

Community Pharmacy Businesses and Community Pharmacists

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PLAGARISM STATEMENT

This thesis describes research conducted in the UCL School of Pharmacy between October 2009 and November 2012 under the supervision of Professor David Taylor and Professor Nicholas Barber. I certify that the research described is original and that any parts of the work that have been conducted by collaboration are clearly indicated. I also certify that I have written all the text herein and have clearly indicated by suitable citation any part of this dissertation that has already appeared in publication.

Signature:

Date:

PUBLICATIONS FROM THIS RESEARCH

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ABSTRACT

The change in community pharmacists' practice from compounding and effectively unregulated medicines supply through to the highly regulated and largely automated high-volume dispensing process of today has been challenging. The economic and social standing of community pharmacy was transformed creating a need for further adaptation. This thesis explores 'how business and professional practice models for community pharmacy in England in ten to twenty years are likely to be structured?'. It has six sections, plus an overarching discussion.

A work sampling study of ten community pharmacies found that pharmacists continue to spend two-thirds of their time on dispensing related activities, compared to one tenth on counselling. The accompanying analysis links this to an increase in prescription volumes and payments that have incentivised pharmacy contractors to focus on medicines supply. A significant decrease in the average prescription duration for eight chronic disease medications over the past decade is revealed, and its desirability questioned.

Using the Kingdon model of the policy process as an evaluative framework, 16 interviews with 'policy leaders' provided insight into how seven factors (identified from a structured thematic review of the implementation of Medicines Use Reviews) have influenced the implementation of the New Medicines Service. In addition, role theory-based thematic analysis involving 17 stakeholders in pharmacy policy highlighted the tensions between community pharmacists' roles as shopkeepers, clinicians and businessmen, and the effects that new technologies will have on them. The analysis identifies a need for pharmacy to embrace a new strategic direction that enhances pharmacy's contributions to health outcomes.

In conclusion, community pharmacy in England should offer timelier and economically efficient ways of solving contemporary health problems. The evidence presented here suggests that without stronger internal leadership and robust external stakeholder support medicines supply will split from the provision of clinical pharmacy in the community setting, leaving community pharmacies as 'commodity cost', low return medicines suppliers.

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ABBREVIATIONS

AESGP	Association of the European Self-medication industry
APPG	All Party Pharmacy Group
BMA	British Medical Association
BPC	British Pharmaceutical Conference (now the RPS conference)
BPSA	British Pharmaceutical Students' Association
CCA	Company Chemists Association
CHD	Coronary Heart Disease
CPPE	Centre for Pharmacy Postgraduate Education
DH	Department of Health
DHSC	Department for Health and Social Care
EHC	Emergency Hormonal Contraception
EPS	Electronic Prescribing Service
FIP	International Pharmacy Federation (Fédération Internationale de Pharmaceutique)
GDP	Gross Domestic Product
GMC	General Medical Council
GMS	General Medical Services
GP	General Practitioner
GPC	General Practitioners Committee (of the BMA)
GPhC	General Pharmaceutical Council
GSL	General Sales List (medicine)
HLP	Healthy Living Pharmacy
IPA	Interpretative Phenomenological Analysis
IQR	Inter Quartile Range
KNMP	Koninklijke Nederlandse Maatschappij ter bevordering der Pharmacie (Dutch Pharmacy Association)
LMC	Local Medical Committee
LPC	Local Pharmaceutical Committee
LPS	Local Pharmaceutical Services
MCA	Medicines Control Agency (now the MHRA)
MHRA	Medicines and Healthcare Products Regulatory Agency
MUR	Medicines Use Review
NAO	National Audit Office
NCCSDO	National Co-ordinating Centre for NHS service Delivery and Organisation
NHS	National Health Service
NHSCB	NHS Commissioning Board
NHSE	NHS Employers
NICE	National Institute for Health and Clinical Excellence
NMS	New Medicines Service
NPA	National Pharmacy Association
NSF	National Service Framework
OFT	Office of Fair Trading
OTC	Over the Counter (Medicines)
P	Pharmacy only (medicines)
PAGB	The Proprietary Association of Great Britain
PCA	Prescription Cost Analysis
PCPA	Primary Care Pharmacist's Association
PCT	Primary Care Trust
PGD	Patient Group Direction
PHE	Public Health England
PIANA	Pharmacy in a new age
PIL	Patient Information Leaflet
PMR	Patient Medication Record

POM	Prescription only Medicine
PPRS	Pharmaceutical Price Regulation Scheme
PRLOG	Pharmacy Regulation and Leadership Oversight Group
PRN	Pro re nata – as required
PSNC	Pharmaceutical Services Negotiating Committee
PwSI	Pharmacists with Special Interest
QIPP	Quality, Innovation, Productivity and Prevention
RPM	Resale Price Maintenance
RPS	Royal Pharmaceutical Society (previously RPSGB)
RPSGB	Royal Pharmaceutical Society of Great Britain
SCOT	Social Construction of Technology theory
SHA	Strategic Health Authority
TSO	The Stationary Office
WHO	World Health Organisation
WOSCOPS	West of Scotland Coronary Prevention Study

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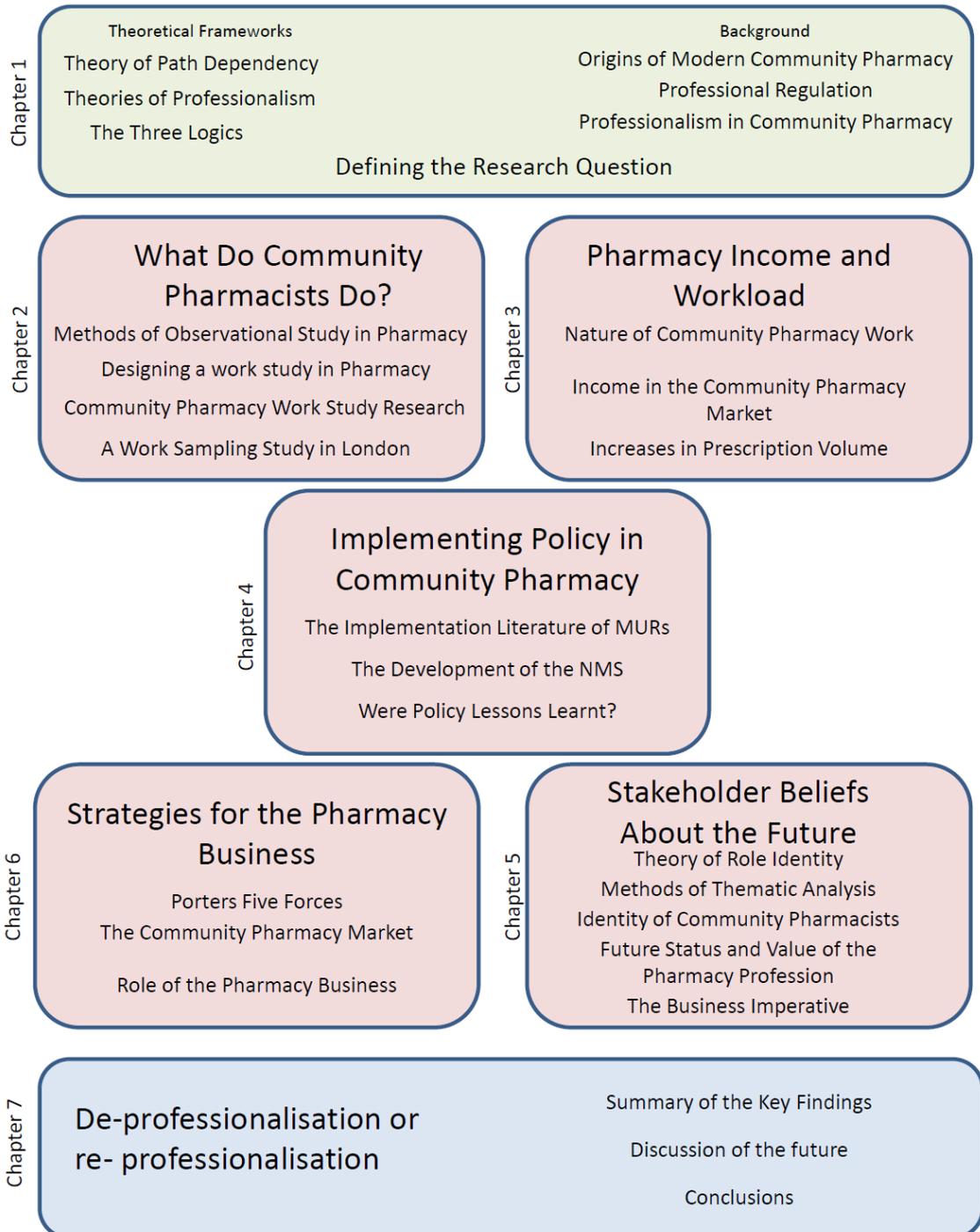
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Plan of the Thesis

Community Pharmacy Businesses and Community Pharmacists



Chapter 1. Introducing the Logics: The Development of Modern Community Pharmacy

Chapter Introduction

This chapter provides the background for - and an introduction to - the research question addressed in this thesis. **How are business and professional practice models for community pharmacy in England in ten to twenty years time likely to be structured?**

Community pharmacy and community pharmacists are components of the complex social world within which we live. The practice of community pharmacists has been driven by the social forces and structures which contextualise their function in society. These social forces have shaped the evolution and development of the pharmacy profession and are therefore a subject worthy of investigation in this thesis. These different threads are then woven together to create a complex tapestry, which reveals the future avenues that community pharmacy businesses and community pharmacists, as professionals, may experience.

Entwined within the literature about the modern development of community pharmacy is a narrative and accompanying debate relating to professionalism and the professional nature of pharmacy practice. Professionalism is a much discussed part of sociology and is the subject of a wide range of published literature. Interpretation of the professional character of community pharmacy practice requires a clear understanding of the literature in this field. For this reason, a significant part of this first chapter provides an overview of the theoretical frameworks and models used by sociologists to explore professions.

Policy analysis also contributes a central role in the academic work that underpins this thesis. Policies express a general set of objectives or a desired state of affairs (i.e. they seek to realise intentions) and as such play an important role in defining future practice. Policy analysis is explored in greater depth in chapter 4. One key concept - path dependency - persists throughout this thesis and therefore deserves an early mention. Path dependency is neither a framework, nor a theory or model. Instead, it is an empirical category, an organising concept that can be used to label a certain type of temporal process (Kay, 2005). This theoretical concept posits that historical pathways are likely predictors of the future, inasmuch as a process is path dependent if initial moves in one direction elicit further

moves in that same direction. Path dependency acts to unpack historical causality to explain how the set of decisions that one faces are limited by the decisions made in the past, even though previous circumstances may no longer be relevant. Therefore, the historical development of community pharmacy is described in this chapter to provide a firm foundation for the rest of this research.

The conflict between pharmacist's roles as businessmen and as clinicians is another thread that runs throughout this thesis. There is an asymmetry of knowledge between the consumer and the provider when a medicine is purchased or collected from a pharmacy. Knowledge asymmetry creates the environment for an imperfect market. The typical market solution to imperfect information exchange is for the consumer to appoint an agent, in this case a pharmacist, to combine information on the patient's expressed preferences with their own information to make a decision for that patient. In the case of perfect agency, pharmacists make the choice that patients would have made if they had been informed. Yet in practice, pharmacists (and most healthcare professionals) are not perfect agents. The information asymmetry gives rise to the possibility of distortions and manipulations of the market.

Society has sought to manage these possible market distortions with ethical codes of practice and professional self regulation to help to prevent the exploitation of the vulnerable. The need to effectively police and monitor these relationships has led to regulation and statute, the complexity of which has vexed governments. Although agency relationships exist in most healthcare interactions, pharmacies are unique in so much as they are often the only section of NHS healthcare in which there is a directly observable financial transaction that takes place alongside a clinical exchange¹. This makes the opportunities for market manipulation more apparent to consumers even if they as likely to exist elsewhere in the health service.

This agency role has allowed pharmacists to claim professional status, but has also provided them with economic rewards through the pharmacy business. However, the interaction between professional status and the economic viability of community pharmacy businesses remains strained. Given this background, the regulation of pharmacists is an important sub plot, which is described within the later part of this chapter.

¹ While other areas such as dentistry and optometry do interact with patients financially, the healthcare provision takes place in a separate room from the financial exchange. England differs in this respect from other health systems around the world.

The final part of this chapter draws together these different perspectives and theoretical backgrounds to outline why the research question presented here is worthy of scholarly investigation.

Therefore this chapter provides a background to the professionalism literature, describes the development of modern community pharmacy practice and explores the evolution and development of professional regulation, in order to establish base for the research question that this thesis seeks to address.

Theory of Path Dependency

Path dependency, as described above, is a concept used to describe how previous societal and human behaviour has a direct influence on the future, to put this in a Newtonian voice, 'everything has causes' (David, 1985). Although Page argues that the wider application of path dependency means that for many it has become a *'trendy way to say that history matters'* (Page, 2006), he acknowledges that the lack of formal models to describe history-dependent processes have led to a justified increase in its use.

The broader literature on path dependency in health systems emphasises that critical events in history shape policy development and the marketplace. Individual decision making early on in a path may lead to a 'lock in'² (David, 1985). These events prove hard, if not impossible to reverse. Therefore actors within the policy field become *'tied to previous decisions and existing institutions'* (Wilsford, 1994: p252) even when these decisions produce arguably sub-optimal solutions. Pierson (2000) suggests that such tendencies to follow previous decisions are exaggerated by the 'increasing returns' (Pierson, 2000: p251) that follow from adopting a particular policy course or strategy.

Path dependency therefore builds upon a notion of incremental change, and therefore a path dependent process is clearly dominated by whatever the status quo happens to be, rather than the potential of big changes. However history tells of 'conjunctures' of events, which create windows of opportunity for actors to deviate from a given path (Wilsford, 1994). It is these windows of opportunity that are the basis for the Kingdon model that is progressed in chapter 4. These 'policy windows' are highly unpredictable in their nature and timing, but crucially they possess the opportunity to overcome the 'weight of history' (Wilsford, 1994: p280).

² An example of such a 'lock in' is the QWERTY keyboard, which was initially designed with typewriters in mind, and has since become the industry standard despite being an inefficient design.

In the context of this thesis, path dependency is applied to both the professional and economic development of pharmacy. Although several studies have applied the concept of path dependency in relation to embedded institutions in health service reform (Wilsford, 1994), less attention has been applied to clinical professions (Kirkpatrick et al., 2009), and indeed none to community pharmacy in particular. This concept is applied here, by exploring the origins and subsequent development of community pharmacy in light of the theories of professionalism outlined below.

Theories of Professionalism

Occupations are a large part of social life, and therefore they have been of interest to sociologists who have created a wealth of literature and theories on professions, which have encountered several different stages of intellectual history. Beginning with the structural-functionalist trait theories from 1930 to the 1960s (e.g. Carr-Saunders and Wilson, 1933; e.g. Goode, 1957), the literature evolved into the market monopoly and power theories of the 1970s and 1980s (e.g. Johnson, 1972), followed by the third logic theories of the 1990s and the new millennium led by Eliot Freidson (Freidson, 2001). It is this intellectual history that will be used as the basis to understand professionalism amongst community pharmacists.

Structural-functionalist trait approach

The early approaches to defining what constituted a profession were accrued from observation of the 'learned professions' of law, clergy and medicine. Early authors such as Carr-Saunders suggested that professions organise themselves into asymmetric expert-client relations for client and social protection, and in doing so display a series of traits or qualities. Researchers began to develop lists of traits by analyzing the observable characteristics of groups believed to be professions (e.g. Goode, 1957).

By definition these traits were outside the reach of the normal labour market, thereby placing the professions in an agency position. This agency status required the professionals to provide their skills in an altruistic manner for the good of the community. The early theorists believed that specialist skills and an ethic of altruism and service to the community legitimately rewarded professionals with autonomy, self-regulation, high social status and income. It was at the time thought that professions present themselves to society as a benefit, taking a functionalist stance, focussing on where professions exist within the social system, rather than analysing the need or desire for their existence. While

it was recognised within these theories that professions made money from their skills, it was understood that this was not their main aim (this position is challenged in the next section).

The functionalist approach considered how professions form part of society, and how they fulfil their societal roles. While it offers a convenient fit, the approach has been criticised as overly simplistic and idealised, partly due to accepting the professions own definitions. It was from this base that the term professionalism developed, described as the characteristics displayed by professionals. Although some researchers continue to be absorbed with the problem of defining a 'profession', some more general descriptors, such as occupational control of work (Freidson, 2001); the sociology of middle-class occupations; or theories of occupations of expert labour (Evetts, 2003), have become the mainstay within this field.

Although many examples of trait lists exist, most contain several essential features - showing technical expertise and judgment; rigorous academic screening and training programs; occupational licensing; value and service ideals and codes of ethics; workplace autonomy; and a self-governing occupational community.

Goode suggested that there is in fact a 'profession continuum' (Goode, 1957), rather than accepting a dichotomous view (professional or non-professional). Against this observation an unskilled worker will possess none of the traits, whereas a traditional profession, such as medicine, will possess them all, implying a hierarchical view of professionals. Therefore, this removes the need to draw a hard line between professions and other occupations. Instead Goode's perspective accepts that they are similar social forms that share many common characteristics. It is for this reason that some authors choose not to define professionalism, but instead to offer a list of relevant occupational groups (e.g. Abbott, 1988). Building on this Wilensky (1964) used the trait approach to develop a professional development model from 'non professional' to 'fully-professional' in stages, allowing professions to develop as 'semi-professional'³.

Attempting to define the professions and understand the patterns of professional development bound these early structural-functional theories. It was only from the 1970s onwards, when the academic field of sociology embraced these areas further that groups began to question the value of professionalism as a social construct. The sociological field

³ As described later, this is a status applied to community pharmacy by some authors.

became dominated by critical theorists. Parsons (1951) recognised (and then showed) that the capitalist economy and rational-legal social order were interrelated and mutually balanced by modern professionals who helped to maintain and stabilise the fragile normative social order (Evetts, 2003). As a result theorists became critical of the overly simplistic functionalist approach leading to the development of 'market monopoly' or 'power' theories.

Market monopoly/power models

Implicit in professional encounters is a level of trust. The lay patient must place their trust in professionals and in doing so, professionals acquire a certain amount of knowledge that they can potentially exploit. In return for not exploiting this knowledge, professionals are rewarded with authority, privilege and higher status. Theorists became concerned with the power and control that professional groups had achieved, legitimised and maintained, suggesting that this trust may have been exploited. Indeed, some believed that the elitist monopolies created by professional groups allowed members to raise fees and increase their incomes in comparison to otherwise open markets, and in doing so restrict the interests of consumers (Freidson, 1970).

Critical theorists began to argue that professional groups developed service ideals and codes of ethics that justified their privileged position in society; despite being superficially held and inconsistently followed. It was this that prompted attack of the medical profession by Eliot Freidson in the 1970s who argued that consumers would best be served by de-regulation of entry and state regulation of practice (Freidson, 1970).

To this point, professionalism had been regarded as a value system. This notion was rejected and replaced by a critical assessment of professional work concerned with whether professions deserved the influence they possessed over public affairs. It was argued that professionals used their specialist knowledge to create a social distance between themselves and 'everybody else' which helped them to protect their area of work (Macdonald, 1995). The culmination of these analyses was scepticism about all of the professions, although particularly medicine and law which were described in the literature as elite powerful occupational groups (e.g. Johnson, 1972).

In order to legitimate their practice each profession had to gain state support for the exclusivity of their market shelter (e.g. Johnson, 1972; Freidson, 1970). Market monopoly (or power) theories began to argue that educational requirements and certified courses

required for licensing an occupation restricted the labour market and created market shelters for professionals. Freidson developed Johnson's argument that through their training and identity professions create market shelters that set each occupation apart (Freidson, 1970).

Larson also focused her attentions on how professions gain control of a marketplace to raise their social status (collective mobility) by tracing the historical development of a limited group of occupations into professions. Larson demonstrated how economic advantage for occupations is achieved by restricting the supply of practitioners and striving for a special position of public respect and influence. The successful outcome for the collective was an occupational monopoly of competence, officially sanctioned expertise and a monopoly on credibility with the public (Larson, 1977). While Larson questioned the development of these monopolies, she importantly asked why and how the work practices of medicine and law became the rallying cry for a whole group of knowledge based professions despite their different employment conditions. This led some to conclude that it was for reasons of power and income – 'a monopoly of practice'.

"Third logic" approach

According to power theories, all professions struggle to attain and maintain control and autonomy in a specific field. To protect their territory, professions must continually negotiate their position with the state. The re-stratification thesis first emerged in the mid 1980s, in response to the growing recognition within sociology that something was happening to medical autonomy. This was supported by the thesis of de-professionalisation and proletarianisation.

Haug (1973), the originator of the de-professionalisation thesis, argued that medical autonomy was being challenged due to a process of rationalisation and codification of medical knowledge and expertise into standardised rules and procedures. At the same time Oppenheimer (1973) argued that professional work was becoming subject to a process of rationalisation in the name of economy and efficacy. He contended that bureaucratic structures controlled by administrative elites were (through administrative routines, measures and targets) controlling the work of professionals effectively making them part of the proletariat.

However, Friedson (Freidson, 1985) described the medical profession as 'stratified', whereby an administrative elite guide and evaluate the performance of those within the

profession. Freidson interpreted the rise of these control mechanisms in medicine as an essential part of re-stratification, rather than a sign of medical proletarianisation. He argued that re-stratification, which involves the medical elites exerting control over members of their profession helps them to maintain the continued dominance of the medical model⁴.

Annandale's (1989) work in obstetrics found re-stratification and hierarchy in the medical profession, which meant that some doctors, some midwives and some nurses were seen as more dominant, suggesting a disjuncture between obstetricians' inability to protect their interests as a corporate body and their relative ability to control the organization of everyday medical work. This re-stratification thesis coupled with the apparent ability of governments to successfully change the professions, undermined the monopoly position perpetuated by the power theorists.

In the 1990s researchers began to reassess the significance of professionalism and its positive (as well as negative) contributions at the macro level to social systems and at the individual level to consumers, returning to a view of the professional from a value system perspective. It began to be argued that public interest and professional interest were not necessarily polar opposites (Saks, 1995). In general this led to a reinterpretation of the concept of professionalism.

In light of these findings, Freidson, once a proponent of the market monopoly model (Freidson, 1970), began to shift his thinking. Freidson (2001) argued that the professional shelter from the market can be defended if –as well as increasing occupational income – it is seen as encouraging a higher quality of work, a greater commitment to the work, and more integrity in the conduct of that work than would be possible without the market shelter. As well as this, the service that a profession provides warrants protection if it has the capacity to produce a high minimum standard of benefit to consumers, and reduce the potential harm that would be caused by unqualified practitioners (Freidson, 2001). Translating this to pharmacists, it suggests that they must provide a service that can produce a quality of supply and standards above those that a market could achieve, if they are to maintain the market shelter currently afforded to them by professional status. In other words, to attract premium income pharmacy requires political and social recognition

⁴ This re-stratification is returned to later in this chapter when discussing the autonomy of the pharmacy profession. In particular building on the research of Armstrong (2002).

that medicines supply is a health protection and improvement function as opposed to a technical and logistic function.

As a result of this change in perspective, Freidson argued that

“a monopoly held by an occupation whose members are committed to maintaining the integrity of a craft that is of value to others is a more desirable and less destructive solution to an important social problem than is the free play of unbridled material interest or the reduction of all work to formally specified procedure proposed by critics” (Freidson, 1994).

While he continued to accept that professional groups could exist to manipulate a market, he presented a defence of professions in the form of the social benefits that the market shelters professions operate under can offer. His beliefs moved away from criticism of the professional model as a force to manipulate markets, instead believing that these occupational groups are subject to stronger forces of labour control⁵.

Freidson (2001) put forward the thesis that there exist three logics in society. The first is the idealised logic of the ‘perfect’ free market, as defined by Adam Smith, which by bringing increased competition and pressures for lower prices places consumers in command. The second logic, founded on the Weberian perspective of a rational-legal bureaucracy, portrays bureaucratic-managerial control as a logic that controls the market meaning that managers dominate. The final logic is that of professionalism, which Freidson develops into the ‘ideal type’ of professionalism, as a form of controlling work in which professional groups lead, bounded by an ideology of serving a transcendent value and asserting greater devotion to doing good work than to economic reward.

