation. Oncologist 2, again, demonstrates this in the HER2 testing case;

“You can piddle about on the coalface and you don’t get a huge amount done. You’ve got to go back to the people in the Network who got the funding and the ability to just say “you’re going to do every sample now” and from now on you have to do it” (O2)

Here, the integration of HER2 testing into Oncology practice is directed by the Cancer Network which undertook the *product* communal appraisal work and has the “*ability*” to construct frameworks and protocols for *process* integration. This relatively top-down integration model is juxtaposed in this quote with integration work at the meso (organisational) and micro (everyday practice) levels which is carried out in everyday practice “*at the coalface*” and understood as having limited capacity for “*getting a huge amount done*”.

What this means is that in reflexively monitoring and integrating PGx, a number of elements become important. Figure 3 identifies these elements as being the scope, nature, level and focus of evaluation and demonstrates the ways in which these elements sit within communal and individual appraisal processes and are linked with each other. This Figure also highlights the relationship between communal and individual appraisal practises and the dual medicines management model proposed in this thesis. It shows that, broadly, communal appraisal processes are undertaken in line with formalised, bureaucratic medicines management policies whilst individual appraisals of PGx are enacted through the pharmacy gaze and the discourse of toxicity at the level of everyday pharmacy practice.

Reflexive monitoring and integration of PGx in community pharmacy is more challenging to analyse given that little of this work has taken place because of the lack of PGx products in primary care. Given this, the data which discusses the integration of PGx processes in community pharmacy is highly speculative and tends to focus on the prospective challenges of this integration work. The data suggest that there are two 'scopes' to these potential challenges (see Figure 3); one which focuses on 'macro' challenges to be addressed at the organisational level of pharmacy and one which focuses on 'micro' challenges which are manifested in everyday routine community pharmacy practice. This is not, however, to say that these macro and micro challenges identified in the data are discrete sets of issues; there are quite clear overlaps where micro challenges require some degree of engagement from organisational bodies and vice versa. Moreover, many of the macro and micro challenges identified sit within the same overarching concerns such as logistics and finance. This chapter now turns to a more detailed overview of these macro and micro challenges.

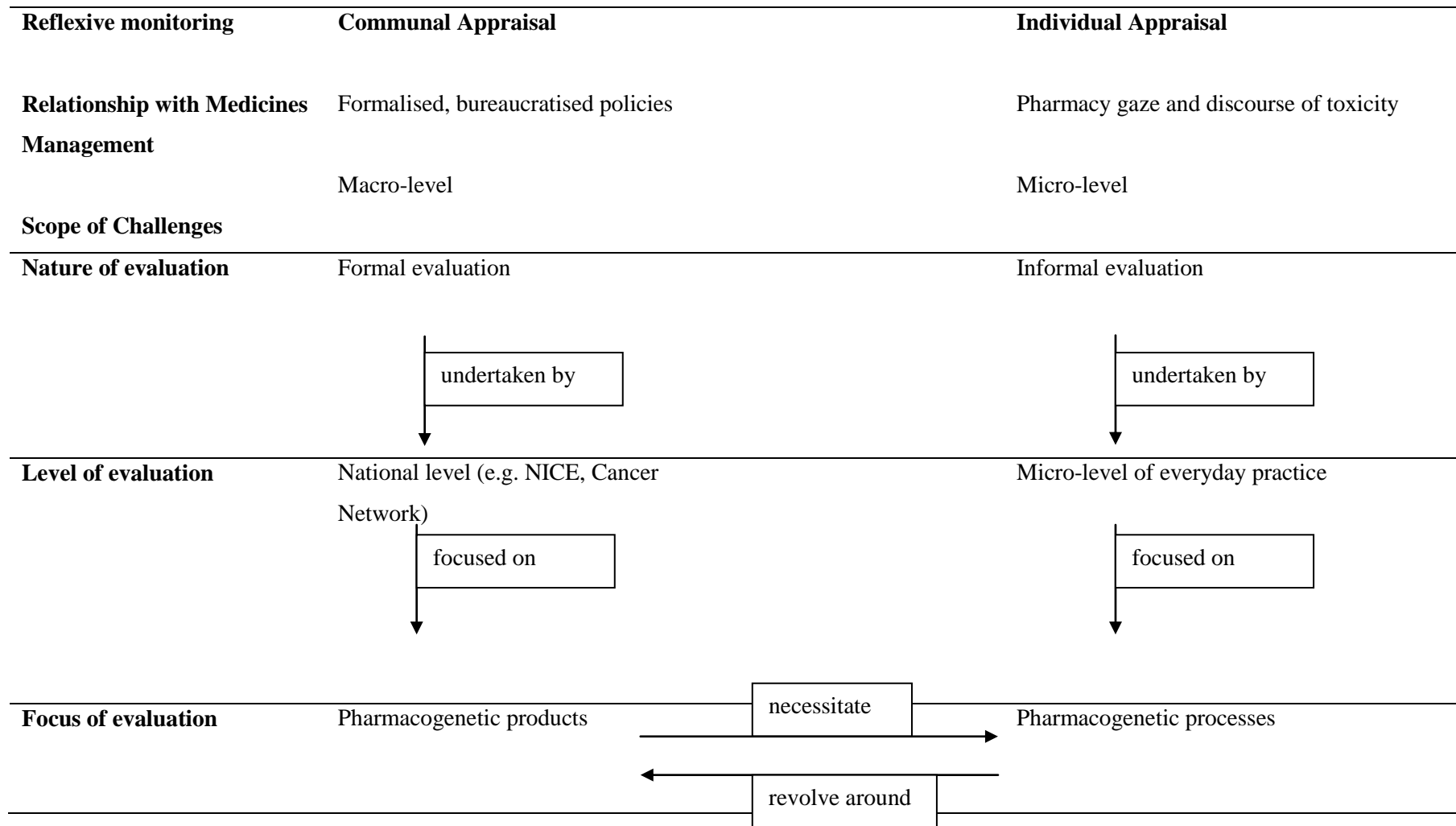


Figure 3: Reflexive monitoring of PGx. Exploring the relationship between appraisal and nature, level and focus of evaluation

8.13.1 Integrating PGx into Community Pharmacy: ‘Macro’ Challenges

Here, the notion of ‘macro’ vis-a-vis the challenges of integrating PGx into routine community pharmacy practice is employed to denote the level of the pharmacy ‘world’ in which challenges are manifested and addressed. The notion of macro challenges, then, refers to challenges which affect the entirety of the community pharmacy structure and practice. These challenges, therefore, fall within the remit of organisational bodies such as the RPS and Department of Health and would require addressing before PGx could successfully become a routine feature of community pharmacy practice.

Most of these macro challenges are centred on the nature of pharmacy practice and the integration of PGx *processes* within it. In addition, the nature of PGx products is seen as a potential macro challenge for community pharmacy by a number of secondary care respondents who are already using such devices as part of their everyday practice. Specifically, concerns around the quality assurance of PGx tests in primary care are highlighted where quality assurance is understood as a “*massive, massive issue*” (O2). Experiences of quality assurance challenges within secondary care are, then, used as reference frameworks for understanding the potential challenges of PGx in primary care. Oncologist 2 emphasises this in the following quote;

“There are significant problems with some of the tests that we do... Quantification or semi-quantitative immunohistochemical assays are not easy, they are prone to error, systematic error, and the quality assurance is very labour intensive and is performed intermittently” (O 2)

In this quote, Oncologist 2 highlights quality assurance vis-a-vis interpreting PGx test results as problematic in the hospital setting. This is then used as a framework for the potential challenges of PGx products in community settings as he goes on to say;

“It’s hard enough to get quality assurance in a centralised system...In terms of testing it would have to be an incredibly robust test to just be farmed out to the community” (O 2)

The above quote suggests that the robustness of PGx products is particularly important in the community setting given the context in which prescription decisions are made and medications are dispensed. Within this such quantification tests (i.e. tests which determine *levels* of gene or protein expression) are challenging for two reasons.

Firstly, the results which they provide are not binaried in the same way as other primary care test results (for example pregnancy tests) and so a fairly high degree of clinical judgement is necessary in translating these results into therapy decisions. In the hospital setting, this is facilitated through the bioclinical collective nature of practice, particularly in Oncology multi-disciplinary teams. This is in contrast to primary care practice in which practitioners, and their therapy decisions, are relatively ‘isolated’ (Cooper *et al.*, 2009).

Secondly, quantification testing requires multiple tests to be carried out in order to assure the quality of results. Oncologist 2 notes, for example, that oestrogen receptor testing in breast cancer is carried out “*on a three month basis*”. The acutely ill and highly toxic nature of the bodies which are being treated in secondary care (and particularly in Oncology) mean that such frequent re-testing is, potentially, less problematic. In the community setting, however, this multiple testing work presents financial and labour challenges for practitioners particularly given the relatively low toxicity of medications which are being prescribed. Oncologist 2 goes on to suggest a “*genomic health approach*” to pre-prescription testing which would be “*more robust and [mean] that you could theoretically do...a single sample, single test*”. The macro challenge vis-a-vis quality assurance, then, is centred on developing such black-boxed “*single sample, single test*” devices for integration into community pharmacy practice.

Other macro challenges in integrating PGx into community pharmacy practice are rooted in PGx processes and their (dis)juncture with contemporary

practice structures. One of the primary challenges presented in the data is the financing of PGx in community practice. This challenge incorporates a number of elements. In one instance, there is uncertainty around who would be responsible for paying for individual tests. There is a question around whether patients themselves would pay for tests given the potential for improvements to their experiences of medications;

“Some patients won’t mind paying for these tests if it means they’ll have a better time of it on their drugs” (CP 10)

Alternatively, Community Pharmacist 2 highlights patients’ wanting to find out about their own bodies as a potential reason for them paying for these tests themselves;

“There will be people that would pay for that because there are some people who want to find out everything about themselves...That would be one way of getting over the cost issue if the patient paid themselves” (CP 2)

This potential model for financing PGx testing is strongly linked with direct to consumer (DTC) testing activities. Although much of this tends to be focused on genomic diagnostics and risk profiling rather than PGx information, a review of DTC testing has shown that two companies were offering PGx testing whilst one UK company made testing kits available in pharmacies (Hogarth *et al.*, 2008). This raises interesting questions about the role of pharmacies (and pharmacists) in DTC genetic testing activities. Hence, whilst most of these tests are marketed online (Williams-Jones, 2003) and most of the results interpretation and counselling work is seen as the responsibility of GPs (Hauskeller, 2011), Hogarth *et al.* (2008) and the data presented here suggest that pharmacists may in practice have a role to play in this process of DTC genetic testing.

This uncertainty about financing PGx tests is also linked to the relatively low cost and low toxicity of primary care medications. In this way, the data suggest that pre-prescription testing in primary care may not be cost-effective given the relatively

low cost and low toxicity of primary care drugs which make trial-and-error prescribing less problematic than in the hospital setting;

“It will depend very much on the cost because if we look at things like codeine you just try it and if it don’t work you try something else because it’s so cheap to try” (CP 6)

Additionally, challenges around financing PGx in community pharmacy practice centre on the remuneration process. Pharmacy Stakeholder 2, for example, questions whether the NHS would pay for community pharmacists to undertake PGx work when other primary care practitioners can undertake this work at a lower hourly rate;

“If it’s just a matter of taking a blood sample and then giving those results to someone else to make the interpretation, like the GP, then you’d go for the cheapest person, not a pharmacist at £25 an hour...you’d go for someone on £10 an hour” (PS 2)

Within this quote, the remuneration challenge is contingent on the nature of work involved in delivering PGx. Here if the interpretation of results is not being done by the same practitioner who is doing the testing, then the “cheapest” practitioners are understood to be the most appropriate to undertake testing work. Pharmacy Stakeholder 2 goes on to comment;

“If the person [doing the testing] then makes an interpretation and a clinical judgement then you’d perhaps pay for that on top but I suspect it would be going back to the doctor... unless it’s a pharmacist or nurse running a clinic where they’re an independent prescriber and they make the decision at the same time” (PS 2)

This quote demonstrates that remunerating pharmacists for undertaking PGx testing work is only cost-effective where clinical judgement is also being undertaken, envisaged as sitting within independent prescribing practices in specialist clinics.