Friedson’s argument is a powerful one because it builds on the accepted theories of the past, and builds a model for future practice in which professionalism is an important ingredient in the mix. Therefore this Freidsonian perspective acts as an underpinning part of the reasoning within this thesis, by comparing and contrasting the effects of the three logics on the community pharmacy profession over time. However, before progressing Freidson’s approach to community pharmacy, one must understand the origins and subsequent political struggles of community pharmacy in managing its relationship with

⁵ It is important to emphasise the distinction here between unions, which seek to further the interest of employees and professions that seek to further the interest of consumers (and in doing so, the interests of themselves). However the line between these two distinctions is being blurred.

the state, and its relationship with the logics of professionalism, managerialism and consumerism. It is this story to which this chapter now turns.

Origins of the Modern Community Pharmacy

By reviewing the literature in the policy field related to community pharmacy in England, it is possible to explore the evolution of community pharmacy and interpret pharmacy leaders' claims of professional status, while considering the accompanying logics of managerialism and consumerism. In doing so, it is possible to explore how previous decisions have sought to influence subsequent practice.

Materials and Methods

The majority of the health policy documents identified in this section were reviewed and abstracted from the free web archives of the Department of Health. Key excerpts from documents that relate to pharmacy policy in England⁶ published after 1997 were highlighted and summarised before being ordered chronologically⁷. The interpretation of these documents was checked for reliability by Prof David Taylor. Disagreements in interpretation were resolved through discussion. The work of Rudolph Klein, who has chronicled the developments and changes in the National Health Service (Klein, 2006), supported this analysis through a wider healthcare policy perspective. Evidence of implementation of policy into pharmacy and context to the developments prior to 1997 were provided through bibliographic references, in particular *Making Medicines* (Anderson, 2005), *Health Policy in Britain* (Ham, 2009) and *Royal Pharmaceutical Society of Great Britain 1841 to 1991: A Political and Social History* (Holloway, 1991). A summary timeline of these policies is presented in table 1.1.

Early Development of Community Pharmacy

The narrative relevant to modern community pharmacy practice in this research begins at the creation of the National Health Service in 1948⁸. By contrast to the complex changes and consultations that took place with other professional groups at the development of the NHS, pharmacy negotiations proved relatively simple. The scheme introduced as part of the National Insurance Act in 1911 was working well. This was expanded to a wider population in 1948 with only relatively minor alterations to the fees that pharmacy contractors

⁶ There have been a wide range of changes in the devolved administrations, especially in Scotland. They do not feature in the policy analysis presented in this chapter. However, where relevant, these innovations are discussed in later chapters.

⁷ This year was chosen due to the ease of accessibility of web archives of policies from this date.

⁸ Anderson (2008) and Holloway (1991) both provide a rich account of the development of community pharmacy practice prior to 1948.

received. For contractors, the main difference experienced was a significant growth in the number of prescriptions as a result of greater public access to free medicines. The rapid expansion of prescriptions significantly changed working practices. Within a year, the number of prescriptions dispensed by pharmacists almost quadrupled from 70 million a year to around 250 million (Anderson, 2005). Today in England alone, this figure stands at over 960 million (The NHS information Centre Prescribing Support Unit, 2012). This unprecedented growth fundamentally impacted upon the business model of pharmacy at the time, moving from an income of 10% or less from these in the 1920s to over 30% in the late 1940s (Anderson and Berridge, 2000). This proportion has grown steadily. At present over four fifths of the income generated in the average community pharmacy is derived from dispensing⁹.

Prescription numbers continued to increase in the 1950s, in part driven by the discovery and marketing of new medicines by the pharmaceutical industry, which included antibiotics, major and minor tranquilisers, anti-depressants and cardiovascular disease treatments and also in part due to the reduction in the number of prescriptions that doctors dispensed themselves. For example, in the 1940s about half of all prescriptions were supplied by doctors, the equivalent figure for the 1950s is about 10% (Anderson, 2008). Prescription item volumes fluctuated following the introduction in 1952 of prescription charges, their subsequent abolishment in 1965, and their reintroduction in 1968. Exemption categories were introduced in 1968 and successively expanded in 1974 and 1975. Yet despite a further rise in charges, overall prescription volumes continued to steadily increase. The increase in workload and income meant that dispensing assumed a dominating position in the role of the community pharmacist.

At the same time, the nature of dispensing went through an equally radical change. The changes in mass scale manufacturing processes introduced at the beginning of the century led to a dramatic shift away from the use of extemporaneously prepared medicines in the dispensary. Instead mass scale factory manufactured medicines were re-packed in the pharmacy to individual patient requirements. The dispensing process became one of interpreting prescribers' instructions, assembling and labelling medicines, and handing them to patients with necessary instructions, as opposed to one of medicines formulation and compounding. Pharmacists, who were once the compounders of medicines, increasingly found their role dominated by checking what others had done. This was

⁹ This proportion is discussed in further detail in Chapter 3.

accompanied by a shift in dosage forms from mixtures and draughts, to solid tablets and capsules. Despite this change in the role, the increased volume of prescriptions created a relatively stable and 'busy', in terms of activity, business in the community.

The normalisation of proprietary medicines as a retail commodity began to infiltrate community pharmacy practice in the UK. For example, in 1952, Boots introduced self selection methods in their shops, which had been pioneered in the USA. This was a significant change from the traditional shop where an assistant found the requested product (Anderson, 2005). A confrontation between Boots and the Pharmaceutical Society ensued, with the latter arguing that medicines were not ordinary commercial articles and therefore should not be self selected. After an appeal to the high court, Boots won the case (although they did not implement self selection of General Sales (GSL) medicines until the 1980s). This judgement was the first of many challenges to the ways in which medicines were supplied to the public despite professional opposition. This led to continued clashes between 'professional' imperative to control supply and the commercially led managerial pressure to increase sales.

Pharmacists became increasingly concerned about threats to their professional practice, particularly from the large commercial operators. A motion at the 1965 Annual General Meeting of the RPSGB called for new pharmacies to be in physically distinct premises and to confine their trading activities to pharmaceutical, professional and traditional chemists' goods. This was prompted by a Pharmaceutical Society report into the general practice of pharmacy (Anon, 1963). It suggested that commercial activities outside healthcare were impacting upon their professional standards, although this could well be interpreted as protectionist behaviour to prevent supermarkets from entering the retail territory of existing pharmacy contractors.

Despite overwhelming support from within the profession for this motion, a challenge by Boots in the court of appeal and the House of Lords, ruled that such a restriction would result in a 'restraint of trade'. Therefore the profession remained powerless to prevent the expansion of pharmacies into supermarkets and other locations, and as a result large bureaucratic organisations began to exert greater control over pharmacists' domain of work.

Meanwhile secondary care pharmacists were confined to the dispensary, often hidden away in the basement of the hospital. In 1958, the Aitken report on dangerous drugs in

hospitals changed this by making pharmacists responsible for the safe and secure handling of medicines throughout secondary care organisations (Department of Health and Social Security, 1958). The regulations made it necessary for hospital pharmacists to work with multidisciplinary teams to ensure that medicines were handled safely on the wards and in doing so laid the early foundations for ward based 'clinical pharmacists' (Crooks and Calder, 1966). This role was further progressed by the first MSc in clinical pharmacy in 1976. Throughout the 1970s the need for pharmacists on the ward was becoming more established, but a shortage of entrants into the hospital sector due to lower salaries compared to community colleagues, led to recruitment problems. A working party under Noel Hall – an economist, academic and member of the Oxford Regional Hospital Board - made specific recommendations about restructuring the service to improve career opportunities (Anon, 1978; Department of Health and social Security, 1970), but even with these recommendations (and salary changes as a result of the NHS reorganisation in 1974) salaries remained too low to attract junior staff (Brookes, 1998). As a result pharmacists began to delegate increasing amounts of work to occupational assistants, laying the foundations for 'pharmacy technicians'.

The Medicines Act of 1968 in the aftermath of the Thalidomide tragedy, which had caused 10,000 or more babies to be born with physical impairments, led to an increase in pharmaceutical testing as well as an improvement in overall manufacturing standards. This effectively prevented the small scale manufacture of medicines in community pharmacies. While in many respects this helped to regulate the sale of proprietary medicines in pharmacies, it also severely curtailed their ability to make commercial gains from 'quack' medicines. The Act also made it explicit as to which medicines required prescriptions. Together these both further disempowered pharmacists as medicines manufacturers and increased their prescription dispensing workload.

In the community, Boots continued to influence community practice pharmacy, and grow through mergers and acquisitions. Companies such as Timothy Whites and Taylors in 1968, and Underwoods in 1989, joined the Boots family, making it the largest retail chemist in Britain. More recently, in 1990 Boots acquired Moss Pharmacy, which had been owned by Unichem PLC. Unichem, a medicines wholesaler merged with Alliance Sante in 1997, forming Alliance Unichem, which subsequently merged into Boots forming Alliance Boots in 2006. This company now trades globally with operations in Brazil and China. It is has grown to become one of the UK's most recognisable retail companies and represent an important

part of the UK economy. Such a large enterprise has a strong focus on commercial trading, which some believe is eroding the 'professional' practice of pharmacists (Bush et al., 2009).

The era of 'new management'

Against this backdrop of developments in manufacturing standards and new 'clinical' roles for pharmacists in hospitals, far reaching economic changes were taking place across the political landscape, directly influencing the delivery of public services including healthcare. Several trade union strikes over pay, followed by other setbacks such as the 1973 oil crisis and the three day working week in 1973-74, led to economic uncertainty. This industrial strife, coupled with rising inflation and unemployment, left Britain in a difficult economic position at the end of the 1970s. In 1979 Margaret Thatcher was elected Prime minister, and her government set about redefining economic policy through deregulation, privatisation, restructure of industrial relations, changes to the tax system, and reform of public services. Such reform precipitated an increase in competition and market forces within healthcare.

Policy developments, particularly around labour relations and privatisation began to have a direct impact on the provision of healthcare. At the creation of the NHS in 1948, the medical profession dominated every level of health service decision-making and had a major influence over health policy decisions (Anon, 1948)¹⁰. The medical profession had managed to establish an 'underlying concordat' with the state in respect to resource allocation. The state determined the level of overall resources devoted to medical care leaving the profession largely free to determine the use of resources under the rubric of clinical autonomy (Klein, 2006).

For the next two decades, under the badge of professionalism, doctors continued to act with relative freedom and with little state interference. But by the sixties and seventies writing by sociologists such as Howard Becker (1962) and Eliot Freidson (1970), began to focus on the medical power that had become an entrenched feature of the healthcare system¹¹. Reports about medical negligence and poor management within the health service began to appear, one of the most significant examples was in 1967 when allegations were made by a nursing assistant at Ely Hospital, Cardiff to the *News of the World* about negligent care. The investigation that followed showed that members of the

¹⁰ This is despite the widespread opposition of much of the medical community to the creation of the NHS. For example in February 1948 over 90% of the BMA said that they, as doctors, would not be a part of the NHS. Then, in July of the same year over 90% of GPs joined.

¹¹ See previous comment on Power Theories of professionals.

health authorities, who were primarily doctors, were not representing the views of consumers in the local community. Ministers, backed by public support and a desire to get a handle on public services, began to challenge medical dominance in the health service – their chosen weapon was management.

In 1983 the government commissioned Roy Griffiths - the managing director of the supermarket chain Sainsbury's - to analyse NHS management. His report identified 'institutional stagnation' and prescribed general management at every level of the NHS as the solution. Medical and nursing representatives on committees lost power and new managers were given incentives through performance related pay to bring about change. Griffiths brought in a new managerial framework, tight budgets and justification requirements for costs. Service outputs of the NHS were no longer decided by the medical profession. Instead new non-medical managers began making the decisions, challenging the very nature of professional autonomy (Hampton, 1983). The power of health service managers slowly increased if not superseding that of the professionals (Freidson, 2001), arguably de-professionalising the clinicians.

Proponents of the de-professionalization thesis have argued that this contributed to the general decline in the medical profession's cultural authority and legitimacy¹². Alongside these new managers other changes were de-stabilising medical power. The increase in the accessibility of medical knowledge driven by technology, the rise in complementary medicine, the fact that doctors became more reliant on new areas of knowledge outside their control, and the preparedness of patients to challenge doctor's decisions (reflected in the steady rise in complaints about medical care), acted to limit doctors control over the health service (Salter, 2001).

The layers of management introduced by Griffiths continued to increase, fundamentally changing the working environment of professionals through the introduction of quality measures such as league tables and rating systems. These tools, initially designed to help develop service improvement at the local level, became political tools to demonstrate the relative successes (or failings) of the NHS. Although the main focus of these changes had been on the medical profession, its relative standing in relation to other professions, meant that all other paramedical professions were affected.

¹² The full discussion on the de-professionalisation thesis is provided by Haug (1973).

'Re-professionalising' Pharmacy?

By the 1980s pharmacists' professional monopoly over the manufacture, preparation and supply of medicinal products had been completely undermined by the expansion of the pharmaceutical industry (Brehm et al., 2006). The 1968 Medicines Act, and subsequent European Legislation, resulted in patient ready packs becoming more commonplace, removing the need to compound medicines in the pharmacy. As the availability of pharmacological treatments increased, pharmacists improved their education, but arguably became 'trapped' as over-educated distributors of medicines (Eaton and Webb, 1979; Wardwell, 1979). The future role of the professional pharmacist was highlighted by a Royal Commission into the National Health Service (Merrison, 1979), which identified for the first time that pharmacists in community were not fulfilling their potential (Taylor and Harding, 2001). The literature began to describe pharmacy as an 'incomplete' or 'marginal' profession due to the conflict between their clinical responsibilities and their growing commercial responsibilities. The legitimacy of pharmacists role began to be brought into question as their previous monopoly over drug manufacture and supply was being eroded (Morgall and Almarsdóttir, 1999). The profession weakened by internal strife became prey to the government's cost cutting activities.

In 1981 Gerard Vaughan, the Minister of Health, announced at the British Pharmaceutical Conference *"One knew there was a future for hospital pharmacists, one knew there was a future for industrial pharmacists, but one was not sure that one knew the future for the general practice [community] pharmacist"* (Anderson, 2007).

This statement stirred the development of community pharmacy in an effort to prove its worth and to redefine the role of the profession. Elite groups, such as Royal colleges, academics and professional leaders, within a given occupation tend to be the key advocates of new roles in any re-professionalization project (Birenbaum, 1982), and pharmacy was no exception. In England, the Department of Health, supported by the RPS, NPA and CCA spearheaded a movement to extend community pharmacist's roles.

Pharmacists began working with others, such as the Family Planning Association to actively deliver contraceptive advice in pharmacies. In 1983 the Trustees of the Nuffield Foundation commissioned an inquiry into pharmacy and the subsequent report, *Pharmacy: a report to the Nuffield Foundation* was duly published in 1986 (The Nuffield Foundation, 1986). This important report made 96 recommendations, 26 of which were specific to community pharmacy. Overall, it was optimistic about the future of pharmacy, suggesting that

pharmacy makes a '*distinctive and indispensable*' contribution to healthcare (The Nuffield Foundation, 1986).

Campaigns to redefine the role of pharmacy within the primary health care arena followed. Pharmacy groups such as the RPSGB and the National Pharmacy Association (NPA), began to act on the Nuffield recommendations. Pharmacists were gifted a further role in minor ailments and self care when in April 1985 a 'black list' of medicines appeared in the drug tariff meaning that many commonly known household medicine brands were no longer allowed on NHS prescriptions, and in the main, could only be accessed from pharmacies.

The administrative elite within the pharmacy profession, grouped around the universities and the professional bodies, began to realise that pharmacists could play a key role in healthcare addressing factors outside of medicines supply. The *Health of the Nation* White Paper, which had identified that social factors such as lifestyle and environment were important for health (making it explicit that health and illness issues were no longer solely the property of doctors), provided an opportunity for community pharmacists to supply health promotion advice. At the same time their hospital colleagues began to further expand their clinical roles on the wards, supported by the Department of Health (Health Circular, 1988).

While pharmacists were seeking to redefine their practice, greater regulation and managerial control of the health service grew. It became evident, through a series of high profile scandals and almost 'daily horror stories about the NHS' (Klein, 2006), that the professional domination of the health service had a scant understanding of consumer needs within it. Up to the 1980s, UK healthcare was characterised by health consumer groups that were non-existent, passive or medically dominated. The policy network was instead an 'iron triangle' between the medical profession, ministers and officials (Salter, 2003). Despite the conservative government's rhetoric regarding the importance of patients, this had been constructed to mean that health consumers should not be part of the health community, but instead rely on the greater legitimacy afforded to managers (Salter, 2003), a shift from professionalism to managerialism.

Margaret Thatcher, boosted by confidence of winning a third election victory, and concerned about funding and the widespread public dissatisfaction with the NHS, set out a manifesto for change in the publication of *Working for patients* (1989). The Patients charter (Department of Health, 1991) which followed began a new paradigm in health policy

transforming patients into consumers, making their rights more explicit in the health service, bringing the logic of consumerism more explicitly to the fore.

The medical profession were further challenged in 1994 when the Department of Health published performance against the Patients' Charter. This performance measure was primarily a managerial tool but soon became a political tool by which politicians could demonstrate the work of the NHS (and their policies) to the public. Although the rhetoric of these policies at the time was concerned with empowering patients in the delivery of their healthcare, some commentators believed that this was simply political cover for combating the ingrained power of the professions (Klein, 2006).

The rise in consumerism over this period is regarded as one of the fundamental developments shaping health service delivery within the UK¹³ (Hibbert et al., 2002). The sociological literature outlines the conceptual distinction between a patient, regarded as occupying a subject position, with implicit dependency and unquestioning compliance with medical expertise, and a consumer, regarded as a rational, dispassionate and calculating person who no longer accepts at face value the authority of science and medicine (Hibbert et al., 2002). The societal shift from patient to consumer in healthcare challenged (and continues to challenge) medical dominance. Indeed in pharmacy this shift was reflected with it becoming less acceptable to talk about compliance, and more appropriate to use concordance, implicit in which is a move towards a shared 'concordant' relationship (The Royal Pharmaceutical Society, 1997).

Following *Working for Patients*, the pharmaceutical society spurred on by Nuffield began to work closely with the Department of Health to respond to changing consumer needs. In 1992 they published a joint report (Department of Health and Royal Pharmaceutical Society of Great Britain, 1992) recommending pharmacists participate in health promotion campaigns. The report also identified extended services for community pharmacy such as the provision of EHC, smoking advice, repeat dispensing, medicines management and medication delivery to GPs and housebound patients. Yet later the same year the government did not include the emerging role of the pharmacist in its 1992 public health White Paper (Secretary of State for Health, 1992) much to the disappointment of pharmacy leaders. Bond (2001) observed that the medical profession received the joint report with severe reservations, echoing the longstanding conflicts between these groups. Many medics believed that community pharmacists were incapable of extending their role. The

¹³ It is worth noting that both the state and the professions claim to be the true representative of the consumer

interpretation of this can go several ways, either as a heartfelt view that pharmacists were not capable of their role or more likely, a protectionist stance to the threat of another group seeking to occupy their professional sphere of work.

The joint report was followed up by the Pharmaceutical Society (RPSGB) with a series of consultative papers in 1995 called '*Pharmacy in a new age*' to help highlight how pharmacists could contribute further to healthcare. A report, *The New Horizon* was published in 1996 followed in 1997 by *Building the Future*, which laid out a strategy for the future development of pharmacy. While it raised the profile of the profession and convinced people that the pharmacy profession wanted to make a contribution to the broader agenda, it failed to produce a consistent message. Despite the celebrated success of these projects within the profession, the full force of their recommendations is still to be seen¹⁴.

The Labour Years

Political support slowly grew for the extended clinical role that pharmacists could provide. The new labour government, under the leadership of Tony Blair, released a public health White Paper in 1999 setting out a health strategy for the next ten years (Department of Health, 1999). The strategy set specific targets for reducing cancer, coronary heart disease (CHD) and stroke, accidents, and mental health. Its stated aim was to improve the health of the population and reduce health inequalities. This heralded the development of pharmaceutical public health and provided a major impetus for health promotion by pharmacists.

Support for the extended role of pharmacists was further boosted by developments across the Atlantic. Two American pharmacists, Hepler and Strand developed the concept of Pharmaceutical care.

"Pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes which improve a patient's Quality of Life" (Hepler and Strand, 1990).

Their work helped emphasize the shift in pharmacy practice from a product focus to a patient focus within the policy community. Pharmaceutical care has since received

¹⁴ PIANA made a contribution to shaping future policy, not least by creating a definition of what pharmacy was for.

endorsement from the World Health Organisation and the International Pharmaceutical Federation (2006) as a concept for developing the pharmacy profession.

Britain's economy recovered from recession in the early nineties leading to economic growth and stability, which translated into a sustained investment in the health service. On January 16th 2000, on the sofa of the BBC programme 'Breakfast with Frost' the Labour White Paper pledge for greater investment in the NHS came to fruition (BBC News, 2000). The Prime minister announced an increase in spending to bring the NHS up to the European Union average. This was followed in the summer of 2000, by the launch of a challenging program of reforms for the NHS, described in the White Paper 'The NHS Plan' (Department of Health, 2000a). The NHS plan was founded on ten core principles including improving quality, helping to keep people healthy, reducing health inequalities, shaping care and services around the needs of the patient and making better use of the skills of the NHS staff. It was this last principle that was developed in the document 'Pharmacy in the Future: implementing the NHS Plan', (Department of Health, 2000b) published later the same year. This set out the government's plans for greater use of pharmacy and pharmacists in the NHS recognising that

"Pharmacists are highly qualified professionals, whose skills the NHS has been under-utilising for too long" (Department of Health, 2000b).

For patients the strategy created a road map to help them use their medicines more effectively, through better access to pharmacy services. These services were to be created by improving the skill mix within pharmacies to free pharmacists from the dispensing process, by increasing the number of pharmacies as well as integrating existing ones into the NHS, by creating legislation changes to allow pharmacists to make minor alterations to prescriptions without contacting the prescriber, by reclassifying medicines to P status, and by developing Patient Group Directives (PGDs) to enable access to a wider range of medicines. Importantly for community pharmacists, the strategy recognised them as NHS healthcare professionals and made a commitment to the development of an Electronic Prescription Services (EPS) and a commitment to care record access in community pharmacy settings.

Throughout the spring of 2002 the government began to develop the strategy for 'Delivering the NHS Plan' (Department of Health, 2002a). Published in April, this document discussed the steps to be taken to reform funding flows. Its political foundations were

rooted in patient choice, providing greater plurality in the health service and increasing the power of front line clinical staff.

At the same time the late Dereck Wanless – a former banker and adviser to the labour party - released his first ‘independent’ review of the resources requirements of UK health departments for the next twenty years (Wanless, 2002). His report described a vision for the Health Service in 2022, where quality, access and patient centred care were at the core. *Securing Our Future Health: Taking a long term view*, detailed the resources required and the investment needed to build capacity for the future and highlighted how levels of patient engagement in self care would proportionally influence future healthcare expenditure. His recommendations included improving the IT infrastructure, renewing the estate and investing in the promotion of good health and disease prevention. Wanless also promoted the concept of a ‘whole system’ response to future costs that shifts healthcare away from relatively expensive secondary care environments towards comparatively cheaper primary care settings. This concept began to feature prominently in labour health policy.

In May 2002 the government endorsed the proposals of the Medicine Control Agency (MCA)¹⁵ to significantly shorten the process of medicines reclassification from one legal status to another, as part of its commitment to improved medication access (as detailed in the NHS plan). At the time it was anticipated that this strategy would enable community pharmacists to manage common minor ailments and some chronic conditions (Department of Health, 2002c). Yet in 2004, the reclassification of the first chronic disease medication, simvastatin, under the brand name Zocor, proved to be a commercial failure (Hansford et al., 2007). This was due to concerns about the efficacy of the 10mg dose, the lack of support from general practitioners and the limited associated pharmacy resources required (Paudyal et al., 2012). But also if the drug was needed then patients could acquire it on prescription at less or no cost.

Despite this set back, the Department continued to push for a changed role, looking systematically at the barriers to new responsibilities for pharmacists. The Department of Health recognised that community pharmacy “*must make much better use of all its staff if it is to meet developing patient and service needs*”. A discussion paper on the pharmacy workforce was published in the winter of 2002 (Department of Health, 2002b). This supported the expansion of the skill mix in community pharmacies. It described the

¹⁵ Now known as the Medicines and Healthcare Products Regulatory Agency (MHRA).

development of pharmacy technicians, drawing on examples of technicians in secondary care, and suggested piloting the dispensing and supply of medicines by qualified technicians without the personal supervision of the pharmacist. It was envisioned that this would allow community pharmacists to extend their roles in medicines management schemes, supplementary prescribing and Local pharmaceutical services (LPS).

Although pharmacist prescribing had been supported in 'Implementing the NHS plan' in 2000, (Department of Health, 2000b), it took until April 2003 for supplementary prescribing, under an agreed clinical management plan, to become legal (Department of Health, 2003b). By contrast, pharmacists were almost a decade behind nurses who were conferred some prescribing rights in 1992, following recommendations in the 1986 Cumberledge report, which were subsequently reinforced three years later by the Crown report. To some extent this demonstrates the political weakness of the pharmacy lobby when compared to other health care professionals. But this may also be a reflection that such a role breaks the traditional - doctors prescribe, pharmacists supply - hierarchy in the health service and as such is a threat professional boundaries.

The importance of community services was set out in 'Tackling Health Inequalities' (Department of Health, 2003c) which further supported extending pharmacists' roles to address health inequalities. Yet, little tangible difference was actually observed in pharmacy practice.

The 'under-utilised' expertise of community pharmacists was again explicitly recognised in the document 'A vision for pharmacy in the new NHS' (Department of Health, 2003d), which documented the progress made in the first three years since 'Pharmacy in the Future' (Department of Health, 2000b). It stated:

"There is considerable scope to build on the current achievements in public health and pharmacists are probably the biggest untapped resource for health improvement".

A vision for pharmacy went on to set out a continuing programme of pharmaceutical service reform by attempting to identify specific roles that pharmacists could play in improving the health of the public. Examples included: supporting patients wishing to care for themselves; responding to the needs of patients; helping to deliver the aspirations outlined within National Service Frameworks (NSF); and helping to promote public health, tackling health inequalities and improving general health. These recommendations were

followed by a Department of Health commitment to ease restrictions on the opening of new pharmacies, to expand the range of medicines available without prescription and to promote minor ailment schemes for members of the public exempt from prescription charges (Department of Health, 2003a).

Commitment to reducing health inequalities was reiterated in 2004 as Wanless produced his second report, which emphasized the cost effectiveness of prevention (Wanless, 2004). His report concluded that only with a public fully engaged in health could society meet the future challenges facing the NHS. Targets to achieve this were set in June 2004 with the publication of the 'The NHS Improvement Plan' (Department of Health, 2004f). These were for CHD, cancer, smoking, obesity, teenage contraception, health inequalities, long term conditions and health outcomes. To help achieve these goals the Government published a framework for health and social care standards (Department of Health, 2004e), followed later that year with the White Paper 'Choosing health: making healthy choices easier' (Department of Health, 2004a). This set out the government's plans to encourage people to make healthier decisions about their lifestyle prioritising obesity, smoking, sexual health, mental health and alcohol abuse. Yet, pharmacist's explicit contribution to these changes was relatively minor. Indeed, during this period, prescription volumes continued to grow, and pharmacists became further entrenched in their dispensing roles.

During late 2003 and early 2004 the government negotiated with healthcare professionals over their contracts as outlined in the NHS plan (Department of Health, 2000a). In April 2004 the new general medical services contract for GPs was implemented. This linked a significant proportion of GP income to Quality and Outcomes Framework targets (QOF) in a drive to improve the quality and consistency of primary care. Community pharmacy, through the Pharmaceutical Services Negotiating Committee (PSNC), negotiated a new national contract which came into force in April 2005 (PSNC, 2004). The new pharmacy contract was a bid to create a remuneration model that was less reliant on prescription volume almost two decades after the Nuffield report recognized this as being inappropriate (The Nuffield Foundation, 1986). This built upon the development of the local pharmaceutical services (LPS) and was intended to move contractors towards service delivery (the contents of the contractual framework are discussed in more detail in chapters three and six). An important innovation included in the framework was nationally advanced services, the first of which was the 'medicines use review' (MUR)¹⁶.

¹⁶ The significance of the MUR to the pharmacy profession is discussed further in chapter 4.

At the beginning of 2005 the Department of Health published "*Self Care – A Real Choice*" (Department of Health, 2005e) which developed policy ideas to empower the public to treat themselves. Again the report recognised community pharmacy as a source of advice for minor ailments. Indeed, pharmacists' role in helping to manage long term conditions was also made more explicit in the same year with the publication of 'Supporting People with Long Term Conditions' (Department of Health, 2005f). Yet, these recognitions in policy failed to translate into economically viable income streams. As a result community pharmacists continued to focus most of their attention on the fast and efficient supply of prescription medicines.

The Department of Health developed its strategy for implementing the priorities outlined in *Choosing Health, making healthy choices easier* in the spring of 2004 (Department of Health, 2004a). This was followed by a detailed map for pharmacy (Department of Health, 2005a), which recognised the contribution that pharmacists could play in improving the health of the public. The plan identified important service priorities for pharmacy such as signposting to other healthcare providers, obesity management, smoking cessation programs, sexual health advice, drug misuse schemes, and the management of long term conditions. While this represented a positive policy message for pharmacy, there remained concerns that the report's ambitions were unachievable due to the current workforce arrangements.

Once again, in response to a pharmacy workforce consultation, proposals were put forward to amend supervision requirements (Department of Health, 2005c) to allow pharmacists to take on these wider public health responsibilities. This recommendation to change supervision and personal control requirement in the pharmacy is still one that current legislators are yet to resolve, as pharmacists retain personal liability for the workings of a pharmacy.

The extension of nurse and pharmacist prescribing was announced in the winter of 2005, allowing them to become independent prescribers (Department of Health, 2005d). Although prescribing was aimed at opening paths of opportunity for pharmacists, it is still only practiced by a relatively small number of pharmacists. A recent study suggests that difficulties in embedding prescribing by pharmacists into the structure of healthcare is making it hard to provide a sustainable service (Baqir et al., 2010a). The embedded structure of the healthcare system since 1948 has been that doctors write prescriptions and pharmacists dispense them. Pharmacist prescribing threatens to subvert this prescriber

dispenser separation. Therefore creating opportunities for these prescribers requires a re-definition of pharmacists' roles within healthcare. Indeed, the public have established expectations of health providers and tend to trust them to deliver familiar services, which in pharmacist's case is medication supply (Gidman et al., 2012).

Yet despite established expectations, a Department of Health consultation in 2005, which included over 40,000 people, identified that the public desired a wider range of healthcare professionals to be involved in disease prevention and health improvement. The government response was the White Paper *Our health, our care, our say* released in early 2006 (Department of Health, 2006c). It outlined four aims for the NHS: better prevention services with earlier intervention, more patient choice and a louder voice for people, more on tackling inequalities and access to community services, and more support for people with long term conditions. Services based around people with long term conditions were identified as an area in which pharmacists could actively improve the patient experience. A guide to support people in self care followed and further emphasised the support role that pharmacists could provide (Department of Health, 2006d).

Opportunity for specialist practice, developed out of the changing nature of pharmacists roles, culminated in the publication of a national framework for pharmacy in September 2006 (Department of Health, 2006b). This guidance made suggestions about how extended pharmacy services could be developed in local areas through the expansion of the pharmacy workforce. It outlined national standards for pharmacists' roles and for consultant posts in secondary care.

Further development of specialist practice in primary care arose in 2007 with the publication of the White Paper 'Our Health, Our Care, Our Say - a New Direction for Community Services', which emphasised the role for specialist pharmacy practitioners to support primary care. The first two Pharmacists with Special Interests (PhwSI), both from Bradford, became accredited in May 2008. Even with these initiatives, many pharmacists working in community struggled to specialise in a meaningful way. Meanwhile many of their colleagues in secondary care settings began to create specialist clinical posts and consultant pharmacist positions.

Despite a sustained policy effort to make better use of pharmacists skills, much of pharmacy practice remained unchanged, driven by dispensing (Blenkinsopp et al., 2009). The All Party Pharmacy Group (APPG) launched an inquiry into the Future of Pharmacy in

June 2007 due to concern that pharmacy was still an 'underused resource' and not sufficiently integrated into the NHS (All Party Pharmacy Group, 2007).

"...across the country, community pharmacy is not being utilised as effectively as it could be as a primary care resource" (All Party Pharmacy Group, 2007).

The work of the APPG helped to create a driver for the subsequent Department of Health pharmacy White Paper, '*Pharmacy in England: building on strengths - delivering the future*' published in April 2008. This set out the vision for pharmacy in the future and aimed to ensure the delivery of pharmaceutical services in the context of wider NHS strategy. This White Paper was heralded by the profession as the most significant document since Nuffield as it was believed to be a comprehensive map for the future of pharmacy in England. Yet, two years after its publication, a new government took office. It therefore remains unclear as to whether the aims of the pharmacy White Paper will continue to be implemented (Anon, 2010).

Many pharmacists and pharmacy organisations felt that the legal framework limited the ability of pharmacists to enhance their clinical role. A regulatory change that came as a result of the White Paper was the responsible pharmacist legislation to support pharmacists in developing their clinical role and contribution to healthcare services. Passed in October 2009, it allows the 'responsible pharmacist' to be absent from the premises for up to two hours in order to extend the range of pharmacy services offered. This was originally suggested in the Nuffield report.

"...it is a handicap for pharmacists that at present they are tied to their premises and, given modern methods of communication, we regard this as unnecessary. We think that the law should be relaxed to enable a pharmacist to leave the premises for a limited period to undertake professional activities elsewhere." (The Nuffield Foundation, 1986)

At the time this position was not accepted by the RPSGB who felt '*every prescription for a medicine must be seen by a pharmacist*' effectively keeping pharmacists tied to the dispensing role (Anderson, 2005: p132). This demonstrates an underlying tension between the argument put forward by those in policy circles that pharmacists are under-utilised and the desires of the professional body to maintain current practice.

Although the Department of Health has indicated that it intends to develop 'remote supervision' (i.e. supply of prescriptions without the pharmacist physical presence in the

pharmacy) further, opposition has come from several pharmacy bodies, in particular the Pharmacists' Defence Association. Many of the English pharmacy board members, elected in 2010, stood under a banner of 'stop remote supervision'. Despite an intention to make community pharmacists work more clinical orientated, early indications on the effect of the responsible pharmacist legislation suggest that it has failed in this aim (TNS UK Limited, 2011). Therefore the issue of supervision and personal control continues as a problem within pharmacy policy.

Economic Downturn

Despite a period of growth and investment for nearly a decade, the NHS like the whole public sector became subject to the global economic downturn in 2008. Following the collapse of several important banks, including Lehman Brothers in September 2008, the country - and world economy - entered an economic recession. Against this backdrop of economic uncertainty, David Nicholson- the chief executive of the NHS - sent a letter in August 2009 to trust chief executives setting out a policy for Quality, Innovation, Productivity and Prevention (QIPP).

This letter came on the back of several economic mandates written by David Nicholson which informed finance directors that the NHS needed to find £20 billion in 'efficiency savings' by 2015 as a result of 'extremely challenging' conditions caused by the economic downturn (Ball and Sawyer, 2009). This was later dubbed by Stephen Dorrell - the health select committee chairman - as the 'Nicholson challenge'. It was not long after this announcement that the media began to report 'cuts' to NHS front line services. Part of these efficiency savings were to be found through the QIPP program, which has been a follow up to Darzi's next stage review that had set out to improve the quality and efficiency of the NHS.

Ara Darzi - a leading surgeon - had been asked in 2006, by NHS London, to lead a review into healthcare provision across the capital. The report, Healthcare for London: A framework for action was published on 11 July 2007. Given his success in leading the project, Darzi was asked by the government to lead a review to determine the course of the NHS over the decade ahead, under a process known as the 'NHS Next Stage Review'. The overall review set out a vision for future healthcare, which was to be embraced by the NHS (Darzi, 2008). The final report updated traditional notions of professionalism and described a new accountability in clinical practice under a mantra of putting quality back into the NHS. In particular, this championed pharmacies as providers of prevention services

building on the pharmacy White Paper. In many respects Darzi's review outlined the boundaries for pharmacists by confining them to prevention and keeping people healthy, rather than treating disease. In doing so it re-iterated the medical hierarchy, keeping pharmacists from crossing professional boundaries.

“Liberating the NHS”

The coalition government came into power in 2010, ending the previous 13 years of a labour led NHS. Andrew Lansley, as Secretary of State for Health, introduced an ambitious program of change for the NHS, beginning in July 2010. Within months of becoming a minister he published the English NHS White Paper *Equity and Excellence: Liberating the NHS*. The aspiration contained within this White Paper was to create GP led commissioning groups, thereby disbanding Primary Care Trusts (PCT) and Strategic Health Authorities (SHAs). These proposals aimed to free the NHS from centralised bureaucratic input and remove the political micromanagement of the health service. However, the creation of a coalition government meant that the planned reforms for the NHS were not solely those that the Conservatives had created in opposition, but contained elements of Liberal Democrat policy. The result was far more wide reaching reform that had initially been anticipated (Timmins, 2012).

To many these changes represented a radical restructure of the health service. Of the changes, David Nicholson said '*It is the only change management system you can actually see from space-it is that large*'. Yet, many of the proposals were continuations of the previous labour policies, such as a focus on outcomes and quality following Lord Darzi's review, a drive towards competition and patient choice, foundation trust status for all hospitals, practice based commissioning, and the separation of provider arms for primary care trusts. Yet the pace of introductions and the scale of the changes all at once led these to be branded a revolution, rather than an evolution in policy terms, creating much opposition to the reforms (Timmins, 2012).

So great was the resistance to the policies that the Government was forced to have an unprecedented pause in the passage of the legislation. Yet the pause failed to silence many critics who were (and remain) sceptical about GPs abilities to take on these new commissioning roles and the ability of the NHS to cope with such significant change in times of economic austerity.

From the perspective of community pharmacy, *Liberating the NHS* is sparse in its specific mention of this professional group, but it did indicate the continuing drive for pharmacist's roles to move beyond the supply of medicines towards optimising their use:

“The community pharmacy contract, through payment for performance, will incentivise and support high quality and efficient services, including better value in the use of medicines through better informed and more involved patients. 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. Pharmacy services will benefit from greater transparency in NHS pricing and payment for services” (Department of Health, 2010: para 3.22).

The Health and Social Care Act 2012 that followed continues to support the shifting pattern of pharmacists' role in its implementation. For example, the White Paper made patient access to electronic health care records a priority, which may in the future permit a pharmacist access to medical information.

The impact of the reforms will depend on how they are implemented, as much as on the provisions within the Act. A detailed debate on their relative merit is beyond the scope of this thesis, although its influence in the collection of data throughout this project should not go unmentioned¹⁷.

Section Summary and Thoughts

The narrative presented here has shown how successive policy mandates have sought to change and control the way that healthcare is delivered. A summary of these policies is presented in table 1.1. Beginning with the Griffiths report in 1983, but seen more recently with the 'Nicholson challenge', managers have acted more extensively to control resource use in the NHS, often against professional desires.

As Nye Bevan is famously quoted as saying at the inception of the NHS

“We shall never have all we need. Expectations will always exceed capacity. The service must always be changing, growing and improving – it must always appear inadequate” (Bevan, 1948).’

¹⁷ An excellent overview of the development of this policy is provided in *Never Again* (Timmins 2012)

Yet until recently the controllers of access, and the managers of resources, were the same people, creating a significant internal conflict. In this position, healthcare professionals can exploit these opportunities for personal profit, although the theoretical basis for not exploiting consumers is professionalism. As described previously, there are two other mechanisms used to cope with this situation. The first is the market based logic of consumerism, which has begun to increasingly contribute to healthcare policy. The second is the logic of managerialism, which since the advent of Griffiths has become a central form of controlling work. Indeed these represent the arguments of private sector versus public sector, and bureaucracy versus competition which have dominated healthcare policy for the last half century.

From a policy perspective the government, through the Department of Health, have attempted to embrace all of these concepts. But arguably they have failed to push the profession down any path adequately. Despite their attempts at reform, there remain several professional barriers for pharmacists that have yet to be adequately resolved.

First is the challenge of 'under-utilisation'. In the middle part of the last century, driven by staff shortages and a growing need for ward based expertise, hospital pharmacists embraced new ways of working with doctors, nurses, and patients. Observing this the government recognised that community pharmacists were also equally capable of taking on greater roles. This led to community pharmacists being described repeatedly as an 'under-utilised' resource in policy. That is as a group whose knowledge and expertise could be developed to enhance patient care. This view has been continually reasserted in areas from the support of common minor ailments to the management of long term conditions. However, this position is conflicted. Pharmacists are being encouraged to move away from the supply of prescription medicines. But there are an increasing number of prescription medicines that require safe and accurate supply, and yet no widely available services exist which embrace these 'under-utilised' skills. This is in contrast to the development in hospital pharmacy where clinical ward based services are commonplace.

Secondly, the development of the community pharmacy workforce and how this aligns with the overall supervision of a community pharmacy has also received continuous attention. In particular, the extent to which pharmacists must oversee the supply process has been a contentious issue to which there is yet to be an adequate resolution. Repeated calls for better use of skill mix in community pharmacy have failed to be enacted. The

profession's desire to maintain control of supply, which is arguably their defining role in the health service, has limited the ability of new models of practice to develop.

Thirdly, motivated by a desire to deliver more health care in primary care settings, attempts have been made to integrate pharmacists with the rest of the NHS, again without adequate resolve, with many pharmacists practicing in isolation.

Fourthly, the boundary of healthcare professionals has created tensions in the delivery of healthcare services. In particular, the relationship between general practitioners and pharmacists has been a constant source of strife that has been played out in policy documentation (Bryant et al., 2009). Defining and maintaining professional boundaries has been seen most acutely in the area of prescribing (Baqir et al., 2010a), but persists in other areas where the dominance and power of the medical profession has been changed (Eaton and Webb, 1979).

Professional behaviour is itself subject to corrupting forces, due to the economic rewards that are given to professionals as a result of their work. For this reason the state has sought to regulate and control professionals in order to protect consumers and the wider public. This regulation is not without its drawbacks, not least the limitation it places of professional autonomy in practice. The dynamic relationship between the state, society and the professionals is the topic of discussion for the next section of this chapter.

Table 1.1 – Key Developments in Community Pharmacy History (1949-2010)

Year	National Health Service Policy	Pharmacy Specific Policy	Prescribing	Healthcare Practitioner Regulation
1948	Creation of the NHS			
1952		Boots Self Selection Case		
1958	Report on the Control of Dangerous Drugs and Poisons in Hospitals (Aitken Report).			
1965		RPS fail in call for restriction in pharmacy trading (Dickson Case)		
1966		Foundations of the 'clinical pharmacist' in Hospitals		
1970		Report of the working party on the Hospital Pharmaceutical Service (Noel Hall Report)		
1979	Margaret Thatcher elected prime minister	Royal commission into the national health service (Merrison) highlights underused role of pharmacists.		
1981		Gerard Vaughan makes announcement at BPC		
1983	Griffiths report on NHS management			
1985		NHS announced 'black list' of drugs		
1986		Pharmacy: the report of a committee of inquiry appointed by the Nuffield Foundation; RPSGB and NPA begin public health campaigns	Cumberledge Report recommends nurse prescribing	
1989	<i>Working for patients</i>		Crown report on recommends expansion of prescribing	
1990s		Hepler and Strand publish principles of pharmaceutical care		
1991	<i>Patients Charter</i>			
1992	<i>The health of the nation: a strategy for health in England</i>	Joint RPSGB/DH report - <i>Pharmaceutical Care: The future for community pharmacy.</i>	Nurse prescribing becomes legal	
1992	Trusts judged against performance to patients charter			
1995		Pharmacy in a New Age Consultative papers		
1996		The New Horizon (PIANA)		
1997		Building the Future (PIANA)		GMC hearing into Bristol Cardiac Surgery begins
1999	<i>Saving Lives: Our Healthier Nation</i>			Medical Professionalism Project
2000	Tony Blair pledges investment in the NHS; <i>The NHS Plan: A plan for investment. A plan for</i>	<i>Pharmacy in the future: implementing the NHS Plan. A programme for pharmacy in the National</i>		Harold Shipman commits murders

	<i>reform;</i>	<i>Health Service.</i>		
2001				Kennedy Report on Bristol deaths; Redfern Report on Aldery Hey.
2002	<i>Delivering the NHS Plan. Next steps on investment. Next steps on reform;</i> Wanless Report long term health trends; Wider access to medicines to allow patients to manage their own healthcare;	<i>Pharmacy workforce in the New NHS: Making the best use of staff to deliver the NHS Pharmacy Programme Pharmacy workforce in the New NHS: Making the best use of staff to deliver the NHS Pharmacy Programme</i>		
2003	<i>Building on the best: Choice, responsiveness and equity in the NHS;</i> <i>Tackling health inequalities: A Programme for Action Tackling Health Inequalities;</i>	<i>A vision for pharmacy in the new NHS</i>	Pharmacists supplementary prescribing legal - Supplementary prescribing by nurses and pharmacists with the NHS in England a guide for implementation	
2004	Wanless - Securing good health for the whole population: Final report; <i>The NHS Improvement Plan: Putting people at the heart of public services;</i> National Standards, Local Action: Health and Social Care Standards and Planning Framework 2005/06 – 2007/08; <i>Choosing health making healthier choices;</i> New GP contract		Shipman inquiry reports; On being a doctor medical professionalism for better patient care;	Committee of Inquiry - independent investigation into how the NHS handled allegations about the conduct of Clifford Ayling; Committee of inquiry to investigate how the NHS handled allegations about the performance and conduct of Richard Neale, Department of Health;
2005	<i>Self Care - A Real Choice. Self Care Support - A Practical Option;</i> Supporting People with Long Term Conditions. An NHS and Social Care Model to support local innovation and integration;	New pharmacy contract; <i>Choosing health through pharmacy. A programme for pharmaceutical public health 2005-2015;</i> Making the best use of the pharmacy workforce: Consultation outcome.	Independent prescribing nurse and pharmacist prescribing powers extended;	The Kerr/Haslam Inquiry full report.
2006	<i>Supporting people with long term conditions to Self Care. A guide to developing local strategies and good practice;</i>	WHO and FIP endorse pharmaceutical care; <i>Our health our care our say;</i> <i>Implementing care closer to home – providing convenient quality care for patients: A national framework for Pharmacists with Special Interests</i>		Foster Review; <i>Good doctors, safer patients: Proposals to strengthen the system to assure and improve the performance of doctors and to protect the safety of patients;</i>
2007	<i>Our Health, Our Care, Our Say - a New Direction for Community Services</i>	APPG Inquiry into Future of Pharmacy; RPSGB commissions Clarke Inquiry;		<i>Trust, Assurance and Safety - The Regulation of Health Professionals in the 21st Century;</i> Report of the working party on professional regulation and leadership in pharmacy;
2008		<i>Pharmacy in England : building on strengths delivering the future;</i> First PwSI accredited		

2009	Nicholson proposes QIPP agenda; "Nicholson Challenge" to save £20 billion announced	Responsible pharmacists legislation enacted		
2010	<i>Equity and Excellence: Liberating the NHS.</i>	Pharmacy Order; GPhC begins taking responsibility for regulation of pharmacists		

Professional Regulation

Successive governments have sought to assert their control over the regulation of professionals. This has happened in tandem with the developments previously described that have sought to extend community pharmacy practice. The political requirement to control the power of the medical profession came to head in October 1997 when the General Medical Council (GMC) began a hearing into the high mortality rate of 15 paediatric cardiac surgery cases at the Bristol Royal Infirmary (Kennedy, 2001). The subsequent report, *Learning from Bristol: the report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary 1984 -1995* published under the chairmanship of Prof Ian Kennedy – an academic lawyer who specialises in health and ethics - made fundamental challenges to the regulation of healthcare professionals and the workings of teams within the NHS. This report made it clear that the previous self regulation models of the medical profession had failed to protect patients, and had resulted in avoidable deaths.

To this point medicine, society and the state had interlocked to form a stable triangle of political forces based on a mutual exchange of benefits. The state provided healthcare to society through the NHS, delivered to an appropriate standard by medicine. In doing so, the state gained respect for its legitimacy from society whilst relying on the medical profession to covertly ration public healthcare expenditure. Through its fulfilment of obligations to both, medicine received the trust of society and the privilege of self-regulation. Yet, this triangle began to decline, mainly due to a weakening of public trust in the medical profession and wider public dissatisfaction with medical attitudes (Stacey, 1989; Stacey, 1992; Rosenthal, 1995; Allsop and Mulcahey, 1996; Smith, 1989).