Elsewhere, however, the data suggest that independent pharmacist prescribing is still to be normalised in community practice;

“I’ve got a friend who’s an independent prescriber...the unfortunate thing is that they’ve done the training but they’ve not had the opportunities to practice” (CP 1)

“At the moment there is a really minimal uptake by GPs on independent prescribers” (CP 3)

Within this, independent pharmacy prescribing is reflexively monitored as being of limited use in everyday pharmacy practice. In the community setting, this lack of normalisation of independent prescribing further reinforces the practice boundaries of the medical technocracy where prescribing work is understood as the domain of GPs.

An additional macro challenge in this area of finance and remuneration is overall funding in community pharmacy practice. Community pharmacies are funded by the Pharmaceutical Services Negotiating Committee (PSNC) where the amount of funding for community pharmacy is negotiated with the Department of Health and set each financial year. A recent PSNC and British Medical Association guide to community pharmacy for GPs¹⁷ notes that 94% of pharmacy funding comes from the NHS in this way. As such, funding for community pharmacy is heavily tied in with a wider economic picture and government policies around this. Given the current financial crisis in the UK (from 2008 onwards), the data highlight funding for the entirety of the community pharmacy profession as being a challenge in contemporary practice;

“It’s a case of how do you get that [pharmacogenetics] forward without the funding, which is what it all boils down to” (CP 3)

¹⁷ Available here:
http://www.bma.org.uk/images/communitypharmacyguideforgppracticestaffapril2010_tcm41-196435.pdf

“People just have their heads down hoping that their funding’s not going to be cut” (CP 1)

“It’s very difficult to guarantee funding from one year to the next and to place ahead in that way” (PS 2)

The above quotes suggest that the implementation of PGx and the structural reorganisations which it may necessitate are given low priority because of the contemporary funding challenges in community pharmacy.

This uncertainty around funding in community pharmacy can also be understood as indicative of a uncertainty about the future of community pharmacy work. The growth of precarious forms of employment is located more generally within neoliberal globalisation trends in the latter half of the twentieth century where the decreased power of unions and the increased ‘flexibility’ of employment eroded the hold of the ‘job for life’ model (Allen and Henry, 1997; Kalleberg, 2009). In their study of the UK’s cleaning, catering and security industries, Allen and Henry (1997) demonstrate the way in which employment ‘risk’ has become a ubiquitous feature of relatively low-status industries and jobs. Given this, much of the social science focus on precarious work has centred around these types of work. The data suggest that pharmacists also position themselves within this framework of employment risk and uncertainty.

The financial challenges of PGx work are, then, highly related to the ‘early days’ discourse outlined above. In this way, developing standardised remuneration policies is challenging given the uncertainty about community pharmacy funding and what roles pharmacists may perform in delivering PGx in the community setting.

Related to this is another ‘macro’ challenge of integrating PGx into community pharmacy, which is concerned with the logistics of community pharmacists engaging in PGx work. Much of this is centred on the location of pharmacists at the dispensing, rather than diagnosis and testing stage, of the patient journey. In other words, most patients experience a similar trajectory through primary care where diagnosis, pre-prescription testing and prescribing is carried out

by GPs with interactions with pharmacists coming later at the dispensing phase. What this means is that various structures and mechanisms are in place in primary care to facilitate and support this demarcation of activities; as Community Pharmacist 1 points out with regards to blood testing;

“They already have a sort of logistical arrangement in place for collecting blood samples which are then taken off to the lab and then set back. They already have that mechanism in place whereas if pharmacists were to be involved in testing, they would have to set those kind of arrangements up” (CP 1)

Here integrating PGx testing processes into community pharmacy practice is thought to necessitate significant structural shifts in order that the patient journey does not diverge too much from the present model. Community Pharmacist 10 demonstrates this well;

“It might be a bit upside down. If we’re doing testing before prescriptions then it’d be going to the GPs for what’s wrong with you, us for testing, GPs for your script and back to us for the drugs. I think it’d need a different way of doing things otherwise patients won’t know if they’re coming or going” (CP 10)

However, this view is based on a model of PGx testing as *pre-prescription* testing. Elsewhere, it has been proposed that pharmacists could become involved in PGx testing where this testing is done *pre-dispension* (Jamie, 2011). In doing so, PGx data would be generated during the patient journey when pharmacists play a *“police man” (PGx 3)* role to check for gene-drug interactions in the same way as they do now with drug-drug interactions:

“I can see that [pharmacists using pharmacogenetic data] in terms of... interpreting it the same way as they are for drug-drug interactions” (PS 4)

“They do drug interactions now as a matter of course...I guess that will become more sophisticated and might include pharmacogenetics” (O 1)

Although this pre-dispensing model of testing would necessitate fewer structural reorganisations of community pharmacy, the cost-effectiveness of performing testing (both pre-prescription and pre-dispension) becomes central once again. Here, the challenges centre on pharmacy’s investment in PGx testing products without certainty as to whether this process would yield financial returns. This is demonstrated by the following quotes;

“I wonder would it be done often enough. I suppose for it to be justified, you’d need to be doing tests hundreds of times a day” (CP 1)

“Some of the community pharmacists the testing would need to be common enough to make it worth their while to invest in doing it. If they only had one patient on a particular drug and they had to buy in a piece of kit to do a test on that individual” (PGx 5)

An additional logistical challenge in integrating PGx into community pharmacy is around the extent of information to which community pharmacists have access. Chapter Six demonstrated that the restriction of patient medical records underpins much of the medical technocracy in primary care settings. The data suggest that introducing genetic information into community pharmacy would necessitate increased medical record access;

“You cannot access a patient’s data or medical information, at least nothing to do with their health...So as it is, that’s already a drawback so if you were to try and introduce a system where you’re introducing genetic data across the nation, I think that would be a big challenge” (CP 1)

Here, access to the patient medical record can be understood as a way in which community pharmacists would be able to manage the increasingly complex patient body. As detailed above, the implementation of PGx into community pharmacy creates a more complex and molecularised patient body and Chapter Six noted that in the hospital setting, the bioclinical collective gaze enacted through shared medical records is central to the management of risky secondary care patient bodies. Given this, then, as PGx information reconfigures a more complex and potentially toxic primary care patient body, increased access to medical records is understood as a way through which this can be managed.

A final ‘macro’ challenge in integrating PGx into community pharmacy is identified in the data as being the education of community pharmacists in (pharmaco)genetic principles. In 2003, the Human Genetics Commission (2003) highlighted the need for a ‘genetically literate’ primary care workforce to manage the increasing presence of genetic principles in medical care. In the same year, Burton and Shuttleworth (2003) argued that although pharmacy undergraduates were in receipt of genetic training, the principles of genetics were not prioritised in preregistration training or professional development. Given this, the data suggest that whilst relatively newly trained pharmacists are fairly familiar with genetics, those who have been practising for some years are less knowledgeable in this area;

“My generation of pharmacist are probably not very familiar at all. Now, whether some of the younger ones cover more of this in their undergraduate course; I would imagine that they probably do and so they would probably be a lot more familiar” (CP 2)

“I think you’ll find that the crusty old school members of staff like myself pharmacogenetics is pretty much a mystery” (HP 1)

“The schools of pharmacy now do teach it to some extent and some of them quite a lot but before that there’s a whole two generations of pharmacists who haven’t had much exposure” (MTC 1- also a previous HP and CP)

This creates what we might call a ‘generational knowledge gap’ which might be translated into differences in the quality of care across different pharmacies.

8.13.2 Integrating PGx into Community Pharmacy: ‘Micro’ Challenges

In addition to these ‘macro’ challenges which are presented in the data as relating to the structure of the pharmacy profession as a whole, a number of ‘micro’ challenges are also identified in the data. These micro challenges are characterised as those which may affect the everyday working practices of community pharmacists and, similarly, be resolved within these everyday routines rather than through national initiatives as is the case with the macro challenges outlined above. As such, these micro challenges are highly related to the pharmacy gaze and the medical technocracy of primary care.

To begin with the data present the medical technocracy within which community pharmacy is practised as being central to the demarcation of roles and expertise in PGx. As such, it is imagined that PGx work activities will primarily be undertaken by GPs and the practitioners with whom they are co-located in surgeries. In this way the higher status of GPs can be maintained through the (re)production of practice boundaries around decision-making and responsibility. In other words, PGx is discursively located within clinical decision-making which is the domain of GPs (as the practitioners who diagnose and prescribe) rather than pharmacists;

“I still think it’s probably going to be done more at the GP ends of things” (PS 3)

“The prescriber would have already have taken responsibility for that sort of thing [genetic information] and that level of screening” (CP 1)

“That information would need to be fed back to the GP, if the GP is responsible for prescribing” (PGx 3)

In this way, PGx can be understood as a set of expertise and technologies through which GPs are able to retain their higher status position in primary care. Community Pharmacist 3 suggests that pharmacists undertaking PGx work may be understood as something akin to boundary encroachment;

“It’s their territory ultimately...some of the stumbling is because we are imposing on their territory” (CP 3)

Here, resonances with Serra’s (2010) notion of a medical technocracy can clearly be seen. Serra argues that a medical technocracy is created by the conquering of a set of technologies and expertise by one group of practitioners. In this quote, Community Pharmacist 3 suggests that GPs may conquer PGx products and processes to define PGx as part of their professional role or “*territory*”. In doing so, the medical technocracy in primary care is reproduced.

May and Finch’s (2009) notion of ‘skill-set workability’ also becomes relevant here. They argue that skill-set workability refers to the distribution of a practice within a division of labour. In the case of teledermatology, they note that this practice ‘was appropriate to the skills of nurses administering it’ (p. 545). In the case of PGx in primary care it can be understood that PGx practices are defined in the data as better suited to the diagnostic skill-set of GPs than the dispensing skill-set of pharmacists. In this way, PGx may be more workable in GP work than in pharmacy.

This relates to another micro challenge of contextual integration of PGx in community pharmacy. As detailed in Chapters Two and Six, a key part of the community pharmacy professional identity is the retail aspects of practice. Elsewhere this has been identified as a central part of the ‘incomplete’ professionalisation of community pharmacy because of pharmacists’ motivations being heavily geared towards profit generation rather than altruistic practice (Denzin and Mettlin, 1968). The data suggest that this retail model of community pharmacy organises practice in a relatively corporate way where the focus of work activities centres on income generation from high volumes of dispensed prescriptions and retail activities as the following quotes demonstrate;

“Pharmacy is basically funded on a volume-based model. That is, the more prescriptions you do, the more you get paid” (CP 1)

“With [large multiple pharmacy company] it seemed to be more corporate, more geared towards the retail... it was a lot more target-drive. So part of the bonus structure ... would be around promotion or selling particular products” (CP 4)

Community Pharmacist 4’s quote suggests that the organisation of work in large multiples tends to be more corporate than that in smaller companies or independent pharmacies. As such, in large multiples, pharmacy is often co-located with non-health retail work given that the latter is understood to generate more profit for the company, as Community Pharmacist 10 highlights;

“Your Boots and the like make their money from selling perfume and lipsticks and loo roll rather than pharmacy. So pharmacy’s stuck at the back of the shop with the make-up stands at the front flogging the high profit stuff” (CP 10)

Given this, the data suggest that large multiple pharmacies are unlikely to be interested in adopting PGx;

“A lot of them are employed pharmacists by big organisations and unless it’s more cost-effective than sticking labels on bottles and boxes, their employers won’t let them do it” (PS 2)

“I don’t think some of the large companies have that much interest. They’re more a retailer than a clinical service so unless there’s a massive profit involved in it for them I’m not quite sure what the drivers are for them” (PS 3)

Given that everyday work routines in community pharmacy (particularly large multiples) are organised around retail activities, the integration of PGx processes into these routines presents a significant challenge in the context of the current structure of everyday community pharmacy work. Generally, most

community pharmacies employ one pharmacist and a number of support staff. The data suggest that the “*target-driven*” (CP 4) nature of pharmacy practice in large multiples places pharmacists under significant time pressures. Hence, integrating a new set of PGx products and processes would be challenging;

“The other [challenge] is actually getting physical time to do it because they’re so tied up in the dispensing process that they’re not available to actually do all this stuff” (PS 2)

“It’s not so much a lack of interest but more a lack of time to learn and understand these things” (CP 1)

“It’s not something that at the moment I have time to pay much attention to” (CP 2)

Pharmacy Stakeholder 2 notes that the integration of PGx processes into this retail context may require a new model of practice where two pharmacists are co-located in one pharmacy with one undertaking dispensing work and the other more clinical (including PGx) work;

“If you were to do these kind of services, you really need ideally two pharmacists in a pharmacy; one making sure the dispensing process carries on easily...and the other freed up to do these more clinical services” (PS 2)