Trust in the medical profession was further reduced by the high degree of media attention that followed the case. This resulted in a trial for the whole of the medical profession who were seen to be more concerned with protecting their members than the public. At the same time other alleged medical misdemeanours came to light, including a large store of human organs held at Alder Hey Children's hospital without consent. A separate inquiry, chaired by Michael Redfern – a barrister who specialised in medical negligence - further increased public scrutiny of medical practice (Redfern, 2001).

Despite the disquiet of the medical profession there was full public support for new radical measures to change medical regulation. These drew further momentum when it was revealed that Harold Shipman, a general practitioner from Hyde, had murdered 15 of his patients. His imprisonment in 2000 led to a series of public reports to safeguard patients

(The Shipman Inquiry (Chairman: Dame Janet Smith), 2004). This began with an overhaul of the GMC (General Medical Council, 2001), and led to a succession of regulatory and managerial bodies such as the Council for Healthcare Regulatory Excellence, the Healthcare Commission, the National Clinical Assessment Authority and the National Patient Safety Agency that all aimed to put 'quality' back into the NHS. Public distrust was further bolstered by investigations into malpractice by Clifford Ayling (Department of Health, 2004b) an obstetrician and gynaecologist who worked in Kent; Richard Neale (Department of Health, 2004c), a consultant obstetrician and gynaecologist who worked in a number of hospitals in North Yorkshire; and William Kerr and Michael Haslam (Department of Health, 2005b), two consultant psychiatrists who practiced in North Yorkshire.

Commentators such as Salter (2001; 2003; 2004) believe these developments mark a watershed in the relationship between the state, health professionals and health service users¹⁸, disrupting the previous 'iron triangle'. Not only did these medical failings provide justification for greater government intervention in previously professional realms, but they have also (whether intentionally or not) been used to impose greater managerial control over the healthcare system (Salter, 2001). While previous policies had disrupted this 'iron triangle', the change in tone created by these cases meant that for the first time these conflicts were visible to the public and therefore could be used to garner public support for change.

These revelations brought the very notion of professionalism into the spot light. The launch of the Medical Professionalism Project in 1999, organized by the European Federation of Internal Medicine, the American College of Physicians, the American Society of Internal Medicine, and the American Board of Internal Medicine was a response to changed professional values. Doctors were:

"experiencing frustration as changes in healthcare delivery systems in virtually all industrialised countries threaten the very nature and values of professionalism"
(Medical Professionalism, 2002).

This led to a raft of projects to redefine medical professionalism in modern society (Askham and Chisholm, 2006; Picker Institute Europe, 2008; Royal College of Physicians, 2005).

Richard Horton, editor of the Lancet and the prime author of a report on medical

¹⁸ These changes (although being seen globally) were seen particularly acutely in England due to the politicised role that the NHS plays. There is an imperative for the government to act when tragedies happen. In this sense England has become more overzealous in its professional regulation of these groups.

professionalism from a working party of the Royal College of Physicians made it clear that a partnership between government oversight and regulation and medical professionalism was needed.

“The chaos that is modern health-care regulation has left the health care professions in disarray. The political consensus is that doctors do not set sufficiently high standards of practice; that even when they do, they fail to act when those standards are not met; and that the profession has shown itself to be insufficiently concerned about protecting patients. The result is inquiry after inquiry, law after law, to bring doctors to heel, to make them more ‘accountable’”(Horton, 2005).

Yet these inquiries failed to resolve the debate on medical freedom and autonomy, but they did provide political legitimacy for the government to intervene. Following a review of the regulation of the medical profession (Department of Health, 2006a), the Department of Health called for a review of the non-medical health professions including pharmacy, nursing, dentistry, optometry, chiropractice and osteopathy (The Foster Review, 2006). These inquiries culminated in the government White Paper, *Trust, Assurance and Safety - The Regulation of Health Professionals in the 21st Century* (Department of Health, 2007b), which led to a complete overhaul of the regulation of medical and allied professions, including pharmacy.

A Department of Health working group chaired by Lord Carter of Coles examined the regulation of pharmacists in the wake of *Trust Assurance and Safety*. This working group for pharmacy recognised the

“transformation underway from a “product-focused service” to a truly clinical profession, directly caring for patients and the public” (Department of Health, 2007a: p4)

The group recommended the formation of a General Pharmaceutical Council to regulate pharmacists that was transparent to the public and the profession, and therefore suggested the separation of professional and regulatory functions from the current regulator, the RPSGB. Ministers accepted the working party’s recommendations and established the Pharmacy Regulation and Leadership Oversight Group (PRLOG). The primary purpose of this group was to oversee the establishment of a new regulator for pharmacy – the General Pharmaceutical Council (GPhC), advising Ministers accordingly.

In 2007 the RPSGB also commissioned an independent inquiry, chaired by Nigel Clarke (a public affairs consultant with a background in government relations, public policy and healthcare), into the possible options for a new professional body for pharmacy and the separation of the regulatory and professional roles. After nearly a year of deliberations a subsequent 'transitional committee' was then appointed and charged with implementing Clarke's prospectus for pharmacy. The process to create a new professional body meant changing the Royal Charter of the RPSGB and lengthy consultations on how this new body should act. This created many internal debates within pharmacy, consuming much time and resource, and distracting the profession from the wider changes in the healthcare system.

The foundations for a new regulator for pharmacy as described by PRLOG were set in motion. The Pharmacy Order 2010, which successfully completed its passage through parliament in February 2010, allowed the formal handover of regulatory powers from the RPSGB council to the GPhC in late 2010. This created both a new regulator for pharmacy to ensure minimum standards of patient safety and care and a new professional body to lead, develop and nurture the pharmacy profession.

The upheaval in the structures at the top of the profession should not be downplayed. To maintain their professional credibility, the profession's elite exerted a significant amount of effort realigning the regulatory systems within pharmacy. Therefore on the one hand these regulatory changes gave the public greater influence and control over the pharmacists, helping to build public trust in pharmacists. Yet on the other hand they removed the profession's self-regulation, a principle component of professional autonomy. It is this notion of professional autonomy that the next section seeks to address.

Professionalism in Community Pharmacy

The new professional body has set out to understand the constraints on current pharmacy practice and to work with the profession to develop future roles, in a function akin to that of a medical college. However, the new professional body will be mindful of the body of literature that has written the obituary of the pharmacy profession, with pharmacists described as an incomplete (Denzin and Mettlin, 1968), marginal (McCormack, 1956) or quasi profession (Birenbaum, 1982).

Sociologists articulated the main difficulties facing pharmacy during the 1950s to 1970s. The sociological literature began to describe how pharmacy had failed to achieve and maintain professional status. In part, the replacement of smaller retail pharmacies by larger

multiple entities was seen as a problematic structural change, pressurizing pharmacists to concentrate on aspects of commercial endeavour rather than professional skills. Shaw (1972) argued that this reduced level of autonomy began to result in pharmacy being perceived less positively by the public.

The limited autonomy of the profession, coupled with the inability of pharmacy to have complete control over the social object that justifies its existence, led Denzin and Mettlin (1968) to brand pharmacy an 'incomplete profession'. Their analysis influenced later sociologists, who continued to highlight the barriers to pharmacy achieving complete professional status. In particular they focused on the spread of technology in pharmaceutical manufacture, as previously noted, which has caused pharmacists to lose their main function as compounders of medicines.

The response to this loss were new models of practice, advocated by the elite groups within the occupation (Birenbaum, 1982). Birenbaum (1982) in the USA contented that 'clinical pharmacy' was needed to 're-professionalise' pharmacy, suggesting the removal of technical tasks to free pharmacists to undertake more professional ones. While some, such as Holloway (1986) criticised Birenbaum's concept as too simplistic for failing to address the dynamic nature of occupations, his overall concept for developing the profession gained credence.

Dingwall and Wilson (1995) reanalyzed the previous claims of Denzin and Mettlin, which they argued lacked original data. Instead they believed that pharmacy did possess many professional traits and was deserving of professional status. Harding and Taylor (1997) on the whole agreed with Dingwall and Wilson's analysis, recognising that pharmacy had increasingly striven to define and establish its role in the face of technological change. However, they argued that pharmacy has the knowledge to control the symbolic transformation of a pharmacological entity (a drug) into a social object (a medicine) and that that pharmacy had failed to capitalize on this when defining its professional role.

In contrast to Birenbaum (1982), Harding and Taylor made a case suggesting that the extended clinical role could be damaging to the professional status of pharmacy. They argued that these activities take the pharmacist away from dispensing and therefore remove the focal point needed for transforming drugs into social objects. They contend that

...strategies which displace the activities associated with dispensed medicines, and emphasise those associated with technology and routinised advice giving, may have a de-professionalising effect, when drugs lose their centrality to pharmacists' activities.

Yet, Harding and Taylor's argument appears to be in contrast to the 're-professionalisation' strategies that followed at the turn of the millennium as has been described in the previous historical analysis reported in this chapter. They recognized that the simplification of the technical skills required in the dispensing of prescription medicines had been equated to a reduction in importance. But they felt that without professional input, presenting a prescription form for a drug would represent no more than a simple exchange, whereas with a professional involved, there is opportunity for symbolic transformation from 'drug' to 'medicine'. Therefore, they argue that pharmacists should consolidate their skills and focus their knowledge on drugs and medicines, rather than spreading themselves too thinly with extended services.

However, the corporatisation of community pharmacy is seen by some to be undermining re-professionalisation (Bush et al., 2009). Indeed, an increasing number of pharmacists are being recruited as employees of multiple corporations. These organisations are forced to adopt distinct working practices in order to operate economically, effectively and competitively. Yet in doing so, they also exert greater control over their workforce. As Harding and Taylor (1997) state

"Successful large bureaucratic organisations require rational routinized procedures for maximizing efficiency, and this is reflected in their delivery of rationalized, standardized pharmaceutical services dictated by company policies. Thus the autonomy of pharmacist employed in such organisations to practice discretion in their occupation is precluded" (Harding and Taylor, 1997: p556)

These companies have used efficiency as a pseudonym for control and power over professional decision making. It has been argued that a future breed of "McPharmacists" may be subjected to de-skilling and ultimately perform solely routinized actives (Harding and Taylor, 2000). Bush et al (2009) contend that in divergence to patient interest, pharmacists working in a supermarket are unable to supply the emergency contraceptive pill to those under 16, even if an appropriate patient group direction is in place, due to nationwide standard procedures.

While some use the commercial imperatives of a community pharmacy as a stick with which to beat the profession, it is the same stick that helps to support the profession. Until the 19th Century, the public could purchase whatever medication they saw as fit. For Chemists and Druggists, their success depended on meeting customer needs. While this liberty, have since been eroded by medicines legislation, the underpinning principle of responding to the 'sovereignty' of the patient remains an abiding principle of pharmacists work today.

Occupational groups have a dynamic relationship with society. They begin to become professions through professionalization, can then lose their professional status, 'de-professionalisation', or indeed regain professional status through 're-professionalization'. In light of the historical development of community pharmacy outlined above, it is evident that community pharmacists have passed through these different stages and continue to drift between de-professionalisation and re-professionalisation. At the heart of this professionalism question lies 'autonomy' (Freidson, 2001).

Autonomy of Practice

Edmunds and Calnan (2001) (in contrast to Harding and Taylor) furthered the debate on the re-professionalisation of pharmacy by suggesting that the extended role of pharmacists' provided an opportunity for the enhancement of pharmacists' professional status. Central to their argument was the notion of autonomy in practice, which Freidson argues is the distinguishing characteristic of a professional (Freidson, 2001).

The concept of professional autonomy is often depicted in professional definitions as self-governance and self regulation. As outlined above, regulations imposed since 1997 have removed the self-regulation governing many professionals, fundamentally reducing their autonomy. Rather than a single entity, Edmunds and Calnan (2001) suggest that autonomy can be contextualised in three ways, economic autonomy (control over remuneration); political autonomy (position to influence policy decisions); and clinical autonomy (ability to make clinical judgements).

For community pharmacists, their position as retailers would suggest a high degree of *economic autonomy*. However, as discussed later in chapter 3, contractors accrue the majority of their income from the NHS, which is predominately governed by the negotiations of the PSNC and the occupations elite. Furthermore the majority of

community pharmacists are employed, and therefore their economic income is dependent on the terms of their employers limiting their economic autonomy¹⁹.

Political autonomy has been difficult to achieve given the political complexities of pharmacy. The wide range of career prospects in a profession of a relatively small number (circa 40,000) from journalism, industry, academia to the more traditional community pharmacy on the high street where the vast majority of pharmacists now practice, limits the united identity of this profession creating fragmentation. Although the RPSGB has been a professional advocate for the pharmacy profession, its role as both a regulator and a professional body has hindered its ability to be a true political advocate. As with any political organisation, pharmacy needs a manifesto of which to act. But at present it lacks sufficient vision or purpose as to where it should progress.

Clinical autonomy is limited because pharmacists in the community sit in the shadow of physician decision making. The ability to use their clinical autonomy to counter-prescribe is restricted by medicines legislation, within stringent product licenses. These licenses have enabled pharmacists to supply more medicines – increasing the collective autonomy- but under more restricted conditions – decreasing individual autonomy.

Armstrong (2002), building on a debate raised by Freidson in the 1980s about professional organisation revealed the tension between the maintenance of autonomy of the profession as a collective and the autonomy of the individual practitioner. To this end, Freidson had suggested that an administrative elite, often grouped around the academy and professional colleges, was emerging to control the work of individual practitioners. Under this approach, the 'freedom' of the profession was justified politically by an elite and implemented through intra-professional controls over the content of everyday practice (Freidson, 1983). Armstrong (2002) observed that 'evidence based medicine' has acted in this was to enable medicine collectively to resist at least some of the challenges to 'traditional autonomy', yet in doing so it has limited the individual autonomy of practitioners (Armstrong, 2002).

Parallel examples of this tension can also be drawn from community pharmacy. For example, in 1995 the Royal Pharmaceutical Society instructed all community pharmacists to implement protocols covering the procedures to be undertaken when a medicine is requested by a customer. This had two functions, on the one hand it formalised practice and re-established pharmacists professional role as the gatekeeper to non-prescription

¹⁹ The PDA estimate that 90% of pharmacists are employees or locums.

medicines driving up the collective autonomy of the profession to supply proprietary medicines. On the other, it limited the individual autonomy of each pharmacist. The RPS has since introduced further overt regulation of practice through professional practice codes and the creation of independent regulatory bodies²⁰. Indeed, this is in itself a 'managerial logic' of standardising treatments for efficiency and effectiveness.

However, individual clinical autonomy has also been subject to more covert labour control through commercial retail managers from within large multiple run pharmacy organisations. This has led to an employer versus employee contest for control. Some suggest that this conflict between labour controls exerted by commercial enterprise and clinical autonomy is at the heart of the profession's marginality (McCormack, 1956), a dilemma that has been repeatedly observed (Benson et al., 2009). Shaw (1972), McCormack (1956), and more recently Bush et al (2009), have argued that an increase in multiple owned businesses has been detrimental to professions' image because pharmacists have been pressurized to emphasize their business role at the expense of their professional role. Particularly in relation to advanced services, evidence is emerging that pharmacy companies are threatening disciplinary action to employee pharmacists who fail to meet targets for MURs (Bush et al., 2009).

The message relayed from this evidence is that both internal and external pressures at the economic, political and clinical levels are assaulting the autonomy of individual pharmacists. This prevailing trend in pharmacists' autonomy represents an important theme that is explored further in this thesis.

The Three Logics in Community Pharmacy

The argument within this chapter goes full circle to return to the arguments of Freidson (2001) described in the early part of this chapter. He contended that there are three logics concerning work in society. The first is the well-known logic of the free 'perfect' market, defined by Adam Smith. It postulates an idealised world (or model) where consumers are fully informed about the quality and cost of goods and services and are able to choose them rationally, to their own best interest. In doing so, value is measured by cost. In this world competition of the free market between suppliers drives efficiency. Put simply, this is a world driven by consumerism and the 'perfect' exchange of trade.

²⁰ This is an example of the re-stratification thesis.

The second of Freidson's logics is that of managerial control based on the 'Weberian' perspective of rational legal order. In this world all goods and services are planned and controlled by the administration of large organisations. Each organisation, whether private or public, is governed by an elaborate set of rules that establish the qualifications of those who can be employed to perform different duties. The effective planning and supervision of jobs standardises production to assure consumers of reliable products at a reasonable cost. In this world managers control those producing goods. The aim is for predictability and efficiency. Put simply, this is a world driven by managerialism.

Finally, the third logic is what Freidson defines as professionalism. In this world workers have specialised knowledge that allows them to provide important services with the power to organise and control their own work. It is enshrined in law that only these workers can offer particular services to consumers. Yet these workers do not abuse their exclusive rights because they are more dedicated to doing positive work for their own satisfaction and for the benefit of others than maximising their income. Therefore consumers and managers know that the work is of high quality at a reasonable cost. This world is driven by professionalism.

As Freidson acknowledges, none of these worlds exist because virtues are accompanied by vices. In unregulated markets, consumers must contend with deception and collusion to inflate prices. In organisations, inflexibility and monopoly can lead to poor treatment of consumers. Occupations may put economic advantage ahead of the good of their clients. Nonetheless, the world that we live in experiences elements of all three of these logics, and Freidson argues that all of these logics are required to counteract the negative effects of the others. Therefore, the policy question is not which of these logics to follow, but instead the precise composition of their mix.

However, we have seen the mix of these logics change over the last century. Consumerism and managerialism have both grown in their political acceptability, meanwhile professionalism, which represents occupational rather than consumer or managerial control, has suffered a loss. Indeed, the free market ideals of 'competition' and 'efficiency' have become the driving forces within much of policy formation. Furthermore the benefits of the private sector and the skilled management of firms have also gained credence. In many respects the UK is unique in the extent to which the mix of these logics has changed, due to the highly politicised nature of the NHS. However, general trends in decreasing

professionalism and increasing consumerism have been experienced in many other western countries (Timmermans and Oh, 2010) .

From this perspective, community pharmacists have also experienced the rise in both consumerism and managerialism. It is argued that these imposing logics have swung regulation from a position of protecting the interests of occupations to protecting the interests of the consumer. In doing so, the 'market shelter' afforded by professional status has been subject to greater regulation and bureaucratic control.

So far this thesis has explored current professional models of community pharmacy in light of the dynamic mix of the three logics in community pharmacy. The question to be considered is how these logics will progress in the future, and which will become the dominant force for community pharmacy business and professional models in the future. Indeed central to this is whether pharmacy is deserving of the third logic, professionalism, at all.

Defining the Research Question

The traditional functions of NHS community pharmacists and pharmacies were eroded during the first half of the twentieth century because of a transfer of responsibility for medicines manufacture to the pharmaceutical industry. This affected the social standing of the profession, as in the second half of the century did factors such as the extension of the 'prescription only' medicines category and increased (original pack) dispensing volumes. The latter decreased pharmacists' contact with the public as prescription volumes increased, while the former almost certainly impacted negatively on pharmacists' perceived authority in the UK.

Since 1948 the rising tide of prescriptions also acted to financially support community pharmacy businesses. They were, and are, paid a premium for the skilled services of pharmacists in medication supply. But recently even this source of security has been challenged. Computer and allied technological advances that have increased the level of automation in the supply process, and now even threaten to replace human labour in 'cognitive service' contexts such as giving information and advice.

Such trends may lead government and other service funders to question whether or not the premiums paid for the expertise of pharmacists in the supply of prescription medicines are required. In this country policy documents have from the early 1980s onwards repeatedly described pharmacists as being 'under-utilised'. This suggests that the centrality

of pharmacists to medicines provision is decreasing and/or that activities such as dispensing alone are being questioned as an adequate core foundation for professional status. A possible implication is that a more direct health improvement role is increasingly being expected.

Wider societal trends have also led to questioning of previously accepted 'paternalist' professional practices and opened the way to relatively assertive forms of consumerism in the health sectors of 'developed' societies. The extent to which this has as yet happened should not be overstated. But increasing 'lay knowledge' of medicines and the determinates of their appropriate use is arguably 'de-mystifying' pharmacists' (and to an extent medical doctors') roles through a weakening of their exclusive ownership of the knowledge base that defines their professional 'territory'. Even ignoring the significance of issues such as those relating to the supply of drugs in non-pharmacy outlets such as supermarkets and petrol forecourts, the 'normalisation' of many medicines seen not long ago as being at the cutting edge of scientific advance means that step-by-step the power enjoyed by pharmacists by virtue of their 'agency relationship' is declining.

Such trends point towards the 'commoditisation' of medicines supply. That is, the pushing down over time of unit dispensing fees to the lowest possible level consistent with public interests in safety and sustainability. Alongside – and possibly as a result of such pressures – the growing 'corporatisation' of pharmacy businesses in settings like that of the UK has led to an increasing number of pharmacists being recruited as employees. To promote efficiency and quality as defined in their terms, large bureaucratic pharmacy enterprises have implemented standardised practices and procedures, which act as a form of work control. Such procedures serve to limit individual professional 'autonomy' and arguably to weaken the traditionally defined professional status of pharmacists.

Reforms across the health care sector have in addition led to a rebalancing of external power and dependency relationships. Hence pharmacy is no longer self-regulated. Instead, the State has created the General Pharmaceutical Council, which is not answerable to the profession's members but ultimately to the public being served. Together, these forces may be taken to be driving a 'de-professionalisation' of pharmacy, characterised by pharmacists' power over their own working environment being systematically reduced.

The political elite or leadership cadre of the profession has attempted to counteract this trend towards 'de-professionalisation' by re-branding pharmacists as 'clinical' practitioners,

and by building on the successes achieved by hospital pharmacists in the 1970s. Members of the leading elite have attempted to move community pharmacy on from its 'traditional' technical and logistic function towards a new health care focused paradigm. This has manifested itself under many names, including 'medicines management', 'role extension', 'pharmaceutical care', 'medicines optimisation' and 'public health pharmacy'. All these terms suggest that pharmacists should embrace roles that support patients (pharmacy service users) to take medicines and behave in ways that further enhance health outcomes.

These approaches may be seen as 're-professionalisation' strategies. But in seeking to introduce them there is an associated 're-stratification' of professional responsibility. Seen from this perspective, the leaders of pharmacy in Britain (like those of medicine) have acted to extend managerial control over individual pharmacists through putting in place standardised procedures and new forms of control in order to retain more internal professional authority than would otherwise be possible. This has involved a subtle shift in the nature of professional, away from an emphasis on individual self-realisation towards collective discipline.

There has been, and remains, much debate as to the details of the strategies the evolving profession should embrace. Anderson (2002) has argued, for example, that a role in public health promotion should form a significant part of pharmacy 're-professionalisation', albeit that he has subsequently stressed that placing too much emphasis on seeking effectively to change health behaviours could result in common failure (Anderson, 2012). Taylor and Harding (1997) suggested that pharmacy should consolidate its knowledge and focus on making medicines 'meaningful social objects', while Edmunds and Calnum (2001) contended that the most appropriate path towards 're-professionalisation' runs via 'extended clinical roles'.

There is disagreement both internally and externally as to the best way to progress. But what is clear is that any successful 're-professionalisation' strategy will probably need to be cognisant of (or at least consistent with) both the commercial contexts within which pharmacists and pharmacies operate, and the profession's wider social environment. With respect to the latter, powerful external influences like that of the medical profession as well as public and political expectation may force (or require) pharmacy to develop down paths that are not necessarily the most rational or beneficial from an internal standpoint. In practice, no successful way forward can afford to ignore such realities.

Against this background and the current high degree of uncertainty regarding the part that (community) pharmacists will in future be able to play in health care this thesis seeks to understand and interpret data relating to the future business and professional development paths for pharmacy in England. It seeks to balance and explore the competing logics of commercialism, managerialism and professionalism, and address the central question:

How are business and professional practice models for community pharmacy in England in ten to twenty years time likely to be structured?

This was to be achieved through:

- Investigating the current practice of community pharmacists in England through a work sampling study (Chapter 2);
- Exploring the economic drivers behind current community pharmacy workload and practice (Chapters 3 and 6);
- Exploring the facilitators and barriers to the implementation of services into community pharmacy (Chapter 4);
- Mapping the development and implementation of policies in community pharmacy (Chapter 4 and 5);
- Analysing stakeholder perception of the future of pharmacy practice (Chapter 5); and
- Discussing future strategies for community pharmacy businesses (Chapter 7).

Chapter Conclusion

This chapter has sought to provide a thorough introductory grounding for the original research presented in the following chapters. Its main goals were to present a critical, comprehensive and structured overview of the literature relating to professional groups, to explore relevant aspects of the historical development of community pharmacy in England and to document the successive policy interventions that have sought to change the professional practice of community pharmacists.

Arguably, professional progress in all fields in part reflects political and economic struggles to attain and maintain control and autonomy in specific areas of activity, and to protect territory in the labour market in order to secure income and favourable working conditions. Seen from this viewpoint pharmacy as a profession, and particularly pharmacists working in the community, have during the twentieth century struggled to assert their identity and protect their economic and related interests. Pharmacy can be said to have undergone a process of 'de-professionalisation'.

This has led various academics, politicians and social commentators to write the obituary of the profession, arguing that pharmacy is no-longer deserving of such a special status in society. As noted above, the profession's members' place in their traditional domain of work, medicines manufacturing, has been lost to the pharmaceutical industry. Pharmacists' working conditions and practices are now rarely controlled by pharmacists themselves, but rather by (public and private) bureaucratic managerial structures. These may be supported by the profession's political leaders, who as in other professional contexts may seek to exert further control over 'their membership' in order to defend collective status. At the same time other social changes are placing more power in the hands of patients and consumers, and shifting the nature of the agency relationships between pharmacists and those they serve.

Such factors, when looking ahead to what follows in this thesis, may mean that as the twenty first century unfolds community pharmacy will cease altogether to exist in its current form. However, the conclusion offered in this thesis is that (community) pharmacy could rebound from this situation by incrementally re-defining its role and purpose. In his later work Freidson offers a lifeline for all professional groups by arguing that they have a legitimate and vital place in societies as and when they provide a form of settlement that neither market forces nor managerial structures can alone achieve. Community pharmacists have an opportunity to justify their professional status by demonstrably providing benefits to society that require the continuation of market shelters to provide protection from both counter-productive competition and inadequately informed external managerialism.

Seen from a financial perspective, pharmacists will only be able to attract premium incomes if they are able to show that their role in medicines supply and health care more broadly is more than simply a technical and logistic supply function, but instead a facet of health improvement to be achieved through the application of their unique abilities in areas such as risk management, safety, and service support. Such a justification of pharmacy could represent an effective 're-professionalisation' strategy, provided that it is genuinely based on value-adding contributions to enhanced public welfare rather than rhetorical sectional claims. With this in mind the next chapter turns to the question 'what do community pharmacists presently do?'

Chapter 2. What do Community Pharmacists do?

Chapter Introduction

As described in the previous chapter, pharmacists who once occupied their time compounding drugs into medicines are instead preoccupied with the comparably simpler manipulative tasks of dispensing pre-packaged dosage forms. This has moved pharmacists from being the creators of medicines from raw drugs, towards being the guardians of safe medicines supply. As this role change has taken place, successive policy documents have indicated the 'under-utilised' nature of community pharmacy, suggesting that pharmacists can use their scientific and clinical skills to greater effect (e.g. Department of Health, 2008a). However, it is unclear as to whether pharmacists are really 'under-utilised' or whether this is simply the rhetoric of the political elite to mask a re-professionalisation strategy. Therefore this chapter sets out to interpret this claim by finding out what community pharmacists actually do, by conducting a work study (Emmerton and Jefferson, 1996).

This chapter describes and contextualises current community pharmacy practice in England and outlines the current path from which future activities in community must progress²¹. The second section of this chapter describes a work sampling study conducted in community pharmacies across London, which is compared to a structured review of previous work sampling literature to establish how policy developments have affected community pharmacy practice over the past few decades. This allows conclusions to be drawn about the effectiveness of current policies designed to change pharmacists' patterns of work.

However, there are many different methods of observational research used in pharmacy practice, each with their own relative advantages and disadvantages. Therefore justification for the methodological approach adopted here provides the opening to this chapter.

²¹ This forms the basis for the exploring the path dependency of community pharmacy policy.

Methods of Observational Research in Pharmacy

The arguments put forward for studying the work practices of individuals began in the early industrialisation. It became recognised that understanding and then manipulating work practices could lead to superior employee performance and in turn superior organisational productivity. The origin of these techniques are often attributed to the social reformer Robert Owen, who in the early 19th century introduced an allocation of time for rest in order to allow workers to recover from fatigue which in turn improved production.

This work was furthered by Frank and Lillian Gilbreth. As a young building contractor, Frank discovered ways to make bricklaying a faster and more efficient process and sought to apply this efficiency elsewhere. The couple studied the work habits of manufacturing and clerical employees in all sorts of industries to find ways to increase output and make jobs easier. In doing so they reduced all of the movements of the hand to a basic set of 17 motions, which they named the therbligs (a reversal of Gilbreth). The individual elements such as grasp, and assemble, were recorded against time, creating the first 'time and motion' studies (Gilbreth, 1911).

These methods of work measurement were developed by industrial engineers and have since been applied across a range of settings, including healthcare. The popularity of work measurement rose in the last decade as a result of the development of 'lean production' and 'total quality management techniques' imported from Japanese car manufacturers. These approaches helped the Toyota car company to create successive gains over their competitors (Liker, 2004). As a result of the apparent advantage produced by these techniques, lean approaches were applied in many different settings, including an inpatient pharmacy (Hintzen et al., 2009). As a result the methodologies of work study have been subject to increased scrutiny from companies seeking to implement the lean principles of continual identification and elimination of waste.

The benefits of work study as a management tool in pharmacies has not gone unnoticed. In the 1970s work study formed a feature in the *Chemist and Druggist* magazine (Downing, 1970), and has since been used in both community and hospital environments around the world (Savage, 1999). Rutter et al, (1998b) and Rascanti et al (1986) both offer reviews of the work study techniques and methodologies used in assessing the work practices of pharmacists.

In their review of the methods (primarily based on hospital pharmacists in the USA), Rutter et al (1998b) categorised the work study techniques used in pharmacy practice research into seven categories (table 2.1): Subjective Evaluation; Self-Reporting; Productivity Data; Direct Time Study; Standard Time Study; Work Sampling; and Multidimensional Work Sampling. This review analyses each of these methodological approaches in turn with a view to justifying the technique chosen in this thesis.

Table 2.1– Work Study Method in Pharmacy

Method	Description
Subjective Evaluation	Workers estimate at the end of the day how much time is spent on tasks
Self Reporting	Use of worker time on various elemental tasks is recorded in log or diary.
Direct Time	Activity is separated into discrete tasks with observable beginning and end points. Observer times each elements as it is performed. Particularly effective for workload of repetitive tasks.
Productivity Data	Work is separated into “units” which can be compared with personnel time
Standard Time	Standard time is the average time for a fully trained operator to perform an activity at normal pace Standard data system – standard times for a job reported are collated and analysed to provide a standard time Pre-determined time systems – based on a detailed description of an activity, an observer assigns a time value to each hand and body movement. These are summed to provide the time necessary to perform a unit of work
Work Sampling	At random or fixed intervals, an observer or the worker, records the activities being performed. The proportion of observations for each activity relate to the total number of observations approximates to the percentage of time staff spend on each activity.
Multi-dimensional work sampling	Jobs are broken down into dimensions. These are measurable aspects of task and job related behaviour (activity, function and contact). At random intervals, staff self report the dimensions of an activity being undertaken.

(based on Rutter et al., 1998b; Rascati et al., 1987; James et al., 2011)

Subjective Evaluation

This is a method of work measurement by which a subject estimates the amount of time spent on various activities based on personal judgement, past experience and tradition. In this approach jobs are first deconstructed into discrete tasks, and then participants are asked to estimate how much time is spent on each of the tasks, usually in the form of questionnaires. These questionnaires are relatively easy to administer, interpret and are able to provide valuable cognitive information.

The method has been used in both hospital and community settings (Oddone et al., 1993; Roberts et al., 1982), but has been reported to be imprecise, due to overestimation biases created by recent events (Sittig, 1993); biases towards professional activities (Nickman et al., 1990) and social desirability (Laurier and Poston, 1992). Therefore, Robertsen (1982) suggests that estimates can deviate from measured standards by about 25% on average, and should not be used for obtaining labour standards. As a result its main utility lies in formulating hypothesis or indicating worker perceptions that highlight areas of future research interest (Rascati et al., 1986). One example of this from the United States (Schommer et al., 2006) highlighted the gap between the desired and actual time spent by pharmacists on various activities. However, Rutter et al. (1998a) validated a subjective evaluation of tasks performed by community pharmacists across a large multiple in England by using a work sampling technique (Rutter, 1999). The consistency of results found between the two methods may be due to the potential for inaccuracies being more appropriate to repetitive work of single activities as opposed to the varied tasks of community pharmacy (Nickman et al., 1990). Indeed, this technique has subsequently been used to assess different aspect of community pharmacy work. For example Humphries et al. (2008) evaluated the impact of an automated dispensing machine in an outpatient pharmacy, while Terry and colleagues (2011) used this approach to discover that hospital prescriptions took significantly longer to dispense in the community when compared to general practice prescriptions.

Self Reporting

Self reporting relies on workers documenting work units in a continuous diary or log. As with subjective evaluation this method allows for personal biases and data collection inaccuracy that can lead to imprecise results, although these biases can be minimised by clearly informing workers of the purpose and importance of the study (Roberts et al., 1982). Although Rutter et al. (1998b) suggests that the potential for inaccurate results using this methodology are high, time standards derived from self reporting are said to be better than subjective evaluation estimates. As a technique it is relatively inexpensive. It allows for cognitive activities to be reported (Nickman et al., 1990) and can generate large amounts of data in a short period time. It is particularly useful for tasks that involve cognitive processing (e.g. prescription monitoring and clinical ward work; Barber et al., 1993) or when participants are constantly on the move (e.g. nights shifts of junior doctors, McKee and Black, 1993).

Self reporting can be aided by data collection tools such as time-ladders, where one column lists the time in minutes, with an adjacent column left blank for participants to record the coded activity. A line is drawn across the column when one task starts and another stops. Mackewicz (1983) used this self reported approach to develop time standards for pharmacy personnel. More recently Robinson and Stump (1999) used this method as a management tool to help benchmark pharmacists time and track clinical pharmacists' patterns of work.

Productivity Data

Although Rutter and colleagues (1998b) refer to these approaches as productivity data, it is often termed 'statistical data' in the literature. Productivity data requires the recording of a number of work units completed (e.g. prescriptions dispensed) by a subject compared to personnel time (Roberts et al., 1982). This can then be used to establish ratios of work units per unit time. This is of particular use in pharmacy workforce planning to create gearing ratios for prescription dispensing (John, 2008). In the hospital environment Cooper and Zaske (1988) compared pharmacy work tasks with hospital census data to show that decreasing the duration of stay in hospital led to nearly a threefold increase in pharmacy workload. More recently Rough and colleagues (2010) reasserted that this method can be used to create bench markers that help measure the impact of pharmacists on patient care. The advantage of this method is that it can be used in situations where detailed studies are not required. This provides results that are approximate, but provide an overall picture of the activity being investigated. However, as this method focuses on complete 'units of work', it fails to take into account factors such as clinical intervention or cognitive processes associated with each unit.

Direct Time Study

According to James and colleagues (2011) direct time study is the 'gold standard' method for measuring workload and has been shown to be a highly precise, accurate and consistent (Emmerton and Jefferson, 1996). This labour intensive method is sometimes known as the 'stop watch' technique, as a one-to-one observer records exactly how much time is being devoted to each task over extended periods of time (Finkler et al., 1993). For this reason direct time study is most appropriately applied to highly repetitive technical tasks, where work is divided into short elements that have a logical sequence (Rascati et al., 1987). Therefore its application in the pharmacy literature has often been used to measure workloads associated with sterile manufacture. For example, this method has been used to

investigate different automated and manual processing techniques for chemotherapy (Patel et al., 2006), to form the basis for a full cost evaluation of the dispensing and administering of fluorouracil (Simon et al., 2010; Suh et al., 2010), to compare different infusion techniques (Florea et al., 2003; Sahni et al., 2007) and to compare outpatient and community chemotherapy preparations (Brixner et al., 2006).

The technique has also been used outside of sterile products to: discover baseline data on prescription dispensing times (James et al., 2011); evaluate the effects before and after computerisation in an outpatient pharmacy (Moss and Pounders, 1985; Unertl et al., 1984); build model projections of a hospital dispensary (Reynolds et al., 2011); calculate standard time in Thailand for each element of outpatient and inpatient pharmacy services (Wisai et al., 2007); discover the feasibility of a robotic courier medication delivery system (Kirschling et al., 2009); assess the needs for clinical pharmacist staffing levels in Australian hospitals (O'Leary et al., 2010); and study the time taken to produce a label for individual patient medication (Ngo et al., 1992).

Although this method has been used to evaluate the counselling practices of community pharmacists in Iran (Garjani et al., 2009) and the time taken to process repeat prescriptions in the UK (Ashcroft et al., 2006), its application in the community pharmacy setting has been limited (Rutter et al., 1998b). This may be because the varied nature of pharmacist's work makes it difficult to use this method in practice, coupled with the expense of one to one observation.

Standard time study

Standard time study is a technique used to determine the average time for a fully qualified and trained operator to perform an activity when working at normal pace, previously determined by other work measurement techniques (Mobach, 2008a). These standards can then be used as targets to incentivise workers. Strictly speaking this is not a separate technique, instead relying on the other methods detailed in this section to develop standards.

The approach can be categorised into two classes; standard time systems and pre-determined systems (Rascati et al., 1987; Rutter et al., 1998b). Standard time systems commonly refer to large scale or macroscopic systems where studies of related tasks are collated to create a standard time from a particular task. By contrast, pre-determined time systems tend to be more microscopic in data where precise time values are assigned to

specific hand and body movements. Using this data the time required for a unit of work can be built up. The applicability of predetermined time studies in pharmacy practice is limited due to their complexity, although efforts have been made to use standard time systems in secondary care (e.g. Bartscht et al., 1965; Hammel et al., 1977; Buchanan, 2003). This approach has led to the creation of benchmarks and targets for specific pharmacy activities (Mitchell, 1996) and more recently to simulate how long clinical pharmacists should spend on the wards (Dean et al., 1999).

Work Sampling

Work sampling is the most common work study technique used in health services research and has been applied in pharmacy (e.g. Bell et al., 1999; McCann et al., 2010a), dentistry (e.g. Marklin and Cherney, 2005) and nursing (e.g. Upenieks, 1998). Work sampling studies collect a large number of observations recorded into pre-defined, mutually exclusive categories, taken at either fixed or random intervals of time. For example, data may be sampled randomly six times an hour, or precisely every 10 minutes, to determine exactly what a worker is doing. The data is often collected by a trained observer (Rutter et al., 1999), but may be self reported by the study participants (e.g. Bell et al., 1999; McCann et al., 2010a). With sufficient sampling, the observed frequency of an activity can be said to reflect the proportion of time that is spent on that activity.

One use of work sampling in pharmacy has been to document baseline work activities (e.g. Bell et al., 1999). However, the most common use of this technique in pharmacy is to assess changes in work patterns following the implementation of a technology (e.g. Franklin et al., 2007; Lin et al., 2009b; Lin et al., 2007) or to compare activities following a change in work conditions (e.g. Schneider and Nickman, 1997; Schneider and Nickman, 1998; Lin et al., 2003a).

Savage (1999) presented a review of work sampling approaches in community pharmacy over the previous twenty years and showed that this technique had been used around the world. More recent examples of the techniques being used internationally include Thailand (Ploylearmsang et al., 2003), the US (Lin et al., 2003b) and South Korea (Ryu and Kim, 2003; Ryu et al., 2002).

Multidimensional work sampling

Although work sampling has been used extensively to observe technical tasks, the traditional technique lacks utility in measuring cognitive processes. Therefore the multi-

dimensional work sampling technique was developed to measure problem solving and clinical thought in professional, executive or highly technical positions by analysing the different dimensions of the job as opposed to an individual's activities. Using the self reporting techniques, participants record their own activities at randomly generated times using portable bleeper devices as a reminder. When a bleep is emitted, the participant chooses one item from each dimension. Although this approach can therefore be labour intensive, Robertsen (1982) suggests over a full day this only takes participants approximately ten additional minutes. As with other methods of self-reporting, concern has been expressed about the possible falsification of results (Hall and Rupp, 2001), although this may be limited by the large number of interrelated records that are collected (Ampt et al., 2007).

The dimensions assigned to any job will vary according to the objectives of the study, although invariably three dimensions; *activity*, *function* and *contact* are used. Other dimensions, such as *location*, may be added where applicable. For example, *activity* is the context of the task, such as using a phone; the *function* relates to the purpose of that task, such as clarifying a dose; and the *contact* refers to the person, such as a junior doctor.

Beech and Barber (1993) were the first to use this method to measure ward pharmacists' work in the UK, which had previously been used in the US (Ried et al., 1991) and has since been replicated in Japan (Hamai et al., 2001). Subsequently the method was used in community pharmacy settings by Dupclay et al. (1999) who analysed the work behaviours of grocery chain pharmacists in the USA, finding that 46.3% of time was spent on only 10 of a possible 1,760 activity-contact-function combinations. Further studies in Holland have successfully demonstrated the use of multi-dimensional work sampling in community pharmacy (e.g. Mobach, 2008a; Mobach, 2008b).

Methods of Work study

The techniques described above all represent different methodological approaches to work study in pharmacy settings. Each of these approaches has their own relative advantages and disadvantages, described in table 2.2 below.

Table 2.2 - Comparison of the different methods

(based on Rutter et al., 1998b; Rascati et al., 1987; James et al., 2011)

Method	Advantages	Disadvantages
Subjective Evaluation	Provides indicators of work patterns Useful for formulating hypothesis Can be used to assess worker perceptions Inexpensive	Highly subjective and therefore can be imprecise Over or underestimation is possible
Self Reporting	Creates large amounts of rich data quickly Self-reporting allows cognitive activities to be recorded Can be used for mobile subjects	Relies on staff being highly motivated to record activities Time consuming and can be imprecise without observer training
Direct Time	If well designed it can accurately assess workload Often used to validate other techniques	Hawthorne effect may influence the behaviour of staff Observers must be trained Reliability required if more than one observer used
Productivity Data	Easy application Output information only	Units of work can be difficult to define for activities that cannot be easily timed Requires access to historical data
Standard Time	Enables comparison of productivity and staffing thereby facilitating manpower planning.	Difficult to apply Time-consuming Resource intensive Requires review and refinement to ensure the unit of work remain accurate
Work Sampling	Allows simultaneous study of several workers Can be applied to repetitive and non repetitive tasks Easy to apply and inexpensive Sampling strategy can be used to reduce bias introduced by continuous workload measurement techniques.	Observers require training and must be familiar with the tasks Data collection must be sufficiently long to ensure all activities are observed Production of a discrete, mutually exclusive categories can be challenging
Multi-dimensional work sampling	Accurate assessment of professional and non-technical activities	Relies on willingness of staff to report

Designing a Work Study in Community Pharmacy

Assessment of the relative advantages and disadvantages of the work study methods is described above (table 2.2). The purpose of this study was to discover what pharmacists spend their time doing. Of the methods, subjective evaluation, self reporting and work sampling are the most appropriate methodological approaches that allow for the proportion of time that pharmacists spend on different activities to be calculated. Yet the bias and additional workload for the participant created by subjective evaluation and self-reporting makes observed work sampling the most preferable technique. The challenge with observed work sampling is the creation of discrete, mutually exclusive categories and the resource intensive nature of observed research. However these disadvantages are deemed to be smaller than the bias and workload created by the alternative techniques.

On this basis a work sampling methodology was selected as the technique of choice.

Central to the success of any work sampling study is the categorisation of work activity, and

the appropriate sampling of work to ensure reliable results. The process by which this was achieved is described in the method section below.

Materials and Methods

Coding Framework

Work sampling relies on the activities of pharmacists being classified into mutually exclusive categories. Previous activity categories from published literature were reviewed (Rutter et al., 1998a; McCann et al., 2010b; Fisher et al., 1991; Bell et al., 1999; Savage, 1997; Dupclay et al., 1999). These were collated, modified and altered to bring them up to date with current UK community pharmacy practice. A working draft of this framework was tested in two community pharmacies outside of the study area with a newly constructed data collection form. Following the pilot, the framework was revised and reviewed by three practicing community pharmacists to create 18 mutually exclusive categories (table 2.3). Activities were grouped into professional, semi-professional and non professional activities through interpretation of a previous frameworks (McCann et al., 2010b).

Table 2.3– Coding Framework

Activity	Classification
1. Prescription monitoring and appropriateness Interpretation of the Rx including checking the correctness of the dispensed item. Includes checking the indication for drug, suitability for patient, e.g. interactions with other medicines. Appropriate dose of each medication. Contacting the prescriber if necessary. Includes ensuring that the product is dispensed as prescribed, e.g. checking any product assembled by dispensary technicians, as well as the legality of prescription.	Professional
2 Assembly and labelling of products Includes the assembly of the product requested on the prescription and generating labels for the container of that product. The process of assembling a prescription [Rx] item from receipt to the final assembly of the product, including the endorsement and filling of an individual prescription.	Semi- Professional
3 Endorsing prescriptions and clerical health related work Includes preparing the end of month returns to the Drug Pricing Authority, coding prescriptions etc., directly related to health provision.	Professional
4 Counselling patients on prescribed medicines Includes personally giving out the medication to the patient and providing information on disease state, medicines supplied, side-effects, dose etc.	Professional
5 Non-prescription medicines counselling/responding to symptoms Includes listening to any problems, advising on problems either to patients or counter staff, recommending a non-prescription medicine or referring the patient to a GP.	Professional
6 Professional encounter with non-patients Discussing new drugs with company representatives, contacting the Pricing Authority etc.	Professional
7 Health Related Communication An activity or function that involves any aspect of health provision, written or verbal, that is not direct counselling to patient. Including advice to GPs.	Professional
8 Provision of Advanced Services This relates specifically to Medicines Use Reviews	Professional
9 Provision of Enhanced or other NHS Services Conducting any additional services that are provided by the pharmacy. e.g. Medicines supplied via PGD (EHC etc.). Smoking cessation advice via PGD	Professional
10 Provision of Private Enhanced Services Conducting any additional services that are provided by the pharmacy e.g. Medicines supplied via Private PGD or paid for vaccinations.	Professional
11 Provision of services to homes As 1 and 2 but directly related to residential and nursing homes.	Professional
12 Inventory and Stock Control Includes stock maintenance of prescription-only medicines (dispensary) and non-prescription medicines (counter) or of non-medicinal products (perfumes/baby products etc.).	Non- Professional
13 Staff training and Education Includes any training given to new and existing staff, work experience students, e.g. formal training for dispensary staff.	Professional
14 Housekeeping Includes General maintenance and cleaning of the work place including merchandising of dispensary or non-dispensary areas.	Non- Professional
15 Sales Transactions The selling of goods between vendor and purchaser, for non health related products, such as perfumes.	Non- Professional
16 Money and Managerial Administration Includes all clerical work such as dealing with mail, filing etc. An activity not involving any aspect of healthcare. Functions that the person in charge must do for the business to run effectively. Includes wages, tax returns, balancing cash at the end of the day etc.	Semi- Professional
17 Rest Waiting and Personal time Includes lunch and tea breaks, resting and toilet breaks etc or Time when the pharmacist is being unproductive.	Non- Professional
18 Non-professional encounters Includes gossip and general chat with non-professionals, e.g. talking about the weather with a customer. Advising customers on non-healthcare related products e.g. perfumes	Non- Professional

Observational Approach

Although Robersten (1982) argues that it is difficult to deliberately bias self reported data as one participant would not intentionally try to be out of step with others, self-reported

data is generally considered less reliable, as workers often do not record activities in a timely fashion, and may not be totally frank concerning what activities were being undertaken at the specified time resulting in bias. For this reason direct observation was the preferred method. However, this requires additional people as observers (Oddone and Simel, 1994), who can produce a Hawthorne effect (Savage, 1996), distract professionals who do not like being observed (Emmerton and Jefferson, 1996) and may bring bias into the study through their interaction with staff (Rascati et al., 1987). While it is recognised that some of these effects can be mitigated through the use of one way mirrors (Finkler et al., 1993) and video surveillance (Lin et al., 2009a), they are impractical in confined community pharmacies. Therefore discrete direct observation was deemed to be the most appropriate approach.