This, however, is understood to be a model which would not “*stack up*” (PS 2) in contemporary community pharmacy practice given the high cost of employing pharmacists. Moreover, Community Pharmacist 3 notes that the employment of additional staff would be particularly challenging in independent pharmacies who tend to offer fewer clinical services;

“Overall most of the independent pharmacies tend to stick to just providing the essential services and they’re not quite geared up to providing the advanced and the enhanced services which involves

a lot more training and skills to provide those extra services” (CP 3)

A third challenge of integrating PGx into everyday routines centres on the logistics and ethics of handling PGx information in the community pharmacy setting. On one level, the data suggest that pharmacy IT systems are not equipped to store such personal information;

“Genetic testing... involves a kit of personal data and trying to store all the data on to a system is quite scary and quite frightening” (CP 3)

On another level, the confidentiality of genetic information on a community pharmacy computer is also identified as a potential challenge where Pharmacogeneticist 2 questions *“you’re dealing with DNA so will there be confidentiality there?”*. Given the number of people working within a community pharmacy, the challenge is identified as restricting access to genetic information to pharmacists only;

“I don’t know how it would work with different members of staff. So would different member of staff have difference access?” (CP 4)

“This goes back to this trust thing....they [GPs] don’t trust a terminal could be in a pharmacy and that people aren’t going to be looking over your shoulder and seeing other patients’ and neighbours’ records” (PS 2)

“You would need to ensure that the patient record could only be seen by the pharmacist and potentially the patient” (MTC 1- also a previous HP and CP)

Pharmacy Stakeholder 2’s quote highlights, again, the importance of the medical technocracy in which community pharmacy is practised. Within this, personal (genetic) information which would be contained within the patient medical

records is regarded as being the responsibility of GPs. Moreover, the above quotes highlight the disparity in approaches to multiple clinical gazes between hospital and community settings. As Chapter Six noted, in the hospital setting a narrative of the patient body is developed through multiple and diverse practitioners accessing and contributing to the patient medical record. Through this, it is argued, the patient body becomes subject to what I have called a ‘bioclinical collective gaze’. In contrast to this, Community Pharmacist 4’s quote demonstrates a resistance to this development of a bioclinical collective gaze in the community pharmacy setting.

These concerns about personal (genetic) information in the community pharmacy setting highlight the nature of the contemporary community pharmacy gaze and the potential changes to it brought about by PGx. The current community pharmacy gaze is centred on a non-molecular patient body which is not linked with personal information. As such, practice structures (such as IT systems) do not facilitate the accommodation of such personal information given that this is not central to current practice. As is shown above, PGx may reconfigure the community pharmacy gaze around a more molecularised body which is intrinsically linked with the genetic information found within it. The challenge arises, then, from the integration of molecular information into a non-molecular construction of the patient body which characterises the contemporary community pharmacy gaze.

8.13.3 Discussion: ‘Macro’ and ‘Micro’ Challenges of PGx in Community Pharmacy

This ‘macro’ and ‘micro’ characterisation of the challenges of integrating PGx into community pharmacy practice highlights the ways in which the ‘scope’ of evaluation work shown in Figure 3 is carried out. As such, the different scopes of evaluation highlight the different levels at which challenges occur and will come to be addressed. As mentioned, however, these challenges are not discrete and there are a number of overarching themes which marry the macro and micro challenges. Figure 4 highlights the key themes of finance, expertise and structure in these macro and micro challenges. Moreover, Figure 4 shows the ways in which macro and micro challenges are related to each other through these overarching themes.

As an example, Figure 4 shows the way in which the theme of expertise encompasses a number of primary (block line) and secondary (dotted line) challenges. Here it is shown that the macro challenge of pharmacists' education in the area of PGx and the demarcation of roles in the primary care medical technocracy are the primary challenges of this expertise theme. As such, providing pharmacists with education in the area of PGx is understood as a challenge to be addressed at the professional body level of the pharmacy world, whilst the demarcation of prescribing and dispensing roles based on their differential fields of expertise, is understood as a challenge for everyday practice and individual pharmacists and companies. Figure 4 also shows that the macro challenge of pharmacists' limited access to patient medical records also sits as a secondary challenge in this expertise theme as, as Chapter Six noted, the demarcation of roles in the primary care medical technocracy is enacted through this limitation of access.

The challenge of medical records access is also shown to be a primary challenge presented by the structure of community pharmacy. Also related to this structural theme are the logistics of carrying out tests in the community pharmacy setting and the demarcation of roles in the everyday work of pharmacists. What this demonstrates, then, is that the challenges presented by the implementation of PGx into community pharmacy are complex and far-reaching. Figure 4 shows, then, that the challenges which are manifested and, thus, addressed, at the level of the pharmacy professional as a whole are also linked with those which are manifested at the level of everyday pharmacy practice and the pharmacy gaze. What this shows is that the challenge of implementing PGx into community pharmacy practice is one which is multi-faceted and involves multiple actors across different sectors within (and outside of) the pharmacy profession. Chapter Nine discusses this in more detail.

Scope of evaluation	Macro Challenges	Overarching themes	Micro Challenges
Manifested at...	Organisational/professional level		Everyday practice/ pharmacy gaze level
Addressed by...	DoH, RPS, professional bodies		Companies/ individual pharmacists
Challenges	<u>Remuneration:</u> Who pays for testing? Pharmacy funding Investment in technologies		<u>(Dis)juncture with retail model:</u> Limited autonomy of pharmacists
	<u>Education:</u> Limited knowledge ‘Generational knowledge gap’		<u>Role Demarcation:</u> Pre-prescription vs pre-dispension?
	<u>Quality Assurance:</u> Quantification vs binaried tests		<u>Medical Record Access:</u> Increasing access Limiting access of pharmacist only
	<u>Logistics:</u> Structures for sample collection		<u>Ethics:</u> Confidentiality

Figure 4: Macro and micro challenges of integrating PGx into community pharmacy practice

8.14 Conclusion

In summary, this chapter has built on the dual medicines management model built in Chapters Six and Seven to analyse the implementation of PGx in hospital and community pharmacy. It is argued that there is a distinction to be made between PGx *products* and PGx *processes*. Within this, the former offer affordance within a formalised, bureaucratised medicines management process as beneficial for practice given their ability to predict, and thus manage, non-responsiveness and ADRs. PGx *processes*, on the other hand, are understood at the level of the pharmacy gaze given the work undertaken to include new genetic practises with current work activities.

The chapter presents the implementation of PGx into hospital and community pharmacy as two discrete processes given the different nature of structure, bodies and medications which are practised in these two spheres. It is argued, however, that in both of these sectors, PGx may come to reconfigure the pharmacy gaze around a more molecularised and complex patient body.

In the community setting, the integration of PGx is presented as a complex picture which is highly speculative given the limited impact of PGx on this sector to date. The chapter argues that PGx in community pharmacy is highly related to the medical technocracy in which community pharmacy practice occurs. As such, the most likely model of PGx practice in the community setting is presented as this paradigm being grounded in the work of GPs with pharmacists occupying an adjunct role if (or when) the delivery of PGx in the community setting becomes too challenging for the structure of GP work. Within this, however, the chapter presents a number of potential PGx futures around testing, results interpretation and patient counselling. These are imagined to reconfigure both the pharmacy gaze and the professional identity of pharmacists.

The chapter also presents an analysis of the process of reflexively monitoring and integrating PGx into everyday community pharmacy practice. Here, it is argued in reflexively monitoring PGx in pharmacy practice, four elements become important- the nature, focus, scope and level of evaluations which are shown, in Figure 3, to relate to the communal and individual appraisal processes and the dual

medicines management process. In this way, it is shown that formalised medicines management policies inform formal (nature) evaluations of PGx products (focus) at the macro-level (scope) of the pharmacy world by its professional bodies (level). Concurrently, more negotiated medicines management practice enacted through the pharmacy gaze inform informal (nature) evaluations of PGx processes (focus) at the micro-level (scope) of pharmacy by individual pharmacists in their everyday practice (level). Figure 4 expands on this and explores individual challenges presented by the implementation of PGx into community pharmacy practice and argues that within this, three overarching themes emerge - finance, expertise and structure.

Chapter Nine explores in more detail the complexities highlighted in this chapter vis-a-vis the integration of PGx into pharmacy. This chapter, thus, brings together the empirical work presented in Chapters Six, Seven and Eight to address the key questions and challenges for pharmacy and health policy makers in terms of integrating personalised medicine. In doing so, Chapter Nine questions the value of PGx and locates these questions within wider health policy foci. To conclude, Chapter Nine makes a series of recommendations based on this empirical work.

Chapter Nine: Concluding Discussion

9.1 Introduction

Pharmacists are key actors in the UK healthcare system and a central part of the patient experience of health and illness. With the recent extensions to their professional role into more clinical work activities pharmacy practice has been re-located away from the dispensary onto the shop floor (in the case of community pharmacy) and to the patient bedside (in the case of hospital pharmacy). This has generated new ways in which pharmacists interact with medicines and patients. Despite this, there has been relatively limited sociological attention given to pharmacy practice, particularly in the hospital setting where the high degree of clinical focus and the absence of retail work has not generated the same questions of professional identity, role strain and subordination as in the community setting (see for example, Cooper *et al.*, 2009; Denzin and Mettlin, 1968; Edmunds and Calnan, 2001; Rapport, 2010).

Running concurrently to the recent changes in the work of pharmacists has been the development of the field of PGx, otherwise referred to as ‘personalised’ or ‘stratified’ medicine. This field of practice, which is concerned with genetically-determined drug response variability, was seen as one of the key applications of the data and technologies arising from the HGP although a personalised approach to therapy and practice is shown in Chapter Three to sit within a longer history of medical practice and therapeutics. As such, PGx has been described as potentially ‘making a major impact in commercial labs and in the clinic’ (Webster *et al.*, 2004: 663) and has been identified in UK health policy as important to the future of safe and effective medicines and healthcare services (Department of Health, 2003a).

PGx, then, is concerned with better targeting medicines in order to gain maximum efficacy with minimal adverse events. Given this, PGx is well aligned with the discourses of medicines management (more latterly medicines optimisation) which underpin pharmacy practice and these links between PGx and pharmacy practice have been discussed elsewhere (see Akhtar, 2002; Clemerson *et al.*, 2006). Despite Ryan *et al.*’s (2004) assertion that pharmacy is likely to be at the ‘forefront’

of PGx medicine and, as such, a sociological analysis of this is necessary, little of these papers have characterised the relationship between PGx and pharmacy from an empirically-informed sociological perspective.

As such, this thesis has addressed this gap in the literature by drawing on data from 38 semi-structured interviews with diverse practitioners to examine the potential impacts of PGx on pharmacy practice in sociological terms. Moreover, this thesis has presented a sociological characterisation of *both* community and hospital pharmacy and the similarities between them where previous sociological work on pharmacy has tended to treat these two sectors as wholly separate areas of practice.

This concluding chapter draws together and reflects upon the key contributions of this thesis. In doing so, this discussion reflects on the sociological characterisation of contemporary pharmacy practice presented here and what implications this might have for sociologists examining pharmacy practice in the future. Within this, the dual medicines management framework proposed in Chapter Six and mobilised subsequently in Chapters Seven and Eight is drawn out as a theme intersecting pharmacy practice in both hospital and community settings. This framework is also offered as a model through which the integrating of PGx in pharmacy may be understood. To do this, this chapter revisits Table 10 (see end of Chapter Seven) but expands it to include the particularities of PGx in hospital and community pharmacy. This chapter also reflects on some of the limitations of the current study and concludes by making a number of policy recommendations for integrating PGx into pharmacy.

9.2 Sociological Characterisation of Pharmacy Practice

To begin with, a key contribution of this thesis is the development of an overview of contemporary pharmacy practice in which *both* community and hospital practice are taken into account. In order to effectively analyse the integration of new technologies, specifically PGx, into pharmacy practice, Chapter Six argued that it is vital to present a sociological overview of the contemporary pharmacy ‘world’ into which they may be implemented. Previous sociological work in the area of pharmacy has examined a wider variety of aspects of pharmacy practice, such as pharmacist-

patient interaction (Nguyen, 2006; Pilnick, 1998; Pilnick, 2003), inter-professional communication (Cooper, 1993; Hughes and McCann, 2003) and professional status (Birenbaum, 1982; Denzin and Mettlin, 1968; Edmunds and Calnan, 2001), but these works have tended to treat community and hospital pharmacy as two fairly discrete landscapes owing to the highly divergent structures, work activities, patients and medications which are present in each. As such, studies of pharmacy practice have tended to be concerned with analysing *either* community or hospital practice, which has meant that a sociological overview of the whole field has been neglected.