Observer Training

Nine third year pharmacy students and the study coordinator were trained to observe community pharmacists. Pharmacy students were chosen as they have been used as observers in previous studies (Rutter et al., 1999; Nelson et al., 1977), and are familiar with the work of pharmacists, an important aspect in work sampling (Rutter et al., 1999). Ensuring reliability between observers necessitated extensive training.

Firstly, the observers were briefed on the method, introduced to the study and provided with background material to read. Secondly, they were given a written questionnaire to assign categories of practice to gain familiarity with the coding framework. Thirdly, the observers practiced observational techniques through coding a series of videos of community pharmacists in a training session using the pre-tested data collection forms. Discrepancies between observers were discussed until observers recoded in a consistent way. Previous studies have reported that observers must correctly assign 90% of observations to be deemed competent (Rascati et al., 1987; Rutter et al., 1999). Fourthly, consistency was tested with a new video in which all observers correctly assigned more than 90% of the observations. Fifthly, the study co-ordinator also coded with the students at different times throughout the observation period to ensure consistent coding whilst at study sites.

The focus of data collection was on the time spent by the pharmacist. Only one pharmacist was observed at any one time. Where two pharmacists were present, the regular 'responsible pharmacist', was the subject of observation. However, data about the number of other staff present during each time period was collected to allow for analysis of the

effects of staff on the allocation of roles, as well as the average number of prescriptions dispensed per month (table 2.4). In situations where the pharmacist was performing more than one activity simultaneously, the observers made a subjective decision about which activity predominated as practiced in previous studies (Summerfield et al., 1978).

Sampling Approach

Given that fixed interval sampling is comparable to random sampling in community pharmacy practice due to the non cyclical nature of community pharmacists' work (Dickson, 1978) and that fixed interval is simpler and cheaper because specialised random generation devices are not required, a one minute fixed interval sampling approach was chosen.

Sample Size

Work sampling studies require a large number of observations over a sufficient period of time to allow confidence in inferences made from the results (Ampt et al., 2007). Previous studies have reported that between 5-10% of pharmacists time is spent counselling (Savage, 1997; Savage, 1999). As a result it was decided that 8% be used as an estimated percentage for calculating the one minute fixed interval sample size (McCann et al., 2010b).

Equation 2. 1 – Sample Size Equation

$$N = \frac{4a^2 p(1-p)}{I^2}$$

p = fraction of time believed to be spent on the activity of greatest research interest. (0.08, i.e. anticipate 8% of time will be spent counselling).

a = 1.96 (based on a 95% confidence interval)

I = Width of the confidence interval (0.01) Confidence interval width, I is 0.01, meaning that the estimate of proportion will span from 0.08 + 0.005 to 0.08-0.005, i.e. Half of the confidence interval

N = minimum number of observation required

Equation 2.2 – Calculation of Sample Size

$$N = \frac{4(1.96)^2(0.5)(1-0.5)}{0.05^2} = 1,311$$

A total of 11,310 observations will measure an activity at this frequency with an accuracy of $\pm 5\%$. In order to obtain 11,310 observations a one minute sampling frame was tested during the pilot which was shown to be practical, equivalent to 118.5 hours of observation.

Selection of Study Sites

For purposes of practicality, ten community pharmacies were selected from across the London area. These were purposefully selected from a 'convenience' sample to represent the four different categories of community pharmacies, namely traditional, specialist, health and beauty led and supermarket pharmacies (Department of Health, 2008a). Of these, five pharmacies were from large multinational chains with the remainder from the independent sector (table 2.4).

Due to the inclusion of ten pharmacies, this equated to 1,131 observations per pharmacy, or with one minute sampling, 18 hours and 51 minutes of observation per pharmacy. In order to ensure an even spread of data across the days of the week and the opening times of the pharmacy, 20 hours per pharmacy was set a target, equivalent to 12,000 observations. The observers visited the pharmacists at different times of day across the opening hours of the pharmacies providing an even spread of data collection throughout the week. Pilot work demonstrated that collecting data for longer than four hours per day was unfeasible due to observer fatigue.

Table 2.4- Demographic Data

Pharmacy	No. of pharmacists observed	Pharmacist status and code	Pharmacist gender	Pharmacist estimated age/years	Mean no. of: Technicians ; Dispensers; Counter assistants; Pre-reg. Students*	Mean monthly prescription volume /items	Pharmacy type	Opening hours
A	1	1a regular	Male	32	1.93 0 0.18 0.95	3500	Specialist	Mon-Fri: 9am-7pm Sat: 10am-3pm
B	2	2a Owner 2b Locum	Female Female	60 32	0 0 2.5 0	4000	Health and Beauty	Mon-Fri: 8:30am-6:30pm Sat: 9am-1pm
C	2	3a Regular 3b Locum	Female Female	30 27	0 0 1.81 1	4000	Specialist	Mon-Fri: 9am-6pm Sat: 10am-4pm
D	4	4a Locum 4b Locum 4c Locum 4d Locum	Female Male Male Female	32 39 58 27	0 0.36 1.17 0	4000	Supermarket	Mon-Fri: 9am-6pm Sat: 9am-6pm
E	2	5a Regular 5b Locum	Female Female	31 55	0 0 1.12 0	4500	Supermarket	Mon: 8am-10:30pm Tues-Fri: 6:30am-10:30pm Sat: 6:30am-10pm Sun: 10am-4pm
F	3	6a Manager 6b Locum 6c Locum	Male Male Male	30 30 70	0.81 0 2.36 0	4000	Health and Beauty	Mon-Fri: 9am-7pm Sat: 9am-7pm
G	1	7a Owner	Male	49	0 1.6 6 1	12000	Traditional	Mon-Fri: 9am-7:30pm Sat: 9am-7pm Sun: 10am-2pm
H	1	8a Regular	Male	34	1 0 0.4 1	4000	Specialist	Mon-Fri: 9am-6pm Sat: 10am-2pm
I	2	9a Regular 9b Regular	Male Male	50 29	1 1.82 0 1	3500	Specialist	Mon-Fri: 9am-6.15pm Sat: 10am-4pm
J	3	10a Manager 10b Regular 10c Locum	Female Female Male	27 27 34	0 0.38 0.64 0.74	3500	Supermarket	Mon-Fri: 9am-8pm Sat: 9am-8pm

*NB. *The data refers to the average/ number of staff observed during the observational study period and does not reflect the exact numbers of staff employed by a pharmacy.*

Data Analysis

The data was entered into Microsoft Excel and analysed with PASW v18 (SPSS) where the number of observations for each activity was expressed as a proportion of the total number of observations. The proportion of time spent on activities was found to be non-normally distributed. Because of this, median and inter-quartile range in addition to the mean is reported. Statistical analysis was carried out using non-parametric tests due to the sample size of ten pharmacies using the Mann-Whitney U test and ANOVA. In all cases significance was set at $p < 0.05$.

Ethics and Approval

Institution ethical approval was received (REC/B/10/03) from the School of Pharmacy, University of London Ethics Committee.

At the onset of the study, the pharmacy superintendents (and where applicable area and local pharmacy managers for the pharmacies) were supplied with detailed information about the study. The study co-ordinator also briefed all of the pharmacy managers on the study process. At data collection, pharmacists were provided with a study information sheet and explained the purpose of the study. At this point informed consent was received from the study participants.

In order to reduce the Hawthorne effect participants were assured of their anonymity and it was explained that the collective, as opposed to individual results would be analysed.

Community Pharmacy Work Study Research

An accompanying structured literature review of work sampling studies in community pharmacy was undertaken to establish if policy changes outlined in the previous chapter had influenced work practice.

Electronic databases, MEDLINE, EMBASE, International Pharmaceutical Abstracts and CINAHL were searched. MEDLINE use of MeSH headings “Time and Motion Studies” OR “Work Capacity Evaluation” OR “Work” AND “Pharmacy” OR “Pharmacies” OR “Community Pharmacy Services” OR “Pharmacy Administration” OR “Pharmacists”. CINAL headings, “Pharmacy and Pharmacology” OR “Pharmacy, Retail” OR “Pharmacy administration” OR “Pharmacy service” AND “Work Assignments” OR “Work Sampling” OR “Work” OR “Work Measurement”. Additional searches were performed with the terms included “work”, “work study”, “Pharmacy”, “Pharmacist”, “Time and Motion” as keywords. As several reviews of the use of work sampling methodology in community pharmacy were published prior to 1998 (Rutter et al., 1998b), the search was limited from 1997 to 2010.

In addition the references of all selected articles were scrutinised, as were the contents lists of the International Journal of Pharmacy Practice and the Journal of American Health Systems Pharmacists between the defined dates. Initial inclusion criteria for articles reviewed by title and abstract and were assessed based on three questions.

- Did the research take place in a community or retail pharmacy setting?
- Does the study use, or appear to use, one of the seven methods (Table 2.1) (as defined by Rutter et al., 1998b)?
- Does the data show the different activities that pharmacists perform?

These selected articles were then assessed for their full eligibility. Inclusion criteria was any study that used work study techniques (Rutter et al., 1998b) in order to show the amount of time that community pharmacists spend on different activities and that met the research question of showing the amount of time that community pharmacists apportioned to different activities. This included ‘before and after’ studies investigating the implementation of a new process or technology. All original research studies and abstracts that met the criteria were included.

Despite productivity data being a valid work-study technique, studies that only reported productivity data, such as the number of prescriptions processed per hour by a pharmacist, but that did not discuss how much time was spent on different activities, were excluded.

This is because such studies would not directly explore the activities of community pharmacists. Studies in outpatient, ambulatory care and hospital settings were excluded as their work practices were considered significantly different to those of community pharmacists. Review articles were also excluded. Studies that exclusively showed the work activities of pharmacy technicians were also excluded.

Literature Review Results

Sixty-six articles were initially identified (figure 2.1), and where possible full papers obtained. It was not possible to acquire five full text papers from the British Library, mainly due to these being local US pharmacy publications. Three conference abstracts were removed as duplicated by full publication. A further 35 papers were excluded. In most cases these were review papers and therefore excluded for not being original research. Other reasons for exclusion included reporting productivity data, being exclusively about pharmacy technician time, or reporting work in non-community pharmacy setting. This left 23 papers and abstracts that were included in the qualitative analysis (table 2.5). Where definitions allowed comparable data was extracted from the papers. Due to differences in definitions statistical comparisons were not performed.

Figure 2-1– Data Flow Diagram

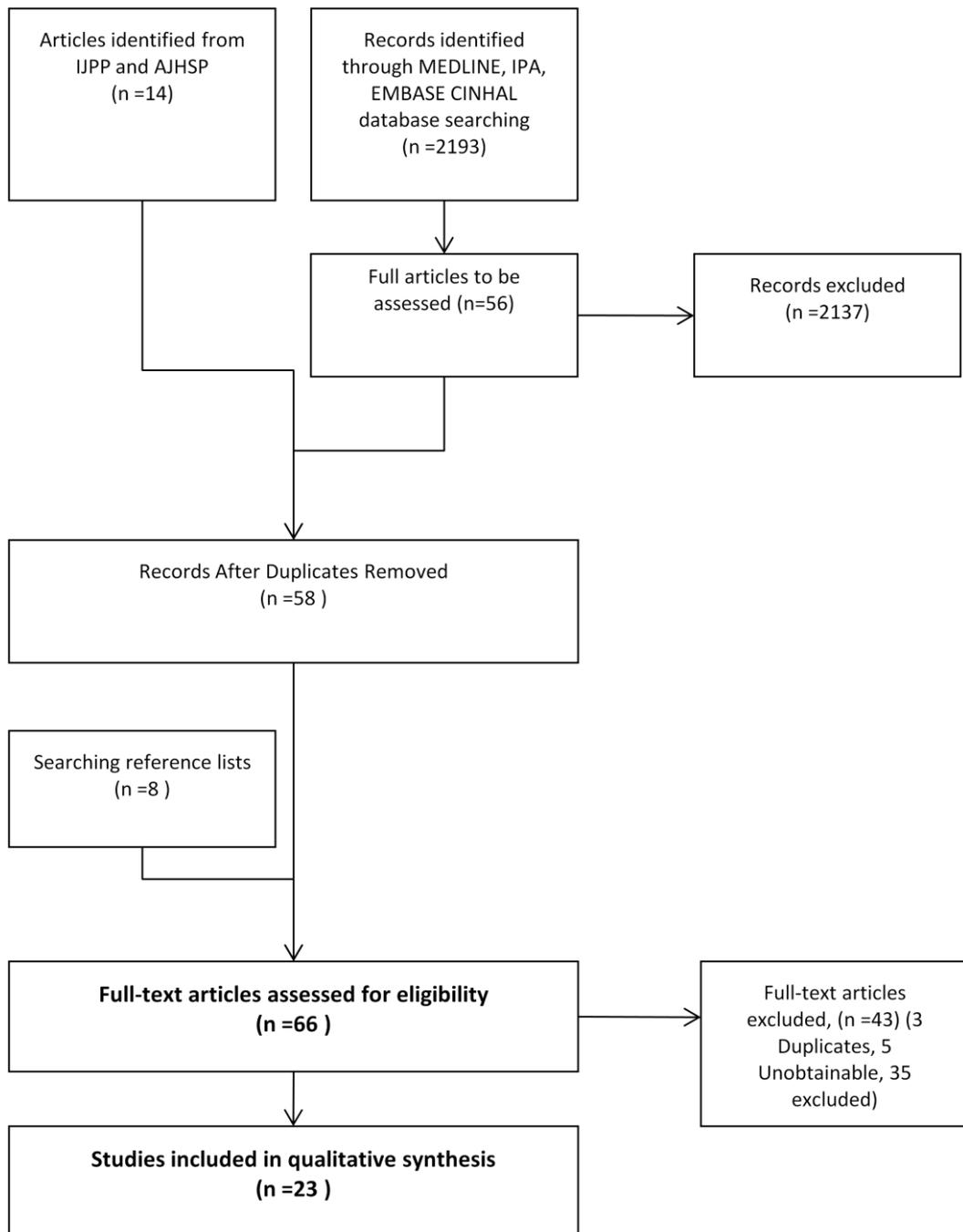


Table 2.5 – Studies included in the Analysis

*this is the submission or publication year when not reported in the text

First Author	Year of Data Collection	Country	Method	Number Involved	Nature of Study
Anderson (Arthur Anderson LLP, 1999)	1999	USA	Direct Time Study	15 pharmacies	Baseline
Angelo (Angelo et al., 2005)	2003*	USA	Direct Time study	Four pharmacies, 11 pharmacists	Before and After
Angelo (Angelo and Ferreri, 2005)	2003*	USA	Direct Time Study	1 pharmacy, 3 pharmacists	Before and After
Bell (Bell et al., 1999)	1998	Northern Ireland	Work Sampling, Self Reported	30 pharmacies	Baseline
Bond (Bond et al., 2008)	2008*	UK	Subjective Evaluation	762 pharmacists	Baseline
Crealey (Crealey and McElnay, 2003)	2003*	UK-Northern Ireland	Subjective Evaluation	268 pharmacy staff at 49 pharmacies	Baseline
Dupclay (Dupclay et al., 1999)	1997	USA – Indianapolis	Multidimensional Work Sampling	15 pharmacies, 25 pharmacists	Baseline
Emmertson (Emmertson et al., 1998)	1996	New Zealand	Multi dimensional Work Sampling, Self Reported	One pharmacy	Baseline
Fleming (Fleming, 1999)	1999*	USA	Subjective Evaluation	917 pharmacists	Baseline
Lin (Lin et al., 2007)	2002	USA, Michigan	Work sampling, Fixed Interval	One pharmacy	Before and After
Mobach (Mobach, 2006)	2004/5	Netherlands	Work sampling, random self reported	One pharmacy	Before and After
Mobach (Mobach, 2008a)	2004	Netherlands	Multidimensional Work Sampling	Three pharmacies	Baseline
Midwest Pharmacy Workforce Research (Midwest Pharmacy Workforce Research Consortium, 2010)	2009	USA	Subjective Evaluation	464 Community pharmacist responses	Baseline
McCann (McCann et al., 2010a)	2009	Northern Ireland	Work Sampling, Self Reported	30 pharmacies	Baseline (Compared to Bell)
Quinones (Quinones and Thompson, 2009)	2005	USA Illinois	Subjective Evaluation	496 pharmacists	Baseline (compared shift and non-shift)
Rutter (Rutter et al., 1998a)	1996	UK	Subjective Evaluation	1084 pharmacists	Baseline
Rutter (Rutter et al., 1999)	1996	UK	Work sampling, fixed interval	5 pharmacies	Baseline
Rutter (Rutter et al., 2001)	2001*	UK	Work sampling, Fixed Interval	One pharmacy	Before and After
Rutter (Rutter, 2002)	2000	UK	Work sampling, Fixed interval	Four pharmacies, 11 pharmacists	Baseline
Schommer (Schommer and Pedersen, 2001)	1999	USA – Minnesota and Ohio	Subjective Evaluation	597 Pharmacists	Baseline
Schommer (Schommer et al., 2002)	2000	USA	Subjective Evaluation	832 pharmacists	Baseline
Schommer (Schommer et al., 2006)	2004	USA	Subjective Evaluation	1,564 pharmacists	Baseline
Scott (Scott, 2009)	2006	USA – North Dakota	Subjective Evaluation	689 pharmacists	Baseline

The methods used in the studies can either be categorised as subjective evaluation, where pharmacists were asked to report the activities that they perform, direct time studies or work sampling, with several using the multi-dimensional work sampling technique.

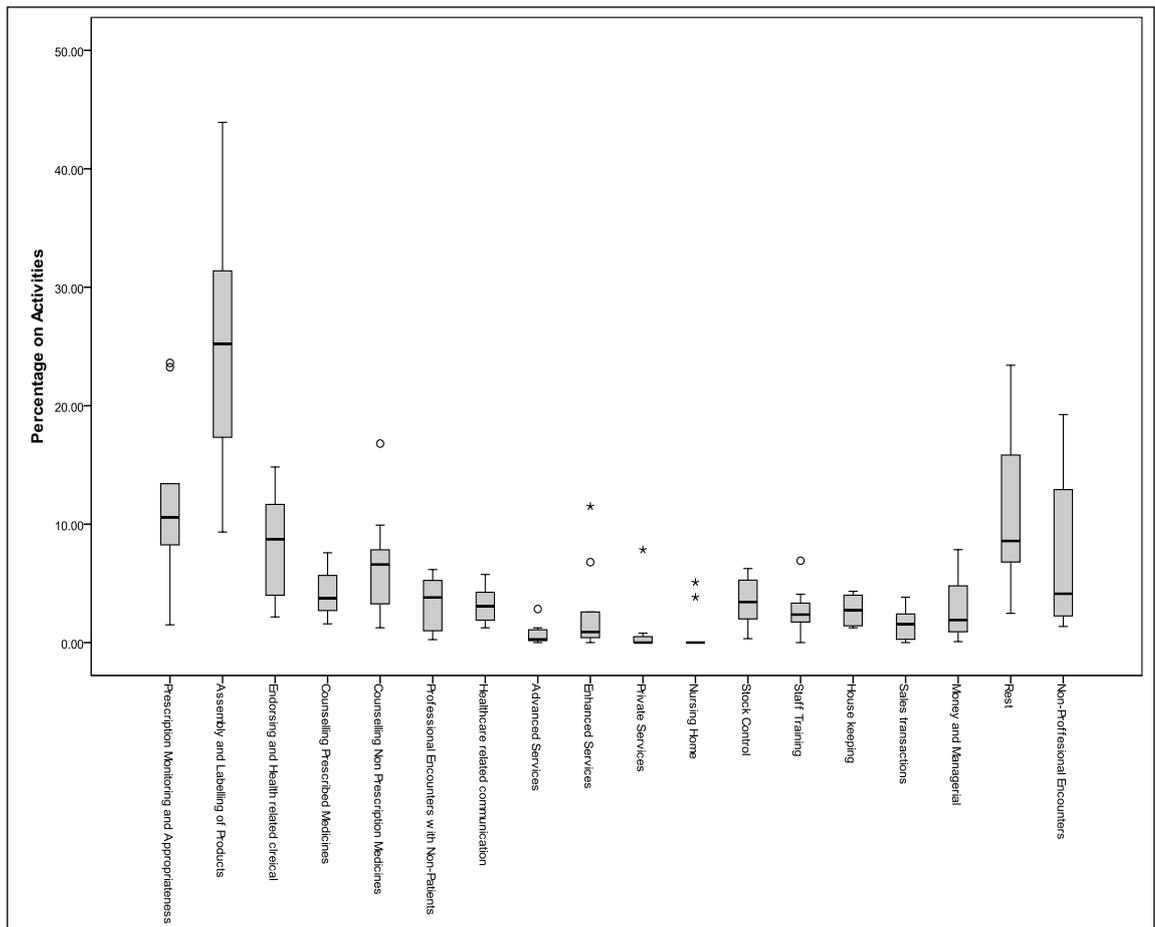
Previous analysis of work sampling in community pharmacy reported little published literature (Savage, 1999; Emmerton and Jefferson, 1996). Yet, the review reported here suggests that popularity of work study methods in community pharmacy has increased, although particularly in the US (Arthur Anderson LLP, 1999; Angelo et al., 2005; Angelo and Ferreri, 2005; Dupclay et al., 1999; Fleming, 1999; Lin et al., 2007; Midwest Pharmacy Workforce Research Consortium, 2010; Quinones and Thompson, 2009; Schommer and Pedersen, 2001; Schommer et al., 2002; Schommer et al., 2006; Scott, 2009) and UK (Bell et al., 1999; Bond et al., 2008; Crealey and McElnay, 2003; McCann et al., 2010a; Rutter et al., 2001; Rutter et al., 1998a; Rutter, 2002; Rutter et al., 1999). Two studies were identified from the Netherlands (Mobach, 2008a; Mobach, 2006), and one from New Zealand (Emmerton et al., 1998).

In these studies, the use of these techniques has been for two main applications, either to assess the implementation of a new process or technology, or to create a baseline of current activity. Five of the studies reviewed were 'before and after' studies, four of which investigated the impact of automation and one investigated the effect of changes in pharmacy design on work flow. A full discussion of this literature review is included in the discussion towards the end of this chapter.

Work Sampling Study Results

A total of 12,306 observations were recorded in ten community pharmacies across London, labelled Pharmacy A-J (A=1252; B=1440; C=1=1200; and J=1214) over a two week period between the 21st March and 3rd April 2011. Data collection predominately took place Monday to Friday (n=11886, 96.6%). However some data were captured on Saturday (Pharmacy B, n=240, 1.95%) and Sunday (Pharmacy J, n=180, 1.46%). Data collection was spread across the opening hours of the pharmacies (Range: 7am-10.30pm) and across different days of the week. The mean opening hours per week for the pharmacies was 61.38 hours per week (range 49-100), with all of the pharmacies being open at least 9am-6pm Monday to Friday. One pharmacy (Pharmacy E) was open under a 100 hour contract and was located in a supermarket. As shown in figure 2.2, the box plot indicates that data captured within some of the activity codes is non-normally distributed, with a wide range of values.

Figure 2-2 - Box Plot of Pharmacist Activities



Overall seven categories accounted for three quarters of all pharmacists time (table 2.6): assembling and labelling of products (mean 25.5%; median 25.2%; IQR 12.0%); prescription monitoring and appropriateness (mean 11.9%; median 10.6%; IQR 4.7%); Rest and Personal Time (mean 11.2%; median 8.6%; IQR 8.5%); Endorsing and Health related clerical work (mean 8.2%; median 8.7%; IQR 6.6%); Non-professional encounters (mean 7.0%; median 4.1%; IQR 8.7%); Counselling non prescribed medicines (mean 6.6%; median 6.6%; IQR 4.1%); and counselling prescribed medicines (mean 4.2%; median 3.8%; IQR 2.9%).

In these pharmacies, which are open on average 61.38 hours per week, on average over 25 hours were spent each week on dispensing activities. The endorsement of prescriptions and health related clerical work, which accounted for about a twelfth of pharmacists time may have been increased by the fact that data collection was collected near the end of the month. Stock control activities accounted for 3.6% (median 3.4%; IQR 3.1%) of the pharmacists' time. Often this was unpacking and checking the delivery on managing the stock within the pharmacy. In the two pharmacies that provided services to nursing homes, this accounted for 4.5% of their time.

Activity codes were grouped together to facilitate further interpretation and comparison with the literature (table 2.6). The two categories for counselling accounted for a mean 10.9% (median 10.3%) of the pharmacists' time, equivalent to 7.4 hours per week. It appeared that the pharmacists spent a larger proportion of their time offering counter advice on non-prescription medicines than on prescription medicines (mean 6.6%; median 6.6%; IQR 4.1). In total the provision of clinical services accounted for about a twentieth of pharmacists' time although the range was between 0.2% and 15%.

Table 2.6 – Combing Activities

Activities (activity codes)	Mean percentage of activities (%)	Median of activities (quartiles)
Prescription related matters (1+2)	37.3%	39.6% (35.5, 44.5)
Non Counselling Communication (6+7+13+18)	16.4%	15.1% (13.5, 18.2)
Rest Waiting and Personal Time (17)	11.2%	8.6% (6.9, 15.3)
Counselling (4+5)	10.9%	12.4% (7.5, 13.3)
Premises (12+14+15+16)	10.8%	8.6% (6.9, 15.3)

Health Administration (3)	8.2%	8.7% (4.8, 11.4)
Services (8+9+10+11)	5.1%	3.2% (0.8, 7.5)

Using the framework defined by McCann and colleagues (2010a), the activities of the pharmacists were separated into professional; semi-professional; and non-professional activities (table 2.7).

Table 2.7 – Activity Categorisations (McCann et al., 2010a)

Activities (activity codes)	Mean percentage of activities (%)	Sum of median combined activities (%)
Professional (1+3+4+5+6+7+8+9+10+11+13)	45.5%	40.1%
Semi Professional (2+16)	28.4%	17.3%
Non-Professional (12+14+15+17+18)	26.1%	20.4%

Statistical Testing

A number of statistically significant relationships were found between the demographic characteristics of pharmacies (table 2.7) and the mean time apportioned to the different activities sampled during the course of the study. There was a statistically significant variation in the proportion of time spent of staff training ($p=0.019$) between those pharmacies with and without a preregistration student. These pharmacists also spent a statistically significant proportion of their time on sales transactions ($p=0.011$) when compared to those without students. It was also found that pharmacies that dispensed more than 4000 prescriptions a month spent less time on advanced services ($p=0.039$). The validity of these findings is questionable given the limited sample size of ten.

Figure 2-3 - Mean time spent on each activity by the pharmacists at each pharmacy

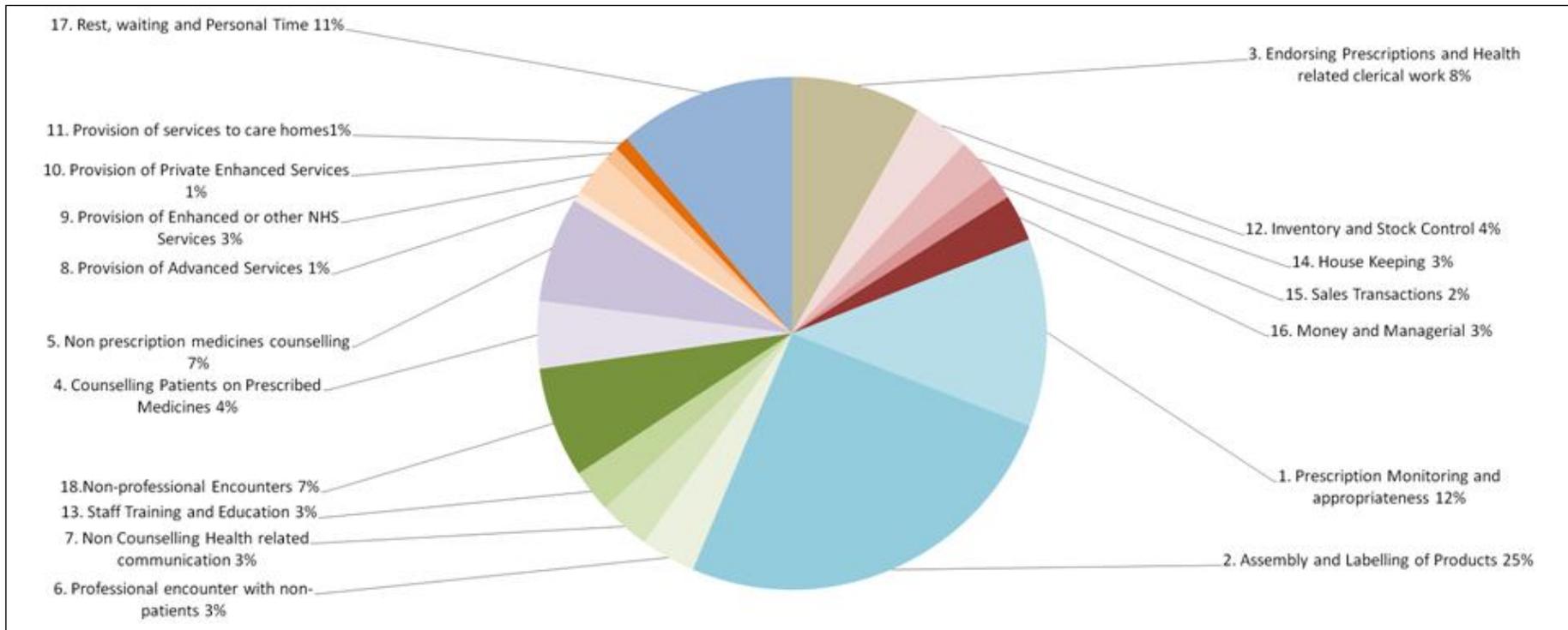


Table 2.8 –Total time spent on each activity code across all ten pharmacies (A-J)

	A	B	C	D	E	F	G	H	I	J	Mean	Median	IQR
1. Prescription Monitoring and appropriateness	23.2%	23.6%	13.4%	1.5%	8.4%	11.8%	8.3%	11.8%	9.3%	7.2%	11.9%	10.6%	4.7%
2. Assembly and Labelling of Products	17.3%	24.9%	24.2%	43.9%	37.5%	29.9%	9.3%	10.8%	25.5%	31.4%	25.5%	25.2%	12.0%
3. Endorsing Prescriptions and Health related clerical work	10.6%	8.1%	7.2%	4.0%	2.4%	11.7%	2.2%	11.7%	9.4%	14.8%	8.2%	8.7%	6.6%
4. Counselling Patients on Prescribed Medicines	5.7%	2.7%	5.6%	2.9%	2.9%	4.6%	1.6%	6.9%	7.6%	2.0%	4.2%	3.8%	2.9%
5. Non prescription medicines counselling and responding to symptoms	3.3%	4.3%	6.8%	3.0%	9.9%	7.8%	1.3%	6.5%	6.7%	16.8%	6.6%	6.6%	4.1%
6. Professional encounter with non-patients	3.4%	5.0%	2.8%	0.3%	4.2%	1.0%	6.2%	5.8%	5.3%	1.0%	3.5%	3.8%	3.8%
7. Non Counselling Health related communication	5.8%	1.3%	2.5%	3.1%	3.1%	1.8%	4.3%	4.2%	4.6%	1.9%	3.2%	3.1%	2.2%
8. Provision of Advanced Services	0.0%	0.3%	1.1%	0.3%	0.2%	0.3%	1.3%	2.8%	0.3%	0.0%	0.6%	0.3%	0.7%
9. Provision of Enhanced or other NHS Services	6.8%	0.2%	2.3%	2.6%	0.0%	0.4%	0.8%	0.6%	11.5%	1.1%	2.6%	0.9%	2.0%
10. Provision of Private Enhanced Services	0.8%	0.0%	0.3%	0.0%	0.0%	0.0%	0.0%	7.8%	0.5%	0.0%	0.9%	0.0%	0.4%
11. Provision of services to residential and nursing homes	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	5.1%	3.8%	0.0%	0.0%	0.9%	0.0%	0.0%
12. Inventory and Stock Control	2.6%	3.1%	5.1%	6.3%	0.3%	2.0%	6.0%	1.3%	3.8%	5.3%	3.6%	3.4%	3.1%

13. Staff Training and Education	2.9%	1.7%	3.3%	0.0%	2.3%	1.3%	2.2%	6.9%	4.1%	2.5%	2.7%	2.4%	1.4%
14. House Keeping	3.0%	4.1%	4.0%	1.6%	1.3%	1.4%	4.3%	1.4%	2.5%	3.8%	2.7%	2.7%	2.5%
15. Sales Transactions	1.5%	0.3%	2.3%	0.0%	0.2%	0.8%	3.8%	2.4%	1.6%	2.7%	1.6%	1.6%	2.0%
16. Money and Managerial	4.8%	7.8%	0.1%	1.9%	1.9%	0.9%	0.9%	6.1%	0.7%	4.3%	2.9%	1.9%	3.7%
17. Rest, waiting and Personal Time	7.0%	6.8%	13.8%	15.8%	10.1%	21.3%	23.4%	7.1%	4.6%	2.5%	11.2%	8.6%	8.5%
18. Non-professional Encounters	1.4%	5.8%	5.4%	12.9%	15.4%	2.8%	19.3%	1.9%	2.3%	2.8%	7.0%	4.1%	8.7%

Discussion of Results

Many of the extended services provided in community pharmacies are believed to be part of a re-professionalisation strategy. However it has been recognised that *“the benefit to the public of pharmacists services....is dependent on the proportion of time that is devoted to pharmaceutical tasks”* (Fisher et al., 1991). The logic follows that pharmacists must have adequate time available to deliver these services if they are to achieve re-professionalisation.

Pharmacists Still Perform Traditional Roles

The results from this work sampling study in London suggest that pharmacists spend the majority of their time on assembling and labelling of products (mean 25.5%; median 25.2%; IQR 12.0%) and prescription monitoring and appropriateness (mean 11.9%; median 10.6%; IQR 4.7%), together accounting for nearly two fifths of pharmacists' time.

When compared to previous studies from the UK, the results found here are similar. A 2003 study from Northern Ireland found that the largest proportion of pharmacists time was spent on assembly and labelling of products (Crealey and McElnay, 2003). In England in the late nineties it was felt that time was disproportionately dedicated to dispensing and could be better utilised (Rutter et al., 1998a). It appears that although this lack of pharmacist utilisation has been a theme throughout policy (chapter 1), dispensing activities continue to dominate, (mean 37.35%; median 35.8%), which is comparable to the 40.3% found by Rutter and colleagues in 1996 (Rutter et al., 1999). The finding that the proportion of time dedicated to dispensing has not appreciably changed is supported by two work sampling studies conducted ten years apart in Belfast, Northern Ireland (McCann et al., 2010b; Bell et al., 1999), which found no statistical difference in the amount of time spent on dispensing activities over the period.

The dominance of the dispensing role was confirmed by similar research in the US (Fleming, 1999; Schommer et al., 2002; Schommer and Pedersen, 2001; Schommer et al., 2006). Although their findings in 2000 did show willingness in the profession to move towards more care based activities (Schommer et al., 2002), a follow up survey in 2004 using the same methods did not appear to show any changes. However, these authors found that pharmacists wanted to spend more time on consultation and drug use management activities, and less time on medication dispensing (Schommer et al., 2006). These sentiments were confirmed by studies in North Dakota in 2006 (Scott, 2009), and in Illinois

in 2005 (Quinones and Thompson, 2009), and nationwide in 2009 (Midwest Pharmacy Workforce Research Consortium, 2010) which also found that medication dispensing took over half of pharmacists' time.

Although there are some challenges in making direct comparisons between the different definitions of dispensing used across the studies, they all suggest that dispensing is a dominant activity. Table 2.9 shows the definitions and proportion of time dedicated to dispensing which across the board represents about half of a community pharmacist's time (Table 2.8). Although policy has sought to drive towards 'utilisation' of pharmacists away from 'traditional' dispensing tasks towards those considered to be more cognitive in nature (Edmunds and Calnan, 2001a), the traditional dispensing still dominates.

Table 2.9 – Percentage of time spent dispensing

	Definition of Dispensing	Average proportion of time spent of dispensing activities
This Study	Interpretation of the Rx including checking the correctness of the dispensed item. Includes checking the indication for drug, suitability for patient, e.g. interactions with other medicines. Appropriate dose of each medication. Contacting the prescriber if necessary. Includes ensuring that the product is dispensed as prescribed, e.g. checking any product assembled by dispensary technicians, as well as the legality of prescription. Assembly and labelling of products - Includes the assembly of the product requested on the prescription and generating labels for the container of that product. The process of assembling a prescription [Rx] item from receipt to the final assembly of the product, including the endorsement and filling of an individual prescription.	37.3%
Arthur Anderson LLP (Arthur Anderson LLP, 1999)	1. Present the Prescription: Includes greeting patient, obtaining appropriate data, manually recording information from ID cards 2. Process the Prescription: Includes entering patient/ doctor/ drug profile into computer system, complying with 3rd party requirements, resolving conflicts with PBMs, correcting clinical conflicts. 3. Prepare the Order: Includes retrieving drug from storage, counting pills, filling container, preparing/ placing label, returning drug to storage, bagging prescriptions. 4. Deliver/Dispense the Order: Includes placing into will call, retrieving drug from will call, delivering prescription to patient, counselling patient, cashiering.	71.8 %
Bell (Bell et al., 1999)	Assembly and labelling of products: Includes the assembly of the product requested on the prescription and generating labels for the container of that product. Checking accuracy of the final product: Includes ensuring that the product is dispensed as prescribed, e.g. checking any product assembled by dispensary technicians.	27.52%
Bond (Bond et al., 2008)	Dispensing Prescriptions	51-75%
Crealey (Crealey and McElroy, 2003)	Assembly and Labelling of products	16.25%
Dupclay (Dupclay et al., 1999)	Drug Distribution: Non judgemental tasks related to the physical distribution of the medication; Prescription: Receiving or transferring a medication prescription	34.1%
Fleming (Fleming, 1999)	Dispensing Prescriptions	50%
Mobach (Mobach, 2008a)	Filling Work ; Computer Work ; Ex tempore preparations	40%

Midwest Pharmacy Workforce Research (Midwest Pharmacy Workforce Research Consortium, 2010)	Medication Dispensing: preparing, distributing, and administering medication products, including associated consultation, interacting with patients about selection and use of over-the-counter products, and interactions with other professionals during the medication dispensing process.	74.25%
McCann (McCann et al., 2010a)	Assembly and labelling of products: Includes the assembly of the product requested on the prescription and generating labels for the container of that product. Checking accuracy of the final product: Includes ensuring that the product is dispensed as prescribed, e.g. checking any product assembled by dispensary technicians.	31.63%
Quinones(Quinones and Thompson, 2009)	Medication Dispensing: preparing, dispensing, distributing and administering medications (traditional dispensing and medication distribution activities).	53.86%
Rutter(Rutter et al., 1998a)	Dispensing: The process of assembling a prescription [Rx] item from receipt to the final assembly of the product. Interpretation of the Rx: including checking the correctness of the dispensed item. Provision of services to homes : As 1 and 2 but directly related to residential and nursing homes.	52.79%
Rutter(Rutter et al., 1999)	Dispensing: The process of assembling a prescription [Rx] item from receipt to the final assembly of the product. Interpretation of the Rx: including checking the correctness of the dispensed item. Provision of services to homes :As 1 and 2 but directly related to residential and nursing homes.	40.45%
Rutter(Rutter, 2002)	Dispensing: The process of assembling a prescription [Rx] item from receipt to the final assembly of the product. Interpretation of the Rx: including checking the correctness of the dispensed item.	35.25%
Schommer(Schommer and Pedersen, 2001)	Medication Dispensing: preparing, dispensing, distributing and administering medications (traditional dispensing and medication distribution activities).	48%
Schommer(Schommer et al., 2002)	Medication Dispensing: preparing, dispensing, distributing and administering medications (traditional dispensing and medication distribution activities).	56%
Schommer(Schommer et al., 2006)	Medication Dispensing: preparing, dispensing, distributing and administering medications (traditional dispensing and medication distribution activities).	56.2%
Scott (Scott, 2009)	Medication Dispensing: preparing, dispensing, distributing and administering medications (traditional dispensing and medication distribution activities).	53.75%

The data from London reported here shows a wide range of time spent on the assembly and labelling of products (range 9.3% to 43.9%) which suggesting some considerable differences in the organisation and structure processes within the pharmacies observed. What this data clearly suggests is that the activities of pharmacists are not homogenous across the group, and therefore other factors are influencing their work practices. Indeed, it is worth drawing attention to the results of Pharmacy D, which was run by locums during the study period. No sales transaction, training or private services were undertaken by the pharmacists, instead over half their time was dedicated to assembly and labelling of products.

A move towards counselling patients

There is similarity between the 10.9% (median 10.3%) spent on consultation activities in this study and the 10.9% (Rutter et al., 1999) and 12.5% (Rutter et al., 1998a) spent from studies in England in the late nineties. By contrast, the Northern Ireland studies found a significant reduction in the amount of time spent handing out prescriptions and counselling (9.46%,1998; 4.84%,2009) over a decade. In a 2008 survey, pharmacists reported spending

10-25% of their time spent counselling patients (Bond et al., 2008), with the accompanying work-log study finding that that median proportion of time spent on patient counselling was 9% (Bond et al., 2008). Over the last decade the number of prescriptions have increased by over 300 million items (The NHS information Centre Prescribing Support Unit, 2010) and therefore the fact that in this study a tenth of the pharmacists' time is still spent counselling patients could be seen as an encouraging. When compared across the studies about an eighth of pharmacists' time is spent counselling patients (Table 2.10).

The proportion of time attributed to counselling non-prescription medicines (mean 6.6%; median 6.6%; IQR 4.1%) and counselling prescribed medicines (mean 4.2%; median 3.8%; IQR 2.9%), is perhaps a reflection that more than 92 medicines have been reclassified from prescription only (POM) to pharmacists supply (P) status in the past 28 years requiring a greater need for pharmacist's advice and intervention with these products. This suggests that the policies that encourage self care advice in community pharmacies may be to the detriment of prescription only medicines counselling. However, a preliminary pilot as part of this study found no difference in the counselling time between pharmacists and pharmacy counter staff.

Despite the inter-pharmacy variation, there were also differences across the week. Sunday saw a large amount of time apportioned to non-prescription medicines counselling (21%), which may be due to the doctors surgeries being closed and therefore reducing prescription numbers at the weekend and where access to other healthcare settings is restricted. However, the Sunday results are only from one pharmacy (Pharmacy J), which was located in a busy supermarket, although previous studies reported that pharmacists spent more time counselling at the weekends (Rutter et al., 1998a).

A US study suggested that the likelihood a patient would receive counselling was not related to staffing levels, automation or workload, but instead the public perception and practice habits of the pharmacists (Angelo et al., 2005). Some studies suggest that pharmacists prefer working alone (Emmerton et al., 1998; Dupclay et al., 1999), actively avoiding patient contact, although this appears to contradict their apparent desire to spend more time on consultation activities reported elsewhere (Schommer et al., 2006). Further studies have endorsed public perception as a factor, suggesting that it would be easier to advise patients if they appreciated counselling (Schommer and Wiederholt, 1994). Research suggests that majority of counselling is performed by counter staff (Mobach,

2008a; Mobach, 2008b; Angelo et al., 2005). The researchers in the study reported here agreed that this was the case although this was not formally recorded.

Table 2.10– Counselling Rates in Selected Papers

Author	Counselling Definition	Average Percentage
This Study	Counselling patients on prescribed medicines: Includes personally giving out the medication to the patient and providing information on disease state, medicines supplied, side-effects, dose etc.	4.2%
	Non-prescription medicines counselling/responding to symptoms: Includes listening to any problems, advising on problems either to patients or counter staff, recommending a non-prescription medicine or referring the patient to a GP.	6.6%
Arthur Anderson LLP (Arthur Anderson LLP, 1999)	Deliver/ Dispense the Order: Includes placing into will call, retrieving drug from will call, delivering prescription to patient, counselling patient, cashiering.	8.9%
Bell (Bell et al., 1999)	Non Prescription Medicines: Responding to Symptoms: Includes listening to any problems, advising on problems, recommending a non-prescription medicine or referring the patient to a GP.	7.22% ± 2.80%
	Handing out prescription products and counselling: Includes personally giving out the medication to the patient and providing information on disease state, medicines supplied, side-effects, dose etc.	9.46% ± 7.15%
Bond (Bond et al., 2008)	Counselling Patients	10-25% (Median)
Crealey (Crealey and McElnay, 2003)	Handing out the product and counselling	14.86%±12.26%
Dupclay (Dupclay et al., 1999)	Proportion of time was spent interacting with patients	17.9%
Emmerton (Emmerton et al., 1998)	Time and in contact with patients in of instances.	14%
Fleming (Fleming, 1999)	Counselling patients	14%
Mark (Mobach, 2008a)	Counter care	4%
	Counter Other	7%
McCann (McCann et al., 2010a)	Non Prescription Medicines: Responding to Symptoms: Includes listening to any problems, advising on problems, recommending a non-prescription medicine or referring the patient to a GP.	6.82%±5.41%
	Handing out prescription products and counselling: Includes personally giving out the medication to the patient and providing information on disease state, medicines supplied, side-effects, dose etc.	4.84%± 4.37%
Quinones (Quinones and Thompson, 2009)	Consultation: consulting and communicating with patients about prescription medications; interacting / communicating with other health professionals on patient's behalf (via phone, face to-face, etc.); patient / provider education.	Non Shift Workers 18.86%
		Shift Workers 18.81%
Rutter (Rutter et al., 1998a)	Counselling: Verbal advice or information given to the recipient of the dispensed medicine	6.71%
	Pharmacist Prescribed Drugs: Counter prescribing or responding to symptoms	5.81%
Rutter (Rutter et al., 1999)	Counselling: Verbal advice or information given to the recipient of the dispensed medicine	8.7%
	Pharmacist Prescribed Drugs: Counter prescribing or responding to symptoms	2.2%
Rutter (Rutter, 2002)	Counselling: Verbal advice or information given to the recipient of the dispensed medicine	8.75%
Schommer (Schommer and Pedersen, 2001)	Consultation: consulting and communicating with patients about prescription medications; interacting / communicating with other health professionals on patient's behalf (via phone, face to-face, etc.); patient / provider education.	31%±15%
Schommer (Schommer et al., 2002)	Consultation: consulting and communicating with patients about prescription medications; interacting / communicating with other health professionals on patient's behalf (via phone, face to-face, etc.); patient / provider education.	20.75%
Schommer (Schommer et al., 2006)	Consultation: consulting and communicating with patients about prescription medications; interacting / communicating with other health professionals on patient's behalf (via phone, face to-face, etc.); patient / provider education.	19.6%

Scott (Scott, 2009)	Consultation: consulting and communicating with patients about prescription medications; interacting / communicating with other health professionals on patient's behalf (via phone, face to-face, etc.); patient / provider education.	18.1%
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This work study suggests little deviation in the work activities performed by community pharmacists compared to a literature from a decade ago (table 2.9, 2.10). The literature suggests that pharmacists are willing and able to provide more counselling but have not yet been afforded the full opportunity opportunities in practice to move this ambition forward.

Unproductive Time

Pharmacists spent 11.2% (mean 11.2%; median 8.6%; IQR 8.5%); of their time on rest, waiting and personal activities, comparable to the 14.1% observed by Rutter and colleagues (1999). Much of this time was waiting for others to complete tasks prior to being checked, or access computer terminals. This indicates that work processes within the pharmacy could be streamlined to reduce this wastage. It is debatable whether the 7% (median 4.1%; IQR 8.7%) spent on non-professional encounters is actually unproductive. This time was spent in conversation with patients on non-healthcare topics, such as the weather. However, these conversations did appear to contribute to the pharmacists' ability to build rapport with patients and therefore assess their pharmaceutical needs. By comparison pharmacists in this study spent 26.1% (median 20.4%) of their time on non-professional activities, which is similar to that observed in the Northern Ireland studies (20% in Bell et al., 1999 ; and 20% in McCann et al., 2010b).

Education and Training

Although not originally powered for in the study, there was a statistically significant variation in the proportion of time spent of staff training ($p=0.019$) between those pharmacies with and without a preregistration pharmacy student. When preregistration pharmacists are present the pharmacists apportion a greater amount of time to staff training. However these pharmacists also spent a significantly more time on sales transactions ($p=0.011$) which may be due to them allowing other staff to perform consultation activities.

Type of Pharmacy

Analysis of the ownership of the pharmacies did not reveal any statistical differences in practice. This is in contrast to studies from the US which found that pharmacists in independent pharmacies reported spending more time in consultation (Scott, 2009) and

that practice settings were found to consistently be the most influential variable in pharmacists' work activities (Schommer et al., 2006).