In contrast to this, this thesis has treated these two sectors of work as, it could be understood, two sides of the same practice coin. As such, it has been argued that whilst the everyday experiences of practising in community and hospital pharmacy settings are divergent, there are a number of elements and approaches which intersect the two sectors and characterise the profession as a whole. It has been argued that whilst community pharmacy practice can be understood in line with Serra's (2010) notion of a 'medical technocracy' given the subordination of pharmacists to GPs, hospital pharmacy practice is more appropriately characterised using Rabeharisoa and Bourret's (2009) notion of a 'bioclinical collective' given the degree of collaboration and multi-disciplinarity in the hospital setting. Further, the thesis has presented the nature of medications and patient bodies which are present within each pharmacy practice setting as being a central difference in structures of everyday practice. In this way, community practice is centred on chronically ill patient bodies to which relatively simple medications are administered whilst hospital practice is focused on acutely ill patient bodies to which complex and more toxic medications are administered.

Despite these differences effective medicines management has been identified as central to practice in both community and hospital pharmacy practice where the management of risk and optimisation of treatment are found in both formalised codified medicines management policies *and* in everyday practice. This is, then, the core framework of the dual medicines management model which is presented in this thesis as characterising *both* community and hospital pharmacy practice.

9.3 Dual Medicines Management Model

This dual medicines management model has been presented here as central to both hospital and community pharmacy practice. It is argued that formalised, codified medicines management practices are enacted alongside more negotiated practices in everyday work and interaction. Within this, formalised medicines management is centred on organisational interests in medicines safety and efficacy and is practised in line with governmental and institutional policies. As such, the optimisation of medicines in this vein is concerned with, for example, the reduction of ADRs and the maximisation of efficacy for the benefit of the hospital or primary care organisation. Concerns around staff resource efficiency and waiting times have been shown here to be central in this organisationally-focused medicines management approach. Running concurrently to this, it has been argued, is a more negotiated practice of medicines management which is enacted in everyday work activities through what has been called here the ‘pharmacy gaze’.

This pharmacy gaze is presented in Chapter Six as being the specific way in which pharmacists, as medications experts, co-construct patients and the medications which are administered to them. It is argued, then, that the ontology of drugs comes into being through its relationship with, and (potential) impacts upon the patient body. As such, medications are made culturally meaningful (in much the same way as Dingwall and Wilson (1995) described) through being constructed as risky and potentially harmful pharmacological agents. Simultaneously, the patient body to which they are administered is also made meaningful through being constructed, and thus ‘gazed’ at, as an at-risk medications using body. Around this co-construction process, then, what has been called here a ‘discourse of toxicity’ is created where medications and the patient bodies to which they are administered are positioned within terms of toxicity which need to be managed by pharmacists whose expertise are in medicines and their associated ‘stuff’ (Barber 2005). In the hospital setting, the patient medical record has been shown to be of central importance to the pharmacy gaze through the emergence of a collaboratively-constructed history, geography and narrative of the patient body (Berg and Bowker, 1997). Here, this has been referred to as the ‘bioclinical collective gaze’, which encapsulates the diversity of practitioner gazes which are recorded in, and mobilised through, the hospital

patient medical record. This importance of the patient medical record is discussed in more detail below.

This novel concept of the pharmacy gaze takes Foucault's notion of the 'clinical gaze' and Barber's (2005) 'pharmaceutical gaze' as its points of departure. Unlike Foucault's clinical gaze, however, the power dynamics between pharmacists and the patient body are not centralised. This is not to say that the power relationships between pharmacists and patients is not of sociological interest but the focus of the research here did not generate an analysis of practitioner power in the pharmacy setting. Perhaps, as is suggested below, such a Foucauldian analysis of these power relations in pharmacy may be forthcoming in future (also see Ryan *et al.*, 2004).

The pharmacy gaze departs from previous work in the area of the sociology of pharmacy as it places the patient body at the centre of the analysis of pharmacy practice. Within this, it is argued that pharmacists cultivate a particular way of looking at, and understanding, the patient body based on their expertise as medications experts. Previous sociological analyses of pharmacy have neglected the patient body as a site through which medications become cultural objects. Dingwall and Wilson's (1995) seminal paper shifted sociological understandings of pharmacy practice to centralise its role in ascribing cultural meanings to inert chemical compounds and, thus, symbolically transforming them into the social objects of drugs. Analyses arising from this cultural understanding of pharmacy practice, however, have failed to take into account that it is through medications' relationship with the patient body that they take on their cultural meanings as, for example 'harmful' or the 'most appropriate'. Similarly, Barber's (2005) Foucauldian notion of the *pharmaceutical* gaze focuses on the ability of pharmacists to 'see' the properties and potential toxicities of medications but does not account for the patient body in which these properties and toxicities are manifested. As such, the pharmacy gaze presented here, emphasises the co-construction of *both* medications and the patient body to which they are administered. A central tenet of the pharmacy gaze perspective, then, is that medicines management practices cannot be fully analysed without an analysis of the patient body to which medications are administered and within which the effects (both harmful and otherwise) are manifested.

As well as offering a framework within which to analyse contemporary pharmacy practice in community and hospital settings, the dual medicines management model provided an analytical tool for examining the definition and integration of new technologies in pharmacy practice.

9.4 Dual Medicines Management and New Technologies

Chapters Seven and Eight demonstrated that the dual medicines management model posited in Chapter Six is useful for understanding the ways in which new technologies and PGx specifically, are defined and integrated into pharmacy practice across different settings. Some components of May and Finch's (2009) NPT, which focuses on the micro-level interactional work undertaken to integrate new innovations into routine practice, were also shown to be important. Within this, the process of defining new innovations through May and Finch's (2009) notion of 'coherence' work was shown to be highly related to the dual medicines management model where new innovations are defined through both aspects of the medicines management model- formalised, codified policies and more negotiated everyday practice enacted through the pharmacy gaze. Through exemplifying a number of recent innovations in community and hospital practice (mAbs, pharmacy robotics, electronic patient records, pharmacy computers for labelling practices and testing and monitoring devices), it was argued that defining new innovations in hospital settings focuses heavily on the organisational interests in medicines management whilst innovations in community practice are more readily defined through their application to more negotiated medicines management processes through the pharmacy gaze.

May and Finch's (2009) notion of 'reflexive monitoring' has also been shown to be useful for understanding the ways in which pharmacists undertake evaluative work through both formalised, communal appraisal processes and more negotiated individual appraisal processes. Table 10 in Chapter Seven demonstrated the ways in which these communal and individual reflexive monitoring processes map onto the dual medicines management model where communal appraisal is carried out in line with formalised, codified medicines management and individual

appraisal is carried out through everyday practice and the constructs of the pharmacy gaze and the discourse of toxicity.

In addition to these more general technologies in pharmacy, the thesis also employed the dual medicines management model and some elements of May and Finch's NPT to analyse the particularities of PGx in pharmacy.

9.5 PGx and Pharmacy

PGx has been subject to some sociological commentary around the implications it might have for doctor-patient relationships (Lehtinen and Kääriäinen, 2005; Pilnick, 2002; Pilnick, 2004), implications for family and kin (Cox and McKellin, 1999; McLaughlin and Clavering, 2011; Weiner, 2011) and racialised medicine and research (Ellison *et al.*, 2008; Smart *et al.*, 2006; Smart *et al.*, 2008; Tutton, 2004; Tutton, 2007b; Tutton *et al.*, 2008). However, no sociological work has focused on the potential implications of PGx on pharmacy practice in hospital and community settings, despite being identified by Ryan *et al.* (2004) as sociologically important.

When analysing the integration of PGx into hospital and community pharmacy practice, the dual medicines management model, once again, has been shown to be of central importance. Also of note is the disparity between the process of integrating PGx into hospital and community pharmacy. Here, then, the differences between the patient bodies and medications which are central features of practice in these two settings become apparent. Thus, the chronically ill patient bodies to which community pharmacists dispense relative simple, low toxicity medications and the acutely ill patient bodies to which hospital pharmacists dispense fairly complex, high toxicity medications construct different 'stories' around the understanding and integration of PGx. Nonetheless, the principles of the dual medicines management model and May and Finch's (2009) NPT can still be seen as intersecting the PGx story in both pharmacy settings.

9.5.1 PGx and Hospital Pharmacy

Chapter Eight demonstrated that hospital pharmacists are relatively knowledgeable about PGx. This is understood to be, partly, due to the co-located and collaborative

nature of the bioclinical collective structure of hospital pharmacy practice where the transfer and sharing of knowledge around PGx principles is easier than in the community setting. Despite this fairly high level of knowledge, PGx is not currently a routine part of *all* hospital pharmacists' routine work activities. It is shown, however, that a PGx approach is increasingly 'normalised' within Oncology practice. That is to say that the molecularisation of the patient body and the medications which are administered to treat it is something of a normalised 'style of thought' (Fleck, 1973) in Oncology practice. It is argued that this is due to the nature and toxicity of patient bodies and medications which characterise Oncology practice. Within this, then, the cancer patient body is understood as particularly complex and the high toxicity medications which are used to treat it are constructed as particularly risky. Hence, cancer patient bodies and medications are understood to require careful management through the bioclinical collective gaze (most commonly enacted through Oncology multi-disciplinary teams). One way in which this careful management is enacted is through the molecular construction of the body and its medications through, for example, molecular diagnostic and PGx testing. It has been argued that in doing this, the cancer patient body is constituted in algorithmic terms as a series of criteria which feed into prescription decisions.

The PGx 'story' in hospital practice is understood to universally begin with its integration in Oncology and subsequent adoption in other fields with relatively high toxicity medications. In this way, PGx products in the hospital setting are defined through formalised, codified medicines management policies as a way in which the time and financial burden of ADRs could be reduced by reducing the number of patients being admitted to hospital due to ADRs or experiencing ADRs during their stay. Hence, the 'promises' (Hedgecoe and Martin, 2003) created around PGx artefacts (testing devices and their outputs) are argued in Chapter Eight to align with the organisational interests in reducing ADRs and it is through these terms that PGx is defined as useful for hospital practice.

Running concurrently to this formalised, organisational definition of PGx products is the coherence of PGx processes at the more negotiated level of everyday practice enacted through the pharmacy gaze. Here, there is an important distinction between PGx products and processes (Damanpour, 1996). Based on the findings

from the empirical data, it has been proposed that there is a distinction between PGx products and PGx processes where the former are cohered and integrated at the level of organisational, formalised medicines management whilst the latter affect the organisation of everyday practice and the pharmacy gaze. Hence, PGx processes refer to the shifts in everyday practice necessary to accommodate PGx testing and data. Chapter Eight demonstrated that PGx testing reorganises pharmacy work around a new set of artefacts which configure an increasingly molecularised patient body. Within this, the hospital pharmacy gaze and the discourse of toxicity which it generates are reconfigured around a more molecularised patient body where the discourse of toxicity is reconstructed around increasingly molecular information. It was argued that this also reconstitutes the patient body and its relationship with risk and ADRs. As such, whilst the pharmacy gaze generally constructs the patient body as an at-risk subject within which ADRs are generated by the risky object of medicines, what might be called a ‘pharmacogenetics gaze’ constitutes the body (owing to its genetic composition) as a risky object, itself generating risk and toxicity. In other words, through PGx testing and this ‘pharmacogenetics gaze’, the body is shifted away from its being understood as an inactive subject within which ADRs occur and is, instead, understood as an active biological object whose genetic composition can contribute to adverse events. In managing this, it was argued that PGx testing constructs the body in algorithmic terms where prescription decisions are made based on a set of criteria through which the body and medications are made meaningful.

It has been shown throughout this thesis that PGx has made relatively limited impact outside of hospital practice due to the comparatively low toxicity medications and unproblematic ADRs in primary care. Nonetheless, as well as the importance of genetics in primary care drug ADRs (Grice *et al.*, 2006) and the centrality of PGx to Warfarin (Wadelius and Pirmohamed, 2006), the (potential) integration of PGx into community pharmacy is both clinically and sociologically interesting.

9.5.2 PGx and Community Pharmacy

In the community setting it was argued that there is a limited degree of knowledge about PGx amongst practitioners given the medical technocratic and isolated

structure of practice which means that the transfer and sharing of knowledge is less easy than in the hospital setting. Given this, Chapter Eight presented what has been called here an ‘early days discourse’ which generates a number of highly speculative scenarios for ‘pharmacogenetic futures’ in community pharmacy practice. These scenarios were presented as being enacted as part of community pharmacy’s adjunct PGx role where pharmacists were imagined to begin taking on PGx activities once the provision of this service within general medical practice becomes too challenging. In this way, the future integrating of PGx in pharmacy practice was argued to be analogous to the provision of flu vaccinations by community pharmacists. Moreover, this adjunct role was presented as a way in which the medical technocracy within which GPs are the dominant primary care practitioners is reproduced through PGx practices.

The data suggested that the most pervasive imagined ‘pharmacogenetic futures’ were around testing services, patient counselling and practitioner and patient education. Within this, the extended clinical role of community pharmacists was argued to be central to their ability to deliver testing and counselling services whilst their position as medications experts places them in a key position to deliver practitioner and patient education in the area of PGx. These futures, however, suggested something of a universal integration of PGx across all community pharmacy settings whereas much of the data presented PGx as being part of a specialist community pharmacy practice.

In a similar way to the hospital setting, PGx is argued to reconfigure the community pharmacy gaze and the discourse of toxicity around an increasingly algorithmic and molecular construction of the patient body and medications. However, a key difference identified between the reconfiguration of the pharmacy gaze in the hospital and community settings is the impact that PGx may have on the professional identity of pharmacists. In the case of community practice, then, it was argued that PGx has the capacity to shift the professional identity of community pharmacists away from that of ‘shopkeeper’ (Masongo, 2005) to one based on a more technoscientific (Pickstone, 2000) way of knowing the patient body.

9.5.3 Reflexive Monitoring and Integration in Pharmacy

May and Finch's (2009) notion of 'reflexive monitoring' has been employed as a useful reference point within this thesis in capturing the process of evaluating PGx in pharmacy at both levels of the dual medicines management model. As such, May and Finch's (2009) 'communal appraisal' has been argued to be related to formalised, codified medicines management policies whilst 'individual appraisal' has been shown to be carried out at the more negotiated level of everyday practice enacted through the pharmacy gaze. Once again, the divergence between PGx products and processes was shown to be important. Here, communal appraisal of PGx products was argued to take place through national activities and networks, such as the Cancer Network and clinical trials, within which whether and how PGx products are useful for everyday practice are evaluated. It was argued that following this communal appraisal work at the national level, micro-level interactional work becomes concerned with PGx processes and the reorganisation of everyday practice around them. It is argued here that the outcomes from this communal and individual appraisal determine whether PGx products and processes become normalised or not. Here, then, links can be drawn with Hedgecoe's (2008a) clinical usefulness model where PGx is appraised as useful and becomes a part of routine practice in some sectors (for example, HER2 testing in Oncology) but not others (for example, APOE4 testing for Tacrine therapy).

In the hospital setting, the evaluative work around PGx was presented as being highly related to the national evaluative work. As such, PGx products which are deemed to be appropriate for treatment were argued to then be implemented into hospital practice in a relative top-down manner. In the community setting, this evaluative work was argued to be more challenging given the limited impact that PGx has made on pharmacy outside of secondary care. The reflexive monitoring work was argued to be centred on the challenges that integrating PGx into routine community pharmacy practice may present in the future. Here, there were argued to be two 'scopes' to these challenges; one focusing on 'macro-level' challenges to be addressed by organisational and policy bodies such as the RPS and Department of Health and one focusing on the 'micro-level' challenges which affect everyday

working practices and are, as such, to be addressed in everyday structures rather than by national and organisational bodies.

The macro-level challenges that have been identified here are centred on four key issues; the quality assurance of PGx tests, the financing of PGx testing in community, the logistics of delivering PGx services in the community and the educational of community pharmacists. Within this, the development of cost-effective, robust PGx tests which can easily be carried out in the community setting have been shown to be of central importance. In addition, the structure of community pharmacy within which pre-prescription work are fairly rigidly demarcated as the role of GPs, rather than pharmacists, may limit the extent to which pharmacists are able to claim legitimate involvement in PGx practices. The education of pharmacists in genetic principles is returned to below. The micro-level challenges, similarly, are highlighted as centring on four key issues; the place of PGx with the retail model of community pharmacy, the positioning of PGx services within the role demarcation within the primary care medical technocracy, community pharmacists' limited access to medical records and the ethical challenges of handling confidential patient formation within the community pharmacy setting. Here, increased collaboration between GPs and pharmacists and increased autonomy of community pharmacists within retail settings are understood as central. These, again, are returned to below in considering recommendations from this thesis.

What the analysis of integrating PGx in to both hospital and community pharmacy shows is that the themes identified at the end of Chapter Seven vis-a-vis other pharmacy technologies once again become important. Hence, the relationship between the sector of pharmacy and the scope of a technology, formalised medicines management policies and everyday practice enacted through the pharmacy gaze are central to understanding the integration of PGx in pharmacy. As such, Table 11 extends that presented at the end of Chapter Seven as a way to understand other technologies in practice, highlighting the ways in which PGx maps on to the dual medicines management model.

In the hospital setting, then, it is shown that the scope of PGx is centred on acutely ill, complex patient bodies and the high toxicity medications which are used

to treat them. Within formalised, codified medicines management processes, PGx is operationalised as a way in which the burden of ADRs is reduced through medications' decreased capacity for toxicity. In this way, patients' experiences of their medications are improved. At the level of everyday practice and the more negotiated medicines management practices enacted through the pharmacy gaze, PGx is understood as configuring a more molecularised patient body through algorithmic prescription decisions. This is understood to make fairly complex hospital medications meaningful by better targeting them to patients' individual profiles and needs and, thus, improving their experiences of their medications regimes.

In the community setting, the scope of PGx is related to the chronically ill bodies and relatively low toxicity medications which characterise this sector of practice. It has been argued throughout this thesis that this is the key reason for the lack of impact of PGx on community practice. Within this sector, PGx is operationalised within formalised, codified medicines management policies as being a way through which toxicity and the burden of ADRs can be reduced and patient adherence to medications regimes can be increased. At the level of more negotiated practice and the pharmacy gaze, PGx in the community setting is positioned as a way in which the patient body can become constructed in more molecular terms where risk is, as in the community setting, managed through an algorithmic construction of the body and its medications. Pharmacists are positioned within this as potentially occupying an adjunct role where PGx practice is undertaken when the structure of general medical practice is placed under strain by the requirements of PGx. This, it has been argued, may shift the professional identity of community pharmacists to more technoscientific practitioners (Pickstone, 2000) but has also identified as presenting a number of macro- and micro-level challenges as highlighted above.

Technology	Relationship between pharmacy sector and technology scope	Formalised Bureaucratic Process	Everyday Practices (Enacted Through the Pharmacy Gaze)
Pharmacy robotics	Sector: Hospital pharmacy Scope: Large pharmacy departments; high stock levels; high patient numbers; complex regimen; high toxicity medications	-Reduces dispensing errors -Improves pharmacy efficiency -Enables clinical practice; time on wards	-Capacity for human error -Increases pharmacists ‘legitimacy’ within the bioclinical collective (Barrett, 2011)
Monoclonal antibodies	Sector: Hospital pharmacy Scope: Acutely ill bodies; high toxicity medications; targeted therapies	-Decreased capacity for toxicity -Reduce burden of ADRs -Improve patient medication experience -Administration outside of the hospital: reduces cost	-Oncology patients; complex bodies -Molecularised gaze and therapies -Administration outside of the hospital: places medicines in the ‘lifeworld’
Electronic patient record	Sector: Hospital pharmacy Scope; Bioclinical collective gazes; complex illness; complex regimen; high toxicity medications	-Improves audit processes -Improves medicines management	-Removes pharmacists from “ <i>traffic warden duties</i> ” (HP6) -Brings the patient body into being -Constructs of a discourse of toxicity around the patient body
Pharmacy computer- labelling practices	Sector: Hospital and community pharmacy Scope: Complex regimen (H); high toxicity medications (H); chronically ill bodies (C)	-Improves audit processes -Improves patient adherence: reduces toxicity	-Symbolic transformation of medicines into social objects -Places medicines in the ‘lifeworld’ -Shifts GP/pharmacist communications

Testing and monitoring devices	Sector: Community pharmacy Scope: Chronically ill bodies; low risk medications; public health ` focus;	-Improves public health -Reconfigures pharmacists as public health professionals	-Constructs a collective public health body -Brings the patient body into being -Moves practice away from the dispensary
PGx	Sector: Hospital pharmacy Scope: Acutely ill bodies; high toxicity medications; targeted therapies	-Reduce burden of ADRs -Decreased likelihood of toxicity -Improve patient medication experience	-Molecularised gaze/body -Algorithmic prescription decisions -Improve patient experiences of complex medications: makes medicines meaningful
PGx	Sector: Community pharmacy Scope: Chronically ill bodies; low risk medications; explains lack of PGx impact	-Reduce burden of ADRs -Improve patient medication experience -Improves adherence	-Molecularised gaze/patient body -Adjunct PGx role -Shifts professional identity -Macro and micro challenges

Table 11:PGx technologies in the dual medicines management model

9.6 Implications for Future Research

Limited sociological research exists in the area of pharmacy practice and whilst there is a wealth of sociological reflections on PGx, none of this has empirically examined the position of pharmacy within the PGx story (Ryan *et al.*, 2004). As such, this thesis has made a novel contribution to these fields by empirically examining the potential impacts of PGx on pharmacy practice in both community and hospital settings. There are, within this thesis, a number of themes which have been highlighted which may be important in future sociological examinations of pharmacy and/or PGx.

9.6.1 Centring the Patient Body

As mentioned, this thesis has presented something of a novel contribution to sociological understandings of both pharmacy and PGx by centralising the body. In the case of the former, although the body is a central part of pharmacy practice given that it is within the patient body that medications have their effects the patient body has been conspicuously absent from sociological examinations of pharmacy practice. This thesis has demonstrated, however, that the body is of central importance to pharmacists' medicines management role and is increasingly present through the clinical activities which characterise contemporary pharmacy practice, particularly in the community setting. Future sociological studies of pharmacy practice, and medications or clinical work within it, then, may benefit from an analysis of the constitution of the patient body within pharmacy practice and its technologies (this is echoed by Ryan *et al.*, 2004). For example, Patrakaki *et al.*'s (2012) study of EPS in community pharmacy is beneficial in terms of understanding the ways in which this technology reconfigures the boundaries of community pharmacy practice but the patient body which is documented within EPS is markedly absent (see Berg and Bowke, 1997). This is in contrast to the findings presented here which suggested that the patient medical record, and particularly the collaboratively constructed one, is of central importance in configuring a risky and potentially toxic patient body in need of expert management.

Within this thesis, the pharmacy gaze has been presented as a key way in which pharmacists construct and manage the patient body. Further work examining the relationship between the pharmacy gaze and the everyday work of pharmacists and other healthcare practitioners would be useful to question whether the pharmacy gaze is a way of knowing the patient body which is limited to pharmacists or whether the pharmacy gaze can be produced and mobilised by other healthcare practitioners in their professional interactions with the patient body. Within this thesis, the pharmacy gaze is highly linked with the act of dispensing medicines but further work into the nature of the pharmacy gaze examining its potential use during prescribing practices would be useful.

In the case of PGx, Chapter Three demonstrated that whilst a racialised body has been tacitly present in previous analyses of the ethical and social implications of PGx, the body is largely absent from analyses of PGx. This thesis has shown, however, that PGx has the potential to alter the construction of the body in everyday clinical practice by configuring it, and its toxicities, at a more molecular level. Here, the thesis has touched upon the notion of a 'pharmacogenetics gaze' which encapsulates the ways in which PGx (re)constructs patient bodies in molecular, algorithmic terms which may be applied to the principles of biomedicalisation posited by Clarke *et al.* (2003). The application of this principle would, perhaps, be of value in future sociological examinations of PGx in clinical practice.

9.6.2 Algorithmic Bodies

Central to this pharmacogenetics gaze is the (re)constitution of the patient body through the outputs from PGx tests. Chapters Seven and Eight demonstrated that new technologies in pharmacy increasingly characterise the patient body in algorithmic terms where prescription decisions are made based on series of criteria and features of the patient body which determine the most or least suitable therapies. It has been argued here that PGx represents an additional set of information through which patient bodies are molecularised and constituted in algorithmic terms within which prescription decisions can be made. Elsewhere, algorithms have been argued to be central to the increasingly digital nature of contemporary society (see Beer, 2009). Despite this, there has been limited sociological work examining the role and

position of clinical algorithms in prescription decisions, medicines management and the construction of patient bodies. Given the recent sociological interest in digital algorithms and their impacts on society, it seems timely for a focus on algorithms within the Sociology of Health and Illness and STS.

Within this, a revisiting of the social life of patient medical records also seems imperative. It has been shown throughout the thesis that patient medical records, and community pharmacists' lack of access to them, are central features in organising everyday clinical work and expertise. It has been argued that the medical technocracy which characterises primary care practice is, in part, reproduced through the limitation of pharmacists' access to patient medical records and, thus, the demarcation of roles and expertise. In the bioclinical collective structure of hospital practice it has been argued that patient medical records represent the key way in which what has been called here the 'bioclinical collective gaze' is enacted through the collation and mobilisation of numerous practitioner gazes within one documentary space. As such, the patient medical record represents a sociologically interesting feature of contemporary medical practice which would benefit from analysis. Moreover, in the case of pharmacy specifically, a discussion of medical records which extends beyond the practice disadvantages brought about by limited community pharmacist access would be beneficial. As such, the implications of medical record access (in the case of hospital pharmacy) and limitation (in the case of community pharmacy) present interesting insights into professional status and role demarcation issues which have not been extensively sociologically analysed previously.

9.6.3 Focusing on Power

This thesis takes Foucault's notion of the clinical gaze as one of its points of departure for understanding the sociality of the patient body within pharmacy and PGx practice. Chapter Four noted that Foucault's concept of the clinical gaze is centred on the ways in which discourses and practice constitute patient bodies within increasingly medicalised (Lupton 1997) and biomedicalised (Clarke *et al.*, 2003) societies. Central to Foucauldian analyses of clinical practice is the notion of power where the clinical gaze is understood as a manifestation of disciplinary power in

which patient bodies are defined through expertise against an established 'norm'. Despite mobilising the concept of a practitioner gaze, this thesis has not centralised power as a key theme in pharmacists' practice or relationship with the patient body. There are a number of reasons for this including (i) power dynamics not being an obvious theme emerging from the data, (ii) the bottom-up thematic analysis not specifically looking for issues of power and (iii) interviews with practitioners not being the best method through which the theme of practitioner-patient power would become clear. In other words, the perspectives of practitioners alone (rather than those of patients as well) do not readily provide insights into the power aspects of pharmacy-patient interactions whilst the application of a bottom-up analytical approach means that power as a specific aspect of pharmacy practice was not being focused on or found to be pervasive in the data. This absence of the notion of power might be considered to be a limitation of the thesis given that much sociological work in the area of the body has highlighted power as a key feature of practitioner-patient relationships (see Pilnick and Dingwall, 2011). However, the novel concept of the pharmacy gaze proposed within this thesis provides a potential framework within which future sociological studies of pharmacy may understand pharmacist-practitioner power through the constitution of the patient body (also see Ryan *et al.*, 2004).

9.6.4 Optimisation Discourses

Chapter Two noted that the discourse of 'medicines optimisation' is beginning to characterise contemporary pharmacy practice following its introduction in a 2010 Department of Health White Paper. This optimisation discourse is sociologically interesting as it centres the patient in medicines decisions and medicines management processes where patients are (re)positioned as decisions makers. This optimisation discourse can, then, be seen as resonating with the dual medicines management model that has been discussed within this thesis where what has been called here patients' 'extracorporeal space' (Armstrong 1997) and 'lifeworlds' (Cribb *et al.* 2011) are highlighted as important factors in constructing medicines as culturally meaningful objects and managing their effective administration, particularly in the community setting. This thesis has not mobilised the discourse of medicines optimisation as fully as perhaps it might owing to the time of publication

of the White Paper. Nonetheless, the principles of medicines optimisation appear to be of central importance and would benefit from further sociological investigation.

Here, then, the positioning of patients as decisions makers and experts in their own medicines management processes would appear to speak to socio-cultural issues such as family, gender, age and race where these socio-cultural issues may be central to medicines management and adherence. A methodological approach involving gathering the perspectives of patients would seem to be of particular value here.

9.6.5 Industry, Primary Care and Academic Pharmacists

As mentioned in Chapter One and above, there is relatively limited sociological attention given to hospital pharmacy and even less providing an overview of the sociological issues intersecting *both* hospital and community pharmacy. Much less attention, however, is given to pharmacists working outside of these two practice sectors with pharmacists working in industry, primary care and academia being given almost entirely overlooked. Chapter One highlighted that 4.1%, 7.2% and 2.8% of active pharmacists worked in industry, primary care and academia respectively meaning that a significant portion of pharmacists are currently employed outside of the two sectors which have received the most sociological attention. These sectors of practice, however, potentially raise some interesting sociological questions.

Particularly with regards to industrial pharmacists, there are questions here around the role of pharmacists engaging in drug production processes where in community and hospital practice this production role is imagined to have almost entirely disappeared. The location of pharmacists within industry also raises questions about the construction of toxicity through a pharmacy gaze at the 'lab bench' rather than at the 'patient bedside'. In the case of primary care pharmacists, the medical technocracy which has been argued here to typify the majority of pharmacy work in the community setting may be tested where the co-location of GPs and community pharmacists (along with, potentially, other healthcare practitioners) may produce something more akin to a hospital bioclinical collective. Moreover, this

co-location also raises questions about the use of space. Whilst previously the community pharmacy space has been represented as being a retail space, its co-location with other healthcare practices may undermine, or reinforce, this representation of the community pharmacy space.

9.7 Recommendations

There are a number of key professional and policy issues which have emerged from this thesis. These issues have been briefly analysed within the empirical chapters in this thesis but, nonetheless, also form the basis of a number of recommendations for the consideration of pharmacy and health stakeholders and policy makers.

9.7.1 Cost-effective Testing

It was shown in Chapter Three that PGx in clinical practice represents a way in which medications can be better targeted to patients in order to improve their experiences of their medications regimen and reduce the time and financial burden of ADRs and non-responsiveness for the NHS. This, however, relies on the production of cost-effective tests where the cost of testing is not more expensive than the cost of treating ADRs or employing a trial-and-error model. It has been argued throughout the thesis that this is the key reason behind the lack of integration of PGx in primary care where medications are relative cheap, ADRs are fairly unproblematic and, as such, the cost of pre-prescription testing outweighs the costs of employing a trial-and-error model and dealing with the ADRs which may emerge from it.

The successful integration of a PGx test into routine practice, particularly in primary care, appears, then, to hinge on the development of cost-effective tests which offer a relative advantage in terms of medications targeting. This issue of cost-effectiveness has been, moreover, demonstrated to be particularly pervasive given the decreasing cost of genotyping technologies. As such, it can be recommended that policy makers engage with cost-effectiveness analyses of PGx technologies whilst funding policies focusing on the production of cost-effective PGx testing, particularly for primary drugs, might be timely and beneficial for the contemporary focus on medicines optimisation.

9.7.2 Pharmacy Funding

Also related to this issue of cost effectiveness is the issue of pharmacy funding which was identified in Chapter Eight as being a potential challenge to the implementation of innovative practices within community pharmacy. Here it was shown that because community pharmacy funding is decided annually by the Department of Health and Pharmaceutical Services Negotiating Committee, pharmacists are relatively reluctant to engage with innovative technologies or practices, given their funding status is fairly precarious. It is recommended that this annual negotiation of community pharmacy funding is addressed by health and pharmacy policy makers. As such, it could be suggested that a shift to a longer term funding period may encourage more innovation in community pharmacy and, in the light of the research focus here, be central to the securing of a central role for community pharmacists in PGx practices. It is recommended, then, that shifting pharmacy funding terms to two or three years may be beneficial for both practitioners (in terms of providing more occupational stability and opportunities to engage with long-term projects and innovations) and patients (in potentially providing more innovative practices and clinical services which may, in fact, shift community pharmacies to ‘community-based healthy living centres’ in tune with the Department of Health (Department of Health, 2008: 118)).

9.7.3 Increased Community Collaboration

Chapter Six demonstrated that the structure of primary care practice makes it something akin to Serra’s (2010) ‘medical technocracy’ whilst the collaborative structure in hospital settings was characterised in line with Rabearisoa and Bourret’s (2009) notion of a ‘bioclinical collective’. It has been argued throughout the thesis that the medical technocratic structure of community practice quite rigidly demarcates roles and places pharmacists within a subordinate position in relation to GPs. Throughout the empirical chapters it has been argued that this hierarchical structure is not beneficial for patients given the limited degree of communication and collaboration between different primary care practitioners. As such, pharmacists checking and querying prescriptions is somewhat challenging, which Cooper *et al.* (2009) argue may lead to ethically problematic practices in pharmacy. It is recommended then, that, increased collaboration between GPs and community

pharmacists ought to be addressed. There are a number of ways in which this can be undertaken such as widening the opportunities for GPs to learn about the role and expertise of pharmacists. This could be encouraged early on in the medical career trajectory with GPs and pharmacists being co-educated. In addition, monitoring and chronic illness projects which GPs frequently undertake might benefit from pharmacists' involvement. Here pharmacists may bring a new set of expertise to these projects and, thus, may contribute to improving outcomes. This, once again, can be seen as sitting within the contemporary medicines optimisation discourse of pharmacy.

In increasing communication and collaboration between GPs and pharmacists, the medical technocratic structure which currently typifies primary care practice may be eroded and replaced with something more in line with the bioclinical collective structure of hospital work.

9.7.4 Medical Records

It has been presented here that patient medical records are central to the construction of the divergent practice structures within hospital and community pharmacy practice. Hence, it has been argued that whilst the extension of medical record access to a diversity of hospital practitioners creates a 'bioclinical collective gaze' through which the patient body is documented and managed, community pharmacists' lack of medical record access is central to the rigid demarcation of roles and work within the hierarchical medical technocracy of community practice. In the community setting, the restriction of access to patient medical records is understood as limiting the capacity of pharmacists to counsel patients and as reproducing pharmacists' subordinate positioning. As such, the extent to which community pharmacists are able to fully engage with medicines management and, more recently, optimisation, practices is questionable. Given this, it is recommended that this issue of pharmacists' access to patient medical records is revisited. Chapter Eight noted that although the availability of patient medical records in community pharmacy settings presents numerous logistical and ethical challenges, one potential solution may be the implementation of restricted records containing relevant disease and medications history but not personal or sensitive details. This examination of access to patient

medical records also seems timely given the contemporary focus on collaborative decision making (Cribb *et al.* 2011) and medicines optimisation.

9.7.5 Education

The adequate education of pharmacists in PGx principles is highlighted in Chapter Eight as being a significant challenge for the integration of PGx into community pharmacy practice. The necessity of a genetic literacy amongst practitioners has been identified elsewhere (Human Genetics Commission, 2003) and, in the case of pharmacy, this was partly addressed by the establishment of the NGEDC in 2007 where the education of pharmacists in genetic principles is a specific focus. However, the data that has been presented here suggests that there is still a lack of knowledge about genetic medicine amongst pharmacists, particularly those who have been practising for a number of years (also see Burton and Shuttleworth, 2003). It seems timely, then, for the pharmacy profession to examine the provision of genetics education as part of both undergraduate curricula and professional development programmes. Given that PGx is understood as presenting the ‘next challenge’ (Clemerson *et al.*, 2006) for pharmacy practice, it seems imperative that an in-depth evaluation of the education provision and educational needs of pharmacists in this area is undertaken.

Appendices

Dear [Participant's Name]

I am writing to you to see whether I might be able to arrange to see you at a date convenient to you sometime over the next few months. I am undertaking a research project funded by the Pharmacy Practice Research Trust and the Economic and Social Research Council that explores the potential impact and implications of pharmacogenetics on hospital and community based pharmacy (see attached document).

I am keen to interview people working in the field of [participant's job role]. This involves conducting interviews with [participant's job role] in order to build a comprehensive understanding of the perspectives of [participant's job role] as [state why the participant has been approached]. As a participant in this field, I am keen to talk with you about your professional practice and would be very grateful if you could spare the time to meet with me at your earliest convenience.

In addition, it would be helpful for the project if you could indicate whether there are any of your colleagues who it may be relevant for me to talk to.

I am available [state dates of availability].

If you could let me know if you are able to meet with me, I will then get back to you to firm up a date. The meeting would only take about an hour.

Best wishes,

Kimberly Jamie

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Pharmacogenetics and the Pharmacy Profession: Project Summary

This doctoral research project is funded by the Economic and Social Research Council (ESRC) and the Pharmacy Practice Research Trust (PPRT), based at the Royal Pharmaceutical Society. It focuses on pharmacogenetic technology (PGx) and its relationship with, and potential impacts upon, the pharmacy profession in England at a time when this profession is experiencing major changes in relation to support and management of prescribed medicines and a move towards independent and supplementary prescribing by pharmacists themselves.

Running concurrently to these changes in the pharmacy profession is the development of PGx, which has the potential to revolutionise how medications are produced and prescribed and reduce the financial burden of adverse drug reactions (ADRs). The uptake of this technology is likely to create greater demands on pharmacists that will require new working practices. Hence, this doctoral thesis will understand how the changing professional role of the pharmacists in hospital and community settings is likely to affect the uptake of PGx and, within this, what might be the specific implications of PGx, as one of the more significant diagnostic tests, for pharmacists working in various sectors.

In line with the University of York's and NHS ethical guidelines, the data from this interview will be treated confidentially with your name and details being anonymised so that the responses can not be traced back to you. In addition, you are free to withdraw your participation in the study at any time and are free to refuse to answer any question during the interview itself.

Please do not hesitate to contact me using the details above if you have any questions.

Kimberly Jamie

Dear [Participant's Name],

Please refer to the e-mail below, which was sent on [date of first e-mail]

I am keen to talk with you about your role as [participant's job role] and I hope you are able to find the time to talk with me over the coming months. So far, I have secured interviews with a number of other [participant's job role], and it would be great to have your input as well in order to build a fully comprehensive picture of the perspectives of professionals in your field.

Just to remind you, the project is funded by the Economic and Social Research Council and Pharmacy Practice Research Trust and is being conducted within the University of York's Science and Technology Studies Unit, under the supervision of Professor Andrew Webster who is the director of this research unit.

An interview with yourself (or one of your colleagues) would only take around one hour.

Please do not hesitate to get in contact with me if you have any questions or queries or to arrange a convenient interview time.

Best wishes,

Kimberly Jamie

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Science and Technology Studies Unit
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YO10 5DD

T: 01904 432 632

E: kj518@york.ac.uk

Dear [Participant's Name],

Thank you again for agreeing to take part in my doctoral study on pharmacogenetics and the pharmacy profession.

I am contacting you ahead of our meeting as part of the standard social science research ethical procedure. I have attached for your information a Participant Information document, which gives details of the study and the steps being taken to ensure the research is done to the highest ethical standards, and a Consent Form.

At this stage, you do not need to do anything with these documents; I am sending them to you at this stage for your information only and I will bring a copy of both to the meeting where I will ask you to sign the Consent Form after you have read through the Participant Information document and asked any questions that you might have. If you have a chance to read through this before our meeting, please do not hesitate to get in contact with any questions or queries you may have.

Looking forward to meeting you on [date of interview] at [time of interview].

With best wishes,

Kimberly Jamie

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PARTICIPANT INFORMATION



Pharmacogenetics and the Pharmacy Profession in England

You have been approached to take part in a doctoral research project focusing on pharmacogenetic technology (PGx) and the pharmacy profession in England. Before you consent to taking part, more information about the project, its funding body and projected outcomes are included in this information document. Please ask if there is anything which is unclear or you require any further clarification.

Purpose of the Study

The aim of this doctoral research project is to investigate how the implementation of pharmacogenetic technology will affect the job role of pharmacists at a time when this profession is experiencing major changes in relation to support and management of prescribed medicines and a move towards independent and supplementary prescribing by pharmacists themselves.

Running concurrently to these changes in the pharmacy profession is the development of PGx, which has the potential to revolutionise how medications are produced and prescribed and reduce the financial burden of adverse drug reactions (ADRs). The uptake of this technology is likely to create greater demands on pharmacists that will require new working practices.

Hence, this doctoral thesis will understand how the changing professional role of pharmacists in hospital and community settings is likely to affect the uptake of PGx and, within this, what might be the specific implications of PGx, as one of the more significant diagnostic tests, for pharmacists working in various sectors.

Organisation and Funding

This research is being undertaken as part of a doctoral studentship in the Science and Technology Studies Unit at the University of York. The project is funded by the Economic and Social Research Council (ESRC) and Pharmacy Practice Research Trust (PPRT), based at the Royal Pharmaceutical Society. It is being undertaken under the supervision of Professor Andrew Webster, who is head of this research unit.

Outcomes of the Project

This project is a doctoral research studentship, where the ultimate aim is to produce a PhD thesis which aims to answer the following research questions;

- how will developments in technology and patient/medicine management affect the occupational status of the pharmacist?
- will the changing role of pharmacists affect the uptake of pharmacogenetic technology?
- within this, what are the specific implications of pharmacogenetics, as one of the more significant diagnostic tests, for pharmacists working in different sectors?

Given the governmental and academic interest in pharmacogenetic technology, the findings from this research will be of interest to a number of parties. Hence, in addition to the completion of a PhD thesis, the findings from this project will be disseminated through annual reports to the PPRT as the funding partner, presentations to stakeholders in the area of genetic research and pharmacy practice and at least one sociologically-driven academic paper.

Your Role in the Project

You have been approached as a participant in this project owing to your work [insert details of participant's work]. The delivery of pharmacogenetic technology may involve practitioners working in your area and it is therefore imperative that the perspectives and understandings of [insert participant's professional group] are reflected in this study.

The Content of the Interview

What you are being asked to consent to is an informal interview where you will be asked about your work as [insert relevant information]. Broadly, the interview will cover your current work and your reflections on the implementation of pharmacogenetics into routine medical and pharmacy practice. Please feel free to elaborate on any answer or area which you think is particularly relevant or important. The interview will take approximately sixty minutes and will be recorded on an audiotape and later transcribed for analysis.

Ethics Approval

This project has been approved by the University of York Ethics Committee and the South Yorkshire Research Ethics Committee and has received R&D approval for your NHS site. These Committees are satisfied that the following potential ethical problems have been addressed;

Consent

Attached to this document is a consent form, which you will need to sign ahead of the interview beginning to acknowledge that you are aware of what the project is about and your role within it. You are free to withdraw this consent at any point before, during or after the interview, which will mean that any responses you have given will not be used during the data analysis. You are also free to refuse to answer any questions during the interview.

Confidentiality

All of your responses will be treated in the strictest confidence and will be completely anonymised so that anything you say can not be traced back to you personally. In addition, any audio files from this interview will be destroyed upon once they have been transcribed.

Risk

The nature of this research presents little, if any, emotional or physical to you as a respondent. In the unlikely event that you are harmed by taking part in this research project, there are no special compensatory arrangements.

Thank you.

Contact Details

Kimberly Jamie	01904 432 632	kj518@york.ac.uk
Professor Andrew Webster	01904 434 740	ajw25@york.ac.uk

Interview Topic Guide for Pharmacogeneticists

General Information

- Background of the research work;
 - What projects are you working on?
 - Where have these projects come from?
 - How long have you been working in the area of pharmacogenetics?
- Why is this area of work important?
- What are the expected outcomes of the project?
- How many group members are working on this project?
- How is the project structured on a daily basis: is it linked to wider work you are doing on this front?

- Are there any other international projects in this disease/drug area?
 - Are any of these other international projects pharmacogenetically-driven?
- How much international collaboration takes place between these projects?

Pharmacogenetics and Clinical Research

- Have pharmacogenetic principles affected the clinical research environment?
 - How?
- How will pharmacogenetics affect the clinical research environment in the future?
- How far away is routine pharmacogenetic drug development?

Pharmacogenetics and Medical Practice

- How far away is routine pharmacogenetic medical practice?
 - Is routine pharmacogenetic medical practice desirable?
 - Are there any particular issues that will need to be addressed before pharmacogenetics can become a part of routine medical practice? What are these? How might they be addressed?
- How has your pharmacogenetic work been integrated into the NHS/medical practice up to this point?
- What do you think the pharmacogenetic future of medical practice will look like?
 - Who will be the key actors in delivering pharmacogenetic medical services?
 - How will pharmacogenetic medical service be experienced by patients?

- Have you any thoughts on the likely wider use/take-up of PGx in the pharmacy profession?
 - How do you think hospital pharmacists will be interacting with pharmacogenetic technology in the future?
 - What about community pharmacists?
 - How prepared do you think pharmacists are for this sort of medical practice delivery?
 - What, if any, roles do you see community and hospital pharmacists having in the practice of pharmacogenetic medicine?

Pharmacogenetic Problems

- What are the challenges of pharmacogenetic research?
- What are the drawbacks of pharmacogenetic medicine and pharmacogenetic medical practice models?
- In your experience, how well do you think medical professionals understand and are comfortable using pharmacogenetics as a medical model?

Other Information

- Is there anything that you would like to reflect on about the pharmacy profession, medical technologies or pharmacogenetics that we haven't covered in this interview?
- Are there any other key people that you think I should be approaching for interviews?

Interview Topic Guide for Oncologists

General Information

- Practice background;
 - When did you start practising?
- Tell me about your work here;
 - What are of oncology do you specialist in?
 - How many staff do you have in your team? How is this comprised?
- Daily Role;
 - Could you talk me through your main responsibilities and tasks here?

Technology and Oncology

- Do you think that new medical technologies have had an impact on the way in which cancer patients are treated?
 - If so, which technologies have impacted on your practice personally?
 - If so, which technologies have you seen impacting on your colleagues practice or practice in general?

Genetics and Oncology

A branch of new medical technology that is often discussed as changing medical practice is genetic technology.

- How much of an impact has genetic technology made on the practice of oncology?

Oncology has been identified as the areas in which pharmacogenetics is likely to make the largest and most imminent impact.

- Has pharmacogenetics had any impact on your oncology practice to date?
 - What about the practice of your colleagues in other specialist areas of oncology?
- What do you think the patient experience of oncology (pharmaco)genetics has been?

Pharmacogenetics and Pharmacy

- What do you think the pharmacogenetic future of medical practice will look like?

- Who will be the key actors in delivering pharmacogenetic medical services?
- How will pharmacogenetic medical service be experienced by patients?
- Have you any thoughts on the likely wider use/take-up of PGx in the pharmacy profession?
 - How do you think hospital pharmacists will be interacting with pharmacogenetic technology in the future?
 - What about community pharmacists?
 - How prepared do you think pharmacists are for this sort of medical practice delivery?

Inter-Professional Communication/ Collaboration

- How much collaboration do you have with the hospital pharmacists here?
 - What about community pharmacists?
- Do you think pharmacogenetic medical service delivery will alter the collaborative working practices in the field of oncology and beyond?

Pharmacogenetic Problems

- In your experience, how well do you think medical professionals understand and are comfortable using pharmacogenetics as a medical model?
- What are the challenges of undertaking pharmacogenetic medical practice?
- How do you think patients understand the process of pharmacogenetic medicine?
- Are there any issues that you think need to be addressed in order for pharmacogenetics to become a routine part of medical practice?

Other Information

- Is there anything that you would like to reflect on about the pharmacy profession, medical technologies or pharmacogenetics that we haven't covered in this interview?
- Are there any other key people that you think I should be approaching for interviews?

Interview Topic Guide for General Practitioners

General Information

- Practice background;
 - When did you start practising?
- Practice information;
 - How many people work at his practice?
 - Do you have any specialists working here or in collaboration with the practice?
- Daily Role;
 - Could you talk me through your main tasks here?
 - Ho do you divide your time between patients and other duties?

Technology and General Practice

- Do you think that new medical technologies have had an impact on the way in general practice is delivered to patients?
 - If so, which technologies have impacted on your practice personally?
 - If so, which technologies have you seen impacting on your colleagues practice or practice in general?

Genetics and General Practice

A branch of new medical technology that is often discussed as changing medical practice is genetic technology.

- How much of an impact has genetic technology made on general practice?
- Has pharmacogenetics had any impact on your practice to date?
- How do you think patients understand and experience pharmacogenetic medicine?
- How do you see pharmacogenetic technology developing in the future and how will this impact on medical practice?
 - Do you see general practitioners playing a role in the delivery of pharmacogenetic medicine?
 - If so, what roles will they have?
 - Will these roles involve any changes to current models of working? What changes?
- How prepared do you think general practitioners are for genetic medicine?

Inter-Professional Communication/ Collaboration

- How much collaboration do you have with community and hospital pharmacists?
 - How would you describe your professional relationship with community pharmacists?
- Do you think pharmacogenetic medical service delivery will alter the current working practices of general practitioners and pharmacists?

Pharmacogenetics and Pharmacy

- What do you think the pharmacogenetic future of medical practice will look like?
 - Who will be the key actors in delivering pharmacogenetic medical services?
 - How will pharmacogenetic medical service be experienced by patients?
- Have you any thoughts on the likely wider use/take-up of PGx in the pharmacy profession?
 - How do you think community pharmacists will be interacting with pharmacogenetic technology in the future?
 - How prepared do you think pharmacists are for this sort of medical practice delivery?

Other Information

- Is there anything that you would like to reflect on about the pharmacy profession, medical technologies or pharmacogenetics that we haven't covered in this interview?
- Are there any other key people that you think I should be approaching for interviews?

Interview Topic Guide for Pharmacy Stakeholders

General Information

- Practice background;
 - What's your role?
 - When did you come to this role?
- Daily Role;
 - What does your everyday work entail in this role?
 - Do you work within a team of practitioners or researchers?

Technology and Pharmacology

- Do you think that new medical technologies have had an impact on the way in which pharmacology is practised?
 - If so, which technologies do you think have impacted on practice?
 - Have these impacted on you personally? How?

Genetics and Pharmacology

A branch of new medical technology that is often discussed as changing medical practice is genetic technology.

- How much of an impact has genetic technology made on the practice of pharmacy?
- Has pharmacogenetics had any impact on your work to date?
- How do you think patients understand and experience pharmacogenetic medicine?
- How do you see pharmacogenetic technology developing in the future and how will this impact on medical practice?

Pharmacogenetics and Pharmacy

- What do you think the pharmacogenetic future of medical practice will look like?
 - Who will be the key actors in delivering pharmacogenetic medical services?
 - How will pharmacogenetic medical service be experienced by patients?
- Have you any thoughts on the likely wider use/take-up of PGx in the pharmacy profession?

- How do you think hospital pharmacists will be interacting with pharmacogenetic technology in the future?
- What about community pharmacists?
- How prepared do you think pharmacists are for this sort of medical practice delivery?

Inter-Professional Communication/ Collaboration

- How much collaboration do you have with practising hospital and community pharmacists?
- Do you think pharmacogenetic medical service delivery will alter current collaborative working practices?

Pharmacogenetic Problems

- In your experience, how well do you think medical professionals understand and are comfortable using pharmacogenetics as a medical model?
- How do you think patients understand the process of pharmacogenetic medicine?
- Are there any issues that you think need to be addressed in order for pharmacogenetics to become a routine part of medical practice?

Other Information

- Is there anything that you would like to reflect on about the pharmacy profession, medical technologies or pharmacogenetics that we haven't covered in this interview?
- Are there any other key people that you think I should be approaching for interviews?

Interview Topic Guide for Hospital Pharmacists

General Information

- Practice background;
 - When did you start practicing?
 - Have you always worked in hospital pharmacy?
 - If not, what made you move over to hospital pharmacy?
 - If so, have you worked in different ‘types’ of hospitals?
- Tell me about the pharmacy department here;
 - How many staff are there?
 - How do things work in terms of specialising in a medical field or any particular practices that this department has adopted?
- Daily Role;
 - Could you talk me through your main responsibilities and tasks here?
 - Is this different for any of your colleagues (e.g. those with specialist interests or those involved in discreet projects)? Ask for details.

Pharmacy Profession

- In the time that you have been practicing, do you think that the pharmacy profession has changed in the hospital setting?
 - How?
- Could you reflect on whether the community pharmacy sector has changed?
 - How?
- Do you think that patients’ perceptions and understandings of the pharmacy profession have changed?
 - If so, how do you think patients’ understandings are different now from how they were when you began practising?

Technology and Pharmacy

- Do you think that new medical technologies have had an impact on the way in which pharmacy is practiced in hospitals?
 - If so, which technologies have impacted on your practice personally?
 - If so, which technologies have you seen impacting on your colleagues practice or practice in general?
- Do you think they have made an impact in the community sector?
 - How?
 - Which technologies?

Genetics and Pharmacy

A branch of new medical technology that is often discussed as changing medical practice is genetic technology.

- How much of an impact has genetic technology made on the practice of pharmacy in hospitals?
 - Is this impact (or lack of) the same for all hospital pharmacists?
 - Differences between different hospitals?
 - Differences between individual pharmacists (e.g. specialisms)?
- How far do you think hospital pharmacists' knowledge of genetics extends?
 - If they have a good level of knowledge, where has this knowledge come from (i.e. practice, under or postgraduate education, continuing education)?
- Could you reflect on the extent of genetic knowledge amongst community pharmacists?

- What about pharmacogenetics?
 - How familiar are hospital pharmacists with pharmacogenetics?
 - What about community pharmacists?
 - Has pharmacogenetics had any impact on pharmacy practice in hospitals to date?
- Could you reflect on the potential roles that hospital pharmacists might have in pharmacogenetics in the future?
 - Could you reflect on the potential roles for community pharmacists?

Inter-Professional Communication/ Collaboration

- How much communication is there between pharmacists working in different sectors?
 - Has this changed since you began practising?
- How much communication is there between pharmacists and other healthcare professionals?
- How far do you think other healthcare professionals understand pharmacists as being key professionals in patient treatment?

Culture Change and Future Roles

- Earlier in the interview you reflected on the potential future roles for pharmacists in delivering pharmacogenetic services to patients. I was

wondering if you could tell me something about where you see these roles fitting into everyday practice?

- Can you foresee any changes to everyday hospital pharmacy practice being made in order to implement pharmacogenetics?
- There is an argument that if pharmacists are to be involved in delivering pharmacogenetic patient care, they will need restricted access to patient medical records.
 - How feasible do you think this is?
 - How do you think other healthcare professionals would understand this move?
 - Do you think pharmacists have the appropriate training in order to effectively and ethically utilise this information?
 - What do you think the implications of this might be for community pharmacists?

Specialists

Here, if the participant is involved in any discreet projects or has a specialist role ask about (if they haven't already talked about these things);

- How they came to have this role
- The role of (pharmaco)genetic technologies in this role
- Different collaborative practices that this role might entail

Other Information

- Is there anything that you would like to reflect on about the pharmacy profession, medical technologies or pharmacogenetics that we haven't covered in this interview?
- Are there any other key people that you think I should be approaching for interviews?

Interview Topic Guide for Community Pharmacists

General Information

- Practice background;
 - When did you start practising?
 - Have you always worked in community pharmacy?
 - If not, what made you move over to community pharmacy?
 - If so, have you worked in different ‘types’ of community pharmacies (e.g. owner-occupied, small multiples, large multiples)?
- Tell me about the pharmacy here;
 - How many staff are there?
 - Do any of the staff, including yourself, have any specialist roles such as running clinics?
- Daily Role;
 - Could you talk me through your main responsibilities and tasks here?
 - Is this different for any of your colleagues (e.g. those with specialist interests or those involved in discreet projects)? Ask for details.

Pharmacy Profession

- In the time that you have been practicing, do you think that the pharmacy profession has changed in the community setting?
 - How?
- Could you reflect on whether the hospital pharmacy sector has changed?
 - How?
- Do you think that patients’ perceptions and understandings of the pharmacy profession have changed?
 - If so, how do you think patients’ understandings are different now from how they were when you began practising?
 - How do you think patients understand the extended role of community pharmacists?
 - Do you think that the extended role is being fully utilised by patients?

Technology and Pharmacy

- Do you think that new medical technologies have had an impact on the way in which pharmacy is practiced in the community?
 - If so, which technologies have impacted on your practice personally?
 - If so, which technologies have you seen impacting on your colleagues practice or practice in general?

Genetics and Pharmacy

A branch of new medical technology that is often discussed as changing medical practice is genetic technology.

- How much of an impact has genetic technology made on the practice of pharmacy in the community?
 - Is this impact (or lack of) the same for all community pharmacists?
 - Differences between different types of community pharmacy?
 - Differences between individual pharmacists (e.g. specialisms)?
- How far do you think community pharmacists' knowledge of genetics extends?
 - If they have a good level of knowledge, where has this knowledge come from (i.e. practice, under or postgraduate education, continuing education)?
- Could you reflect on the extent of genetic knowledge amongst hospital pharmacists?
- What about pharmacogenetics?
 - How familiar are community pharmacists with pharmacogenetics?
 - What about hospital pharmacists?
 - Has pharmacogenetics had any impact on pharmacy practice in the community to date?
- Could you reflect on the potential roles that community pharmacists might have in pharmacogenetics in the future?

Inter-Professional Communication/ Collaboration

- How much communication is there between pharmacists working in different sectors?
 - Has this changed since you began practising?
- How much communication is there between community pharmacists and other healthcare professionals?
- How far do you think other healthcare professionals understand pharmacists as being key professionals in patient treatment?

Culture Change and Future Roles

- Earlier in the interview you reflected on the potential future roles for pharmacists in delivering pharmacogenetic services to patients. I was wondering if you could tell me something about where you see these roles fitting into everyday practice?

- Can you foresee any changes to everyday community pharmacy practice being made in order to implement pharmacogenetics?
- If so, what will these changes be?
- Will they be easy to implement?
- There is an argument that if pharmacists are to be involved in delivering pharmacogenetic patient care, they will need restricted access to patient medical records.
 - How feasible do you think this is?
 - How do you think other healthcare professionals would understand this move?
 - Do you think pharmacists have the appropriate training in order to effectively and ethically utilise this information?
 - What do you think the implications of this might be for community pharmacists?

Specialists

Here, if the participant is involved in any discreet projects or has a specialist role ask about (if they haven't already talked about these things);

- How they came to have this role
- The role of (pharmaco)genetic technologies in this role
- Different collaborative practices that this role might entail

Different Community Pharmacy Settings

There are likely to be differences in experiences of practice between pharmacists working in large multiples (such as Boots) and owner-occupied establishments. If it hasn't already been covered, talk about;

- How will managerial structures in large multiples affect the implementation of pharmacogenetic technology in those settings?
- What degree of autonomy to involve themselves in innovative practices do pharmacists in different types of community pharmacy have? How might this impact on their involvement in pharmacogenetics?

Other Information

- Is there anything that you would like to reflect on about the pharmacy profession, medical technologies or pharmacogenetics that we haven't covered in this interview?
- Are there any other key people that you think I should be approaching for interviews?



CONSENT FORM

Pharmacogenetics and the Pharmacy Profession in England

- I confirm that I have read and understood the Participant Information document for the above study and have been given the opportunity to ask questions
- I understand that my participation is entirely voluntary and that I am free to withdraw at any time without giving a reason.
- I understand that I am free to refuse to answer any question during the interview.
- I agree to the interview being recorded and later transcribed.
- I agree to take part in the above study.

Participant's Signature:

Participant's Name:

Date:

Researcher's Signature:

Researcher's Name:

Date:



Confidentiality Agreement for the Transcription of Qualitative Data

Project Title: Pharmacogenetics and the Pharmacy Profession in England

In accordance with the University of York Humanities and Social Science Ethics Committee and the National Research Ethics Service, all participants in named study above are anonymised. Therefore any personal information or any of the data generated or secured through transcription will not be disclosed to any third party.

By signing this document, you are agreeing:

- not to pass on, divulge or discuss the contents of the audio material provided to you for transcription to any third parties
- to ensure that material provided for transcription is held securely and can only be accessed via password on your local computer
- to return transcribed material to the research team when completed and do so when requested

Your name (block capitals)

Your signature

Date

Glossary

ADRs	Adverse drug reactions
CAM	Complementary and alternative medicines
CF	Cystic fibrosis
CNV	Copy number variation
DTC	Direct-to-consumer (genetic testing)
EPS	Electronic prescribing systems
FDA	Food and Drug Administration (US)
HER2	Human epidermal growth factor receptor 2
HGP	Human Genome Project
INDEL	Insertion or deletion (of DNA)
ISP	International Society of Pharmacogenomics
mAbs	Monoclonal antibodies
NGEDC	National Genetics Education and Development Centre (UK)
NIH	National Institutes for Health (NIH)
NHS	National Health Service (UK)
NPT	Normalisation process theory
PGx	Pharmacogenetics (or pharmacogenomics)
PSGB	Pharmaceutical Society of Great Britain
PSNC	Pharmaceutical Services Negotiating Committee
R&D	Research and development
REC	Research ethics committee
RP	Research Passport
RPS	Royal Pharmaceutical Society (from 2011)
RPSGB	Royal Pharmaceutical Society of Great Britain (as was, until 2011)
SCM	Sasang Constitutional Medicine
SNP	Single nucleotide polymorphism

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