Delivering Pharmaceutical Services

The results from this study and the literature review suggest that around the world pharmacists spend a substantial proportion of their time on the activities and functions associated with the distribution of products, which they are contracted to do (Crealey and McElnay, 2003). The 2005 contractual framework was heralded by professional leaders as an opportunity for the pharmacy profession to use its knowledge and skills more fully in the interests of better patient care. However this study suggests that pharmaceutical services occupy less than 5% of pharmacists' time, with several pharmacies failing to complete a single MUR during the observation period. This suggests that the contractual framework has failed to achieve the desired change in roles from technical to cognitive (Bond et al., 2008). The barriers and facilitators of service delivery in relation to Medicines Use Reviews are multi-factorial and are discussed in detail in chapter 4. It is worth noting that this research was conducted towards the end of the financial year, where some pharmacies had already reached their annual MUR target. Also some pharmacies did complete MURs during the study period, but these were not during observation times.

Whatever the reasons, the contractual framework, which represented a theoretical increase in workload for community pharmacy (Bond et al., 2008) has failed to appreciably impact pharmacists' work practices. Similarly in the US, changes made to enhance medication therapy management services under Medicare Part D have not delivered the intended shift to more patient care activities (Benner and Kocot, 2009).

Implications for Policy

The evidence presented here suggests that pharmacists' time continues to be dominated by medicines supply, and that work practices have remained relatively unchanged (McCann et al., 2010a), despite policy aims to better 'utilise' pharmacists skills (chapter 1). Yet, few would argue that checking the appropriateness of prescription medicines, counselling patients, or providing enhanced services were an inappropriate use of pharmacists' skills. It is the domination of assembling and labelling products, a task that could be done by other staff, that supports the 'under-utilisation' argument.

Schommer and colleagues (2006) argue that "*Pharmacists appear ready and willing to provide consultation and drug use management services in community settings*", but

suggest that pharmacists have not been provided with the “*full opportunity to engage in these desired activities*” (Schommer et al., 2006). However, within the British context policy statements mean that this opportunity has been created in political rhetoric, but this has not filtered to the activities of grass roots of the profession.

Authors of work sampling studies in the late 1990s expressed concern over pharmacists’ ability to expand their role if practice remained the same (Emmerton and Jefferson, 1996). Dupclay and colleagues (1999) articulated unease that only 2.3% of pharmacist time in grocery chain pharmacies in the US was spent performing medication interventions and 2.9% on health interventions. These concerns have been repeated more recently in the Netherlands. Mobach (2006) advises that automation and robots, task specialization and interior design will be required because these have been shown to decrease workload, waiting time and congestion and create an increase in counterwork and pharmaceutical care (Mobach, 2006). However, in England, stock issues actually increased the time spent dispensing when a robot was installed (Rutter et al., 2001). Comparison studies between automated and non-automated community pharmacies in the US found that although automation was associated with high prescription productivity, actual counselling rates were no different (Angelo et al., 2005; Lin et al., 2007). By contrast, work flow redesign was shown to increase the number of patients offered counselling from 5% to 85% (Angelo and Ferreri, 2005). Even though the offer to counsel significantly increased after the intervention, patients appeared to be accustomed to declining communication with the pharmacist, which the authors suggest is a function of the poor expectations patients have of pharmacists. New technology and re-designed pharmacies provide increasing opportunities for pharmacists to use their skills for patient centred roles, yet many continued to perform tasks that could be performed by technicians. Therefore the conclusion of these studies suggests that staffing adjustments were needed to optimise the efficiency gained.

Staffing and skill mix have been themes which have appeared in successive policy documents (chapter 1). Currently a large proportion of pharmacists’ time is spent on activities that others could perform (Arthur Anderson LLP, 1999). However, redeployed staffing will only create opportunities if properly managed. Rutter (2002) found that the same basic functions of dispensing, communication, checking and rest and were not significantly affected by staffing and prescription workload. This lack of change was attributed to pharmacists’ lack confidence in their staff’s ability when delegating (McCann

et al., 2010a; Bell et al., 1999). Some have suggested that this may be due to issues of liability (Bond et al., 2008), whereby the profession has adopted defensive strategies in light of recent high profile cases²². Expressions of concern over the lack of sufficient training in pharmacy staff has been described as threatening the safety of medication dispensing (American Society of Hospital Pharmacists, 1989; American Society of Health-System Pharmacists and the American Pharmaceutical Association, 1996). This suggests that deft human resource management skills and a new paradigm that emphasizes the allocation of pharmacist time to those aspects that cannot be delegated may be required to overcome the entrenchment of roles and responsibilities in community pharmacy (Dupclay et al., 1999).

Hall and Johnson argue that processes (in modern process management) consist of two functions, 'art' and 'science'. However, many processes work best if they are treated as artistic work as opposed rigidly controlled. Hall and Johnson argue that *"If businesses employ both artistic and scientific processes (the rule rather than the exception), managers should work to separate them and then carefully manage the areas where they intersect"* (Hall and Johnson, 2009: p62). In the case of pharmacy the *science* is the rigid dispensing process, which should therefore be separated from the *artistic* counselling process. Creating a separation between the rigid, protocol driven, 'McDonald' processes of dispensing, with the artistic processes of patient centred care offers one possible way for the pharmacy profession to progress. Yet, if this separation were the only barrier to 'utilisation' of pharmacists skills, then undoubtedly it would have already been implemented. Therefore the findings here suggest that there are other drivers at play. It is these other barriers that are explored in the next chapter.

Limitations

It is important to acknowledge the limitations of the fixed interval work sampling approach used here. Information was not provided about the quality of consultations or services; only the proportion of time. The results provide descriptive statistics of what is observed, but this method will always be a statistical estimate.

Despite the extensive training and supervision of coding undertaken by the observers, there was still opportunity for inter-observer variance in recording activities as well as the confounding factors of observer bias and the Hawthorne effect. Taking this into

²² In the UK the 'Elizabeth Lee' case is one example, which is described in more detail in chapter 3.

consideration, these results cannot be said to be generalisable beyond the London area. However the similarity of these results with those elsewhere support the conclusion that pharmacists continue to spend the majority of their time dispensing and checking prescriptions (McCann et al., 2010b; Bond et al., 2008). The sample of pharmacies selected had below average prescription volumes when compared to national figures which may have affected pharmacists' work patterns.

The literature included in the discussion is qualitative in nature. The differences between the countries, their national pharmacy practice and the data collection methods will all influence the results. One of the main challenges has been combining the definitions for the studies for analysis. For example, a review of 42 studies showed that there was no common definition for advice-giving, better lone other functions that are carried out in the community pharmacy setting (Tully et al., 1997).

Chapter Conclusion

Work sampling studies provide an effective way of showing the proportions of time community pharmacists spend on different activities. Studies from New Zealand, USA, Netherlands and the UK appear to imply that work practices are remarkably similar, and across the board community pharmacists spend the majority of their time on traditional prescription dispensing and supply activities.

Policy efforts have called for better utilisation of the skills of community pharmacists (chapter 1) and yet only about an eighth of their time is spent directly counselling patients. These results suggest that overall the roles of pharmacists have remained fairly static over the course of the last decade, dominated by the supply of prescription medicines. Although pharmacists spend a proportion of their time of activities that no others could perform, the charge of 'underutilisation' of their skills hold weight.

While accepting that practice change will be evolutionary, rather than revolutionary, at the current pace it will be many decades before pharmacy skills are properly utilised. There is still scope for pharmacists to use the opportunities offered by appropriate staffing to delegate tasks more effectively. However this movement of responsibility will require a new paradigm that emphasizes the allocation of pharmacist time to those aspects that cannot be delegated, in order to overcome the entrenchment of roles and responsibilities in community pharmacy.

Work flow improvement, automation and process standardisation can be used to improve the efficiency of the pharmacy environment. Extrapolation of evidence from process management (Hall and Johnson, 2009) postulates that the separation of *science* -the rigid dispensing process- from the *art* - the counselling processes - will provide efficiency and patient benefits. After all, if pharmacist really wish to enter the medical domain then they must accept that *“If it were not for the great variability among individuals, medicine might as well be a science and not an art” (Sir William Osler, 1892)*

The evidence presented here suggests that the current policy direction has failed to deliver the anticipated utilisation of community pharmacy skills. Although the desire for this change is largely supported within the profession and current policy creates an opportunity for this path to be followed, the practical implementation of this policy is yet to be achieved. On this basis; further research is required to understand why the implementation of these policies have not been realised, and to discover why pharmacists have not moved beyond the traditional dispensing role. It is this research that forms the basis of the next chapter.

Chapter 3. The Community Pharmacy Income and Workload

Chapter Introduction

The work sampling study in the previous chapter demonstrated that pharmacists remain deeply rooted in the medicines supply process. This is despite policies which seek to propel community pharmacy towards extended clinical services and care based activities on the high street.

It is not solely these findings that acknowledge the lack of change in community pharmacy activities. A review of the contribution of community pharmacy to health services in Wales by the National Assembly for Wales concluded that significant barriers still exist in realising the full potential of community pharmacy, and that community pharmacy can do more to contribute to health services in Wales (National Assembly for Wales Health and Social Care Committee, 2012).

This thesis explores why this has been the case, and why these policy ambitions are yet to be realised in practice. The answers to these questions are multi-factorial and will be explored in this chapter through an analysis of the business, by understanding the financial models that incentivise practice and drive commerce.

The 'underutilisation' of community pharmacists may be attributed to the workload increases that pharmacists have experienced. However, this workload can only be understood in context, which necessitates analysis of the income streams that support community pharmacy businesses. Community pharmacy workload is explored in greater detail in appendix A. Through extrapolation, this chapter explores the trends in community pharmacy income and relates this to anticipated future workload. Based on this, predictions are made about future occupational workload. Finally, the chapter closes by turning to the trends in prescription supply volume and the factors associated with them as these have dominated professional pharmacy practice since the creation of the NHS.

The evidence and case for a reform of the current workload and practice is presented at the end of the chapter. Using a range of evidence, including original research into the shortened durations of prescriptions, this chapter indicates that the current policy community pharmacy objectives are unsustainable given the current framework.

Income in the Community Pharmacy Market

In simplistic terms, companies take inputs to which they apply a service or process that adds value in order to produce an output²³. At the basic level the difference between the input and processing costs compared to the output costs represents the profit.

Under this basic model community pharmacies produce several outputs: prescription medicines and associated advice; consumer goods (in particular OTC medicines); privately or NHS funded pharmaceutical services; and finally, and some would argue most importantly, a pharmacy business produces profit as an output - a return on capital investment, required for sustainability.

Pharmacies have traditionally been associated with two types of process to achieve these outputs: the dispensing and supply of prescription medicines, and the provision of certain consumer goods sold in the pharmacy. More recent changes in the pharmacy contract coupled with certain drivers from the professional leaders within community pharmacy have led to a third type of process, broadly defined as 'extended pharmaceutical services'.

This section of chapter three explores the main income streams into a community pharmacy behind each of these processes and reflects on how the changing mix of the income streams influences the workload of pharmacists and pharmacy staff. Workload trends are identified from extrapolation of historical data. Such trends provide insight into future workloads, practice and incomes. This section begins by analysing the trends in medicines supply before looking at the other factors associated with the pharmacy business.

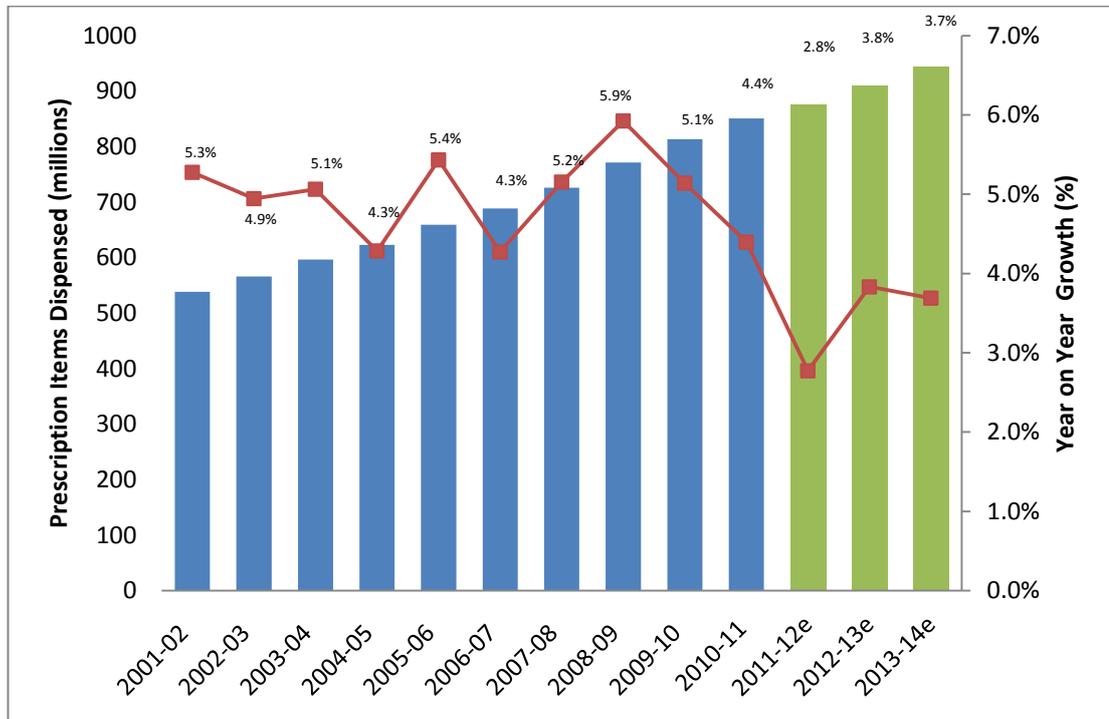
Prescription Medicines Supply

Community pharmacies in England received 877.2 million dispensing fees from the NHS in 2010/11. These prescribed items had an average net ingredient cost of £9.04 each (The NHS Information Centre, 2011). This equates to £7.9bn being spent on prescription medicines in primary care supplied from pharmacies, out of a total spend of £8.81bn on drugs in primary care in 2011 (Adams, 2012). Therefore over 90% of NHS primary care drugs by value are supplied from community pharmacies (Adams, 2012). In addition to this, there is a small market for private primary care medications, estimated at the market level to be less than 1% by value.

²³ A discussion of the value added by community pharmacy business is provided in Appendix C.

The number of prescription items is expected to continue to grow driven by patient demographics, but the rate at which this growth continues is likely to decrease (figure 3.1). Based on previous trends the forecasts suggest that prescription items will continue to increase at about 3.7% each year.

Figure 3-1 - Prescriptions Items dispensed in England (millions)



Source: NHS Information Centre. Forecast estimations in green.

While the volume in item terms (and therefore in workload terms) is increasing, the relative value of each item is decreasing. In previous years the expenditure on the drugs budget grew by around 3 – 4 % per annum to keep pace with volume increase. Yet despite a steady increase of between 4 and 5 % in prescription volume (figure 3.1), the relative budget for primary care prescribed items in the NHS dropped by 0.1% in 2011 from the £8.83 billion spent in 2010. This change has been due to several factors that are likely to persist in this market.

Firstly, the Medicines Margin Survey led to adjustments in Category M for generic drug reimbursement prices. This forced community pharmacy contractors to negotiate for lower prices on generic medicines.

Secondly, there has been an increase in generic prescribing rates, driven by initiatives such as ‘better care, better value’ indicators and the patent expiry of some high volume branded

medications. Notably, this has been observed in the cardiovascular disease arena, where spending decreased from £1.51 billion in 2010 to £1.35 billion in 2011. In part this reduction was aided by a cut in spending on clopidogrel which reduced from £46 million in 2010 to £12 million in 2011, due to generic entry, despite an overall volume terms increase in supply. Other high value drugs (table 3.2) have become or are about to become generic, and therefore likely to lead to further savings. Atorvastatin (Lipitor) was the second biggest spend of any drug in 2011, at £310.8million. However, its switch to generic will lead to a significant reduction in the cost of this commonly prescribed lipid lowering medicine.

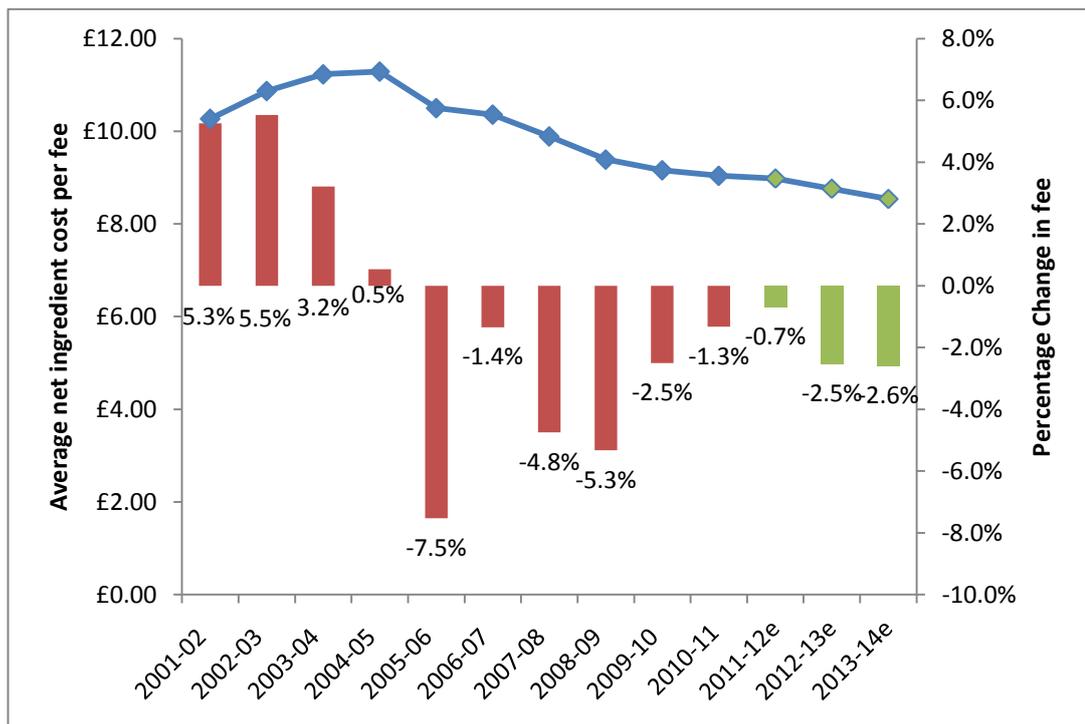
Table 3.1 – UK Patent Expires 2012-13

Brand Name	Generic Name	Expiry Date	NHS Primary Care Cost 2010 (millions)
Lipitor	Atorvastatin	May-12	£305.8
Seroquel	Quetiapine	Mar-12	£92.8
Aricept	Donepezil	Jan-12	£63.1
Amias	CandesartanCilexetil	Apr-12	£85.7
Aprovel	Irbesartan	Aug-12	£46.6
Plavix	Clopidrogrel*	Aug-12	£46.4
Serevent	Salmeterol	Sep-13	£45.1
Singulair	Montelukast	Aug-12	£43
Viagra	Sildenafil	Jun-13	£41.4
Destrusitol	Tolterodine	Sep-12	£34
Reminyl	Galantamine	Jan-12	£17
Cymbalta	Duloxetine	Dec-12	£16.8
Amanex	MometasoneFuroate	Feb-12	£16.5

Source: (Adams, 2011). Cost data based on Prescription Cost Analysis report for England 2010 (only primary care). *Clopidogrel has been available as a generic since 2009 due to a patent loophole.

Thirdly, the Pharmaceutical Price Regulation Scheme (PPRS) has resulted in a reduction in branded drug prices (with price cuts of 7.0 per cent in 2005, 3.9 per cent in 2009 and 1.9 per cent in 2010) which have further reduced the cost of medicines in primary care. The combination of these factors since 2005, has contributed to a steady decrease in the net ingredient cost of each prescription item (figure 3.2).

Figure 3-2 - Value of Prescriptions



Source: NHS Information Centre; forecasts in green.

The average net ingredient cost per prescription item is forecast to continue to decrease by at least 2.5% per annum. Meanwhile the overall volume is expected to increase by 3.7% (figure 3.1).

The decreasing trend in ingredient costs from 2005 onwards (figure 3.2) can be attributed to the new pharmacy contractual framework, which restricted the purchase profit available on generic medicines through the Category M mechanism. Contractors are reimbursed from the NHS at a price listed in the Drug Tariff (Department of Health and the Welsh Assembly Government, 2012), a monthly publication from the Department of Health. If pharmacies are able to purchase medicines from wholesalers at less than the listed Drug Tariff price, then they can retain the difference – the ‘purchase profit’. The contractual framework limits the amount of purchase profit that pharmacy contractors can retain to £500 million per annum. When the £500 million target was originally set in 2005, it was estimated that there was £800 million of retained profit in the system, but evidence showed that this was an underestimate (National Audit Office, 2010).

Successive reductions in the list price of Category M medicines have continued to reduce pharmacy income. For example, in 2007 the list price of generic medicines was cut by £400 million. In 2008, Category M was reduced by a further £32.5m per quarter, which equated

to a reduction of approximately 16 pence per item (Pharmaceutical Services Negotiating Committee, 2008) due to the £500m agreed purchase price being exceeded in the previous year.

The reason for margin targets to be exceeded is principally because pharmacy contractors negotiate lower purchase prices for medicine, which in turn creates lower than expected prices in the medicines market. These reductions are then factored into the following year's negotiations, incentivising pharmacies to keep driving down medicine prices year on year. This cycle has helped to reduce the cost of medicines, but cannot continue indefinitely. Eventually prices will reach a point where pharmacies are unable to gain £500m from the system.

Invoices of independent pharmacy contractors govern this £500m limit, but delays in the system sometimes allow contractors to accrue more than £500m. The system fails to account for those pharmacies with vertical integrated supply models, that have been able to extract more than this figure from the overall supply chain. For example, a margin of £3.61bn was retained between 2005/06 and 2008/09 (National Audit Office, 2010). This represented a difference of £1.57bn from the agreed £2.03bn (although £0.46bn of this was recouped through reduced practice payments (National Audit Office, 2010)).

About 90% of medicines are delivered to pharmacies by wholesalers (within which approximately 6% is by short line wholesalers). The remaining 10% are either self-supplied by the pharmacy, or supplied direct from the manufacturer (Office of Fair Trading, 2007). Wholesalers and distributors also need to acquire their income from the £8bn paid by the Department of Health for medicines. It was established in 2007 by the Office of Fair Trading that the vast majority of branded medicines (which represent three quarters of NHS primary care medicines spend) are sold at a 12.5% discount to wholesalers, who supply the medicines to pharmacies at around a 10.5% discount. The exceptions to this account for less than 3% of sales value (Office of Fair Trading, 2007). Wholesalers will take their share of the discount and then supply this onto pharmacies. Pharmacies then have a claw-back of around 10% (between 5.63% and 11.5%) applied to their monthly reimbursement to allow the DH to gain from these reductions (Office of Fair Trading, 2007).

In conjunction, these two mechanisms (Category M and claw back) help limit the cost of medicines across England. However, the system can leave pharmacists in a position where they are dispensing items as a loss. Firstly, some manufactures and wholesalers change

their discount terms to remove or reduce discount from certain products. After claw-back is imposed these contractors are reimbursed less than the price they paid. This particularly affects those contractors who have an above average number of items for which discount is not available. Secondly, for generic medicines there have been cases where the time-lag between price setting and current market conditions have left contractors with a loss following the purchase of a product. This is because Category M is based on data from generic manufacturers that is provided quarterly (e.g. data for October to December will be provided to the Department of Health by February to set prices in April to June) creating a time lag between data collection and setting.

The recent implementation of direct to pharmacy or limited wholesale arrangements by pharmaceutical manufacturers provides them with a strong platform to reduce the level of discount they offer, in order to increase their own profitability. Roughly a one percentage point reduction in the level of pharmacy discount could result in a £50 million loss to pharmacy. Pfizer, among others, have assured the Department of Health that this will not lead to increases in medicines costs, however this may not be the case in the future (Office of Fair Trading, 2007).

Overall there is a total market for both private and NHS primary care prescription medicines in England of £8.9bn. Of this, about £8bn is turned over through community pharmacies. About a £1bn of 'purchase profit' is shared between the wholesalers and the pharmacies. Some of this is clawed back by the Department of Health. Yet, the overall amount of profit available to pharmacy contractors from this market is highly dependent on their ability to secure discounts on list price, and is likely to be highly variable in the future.

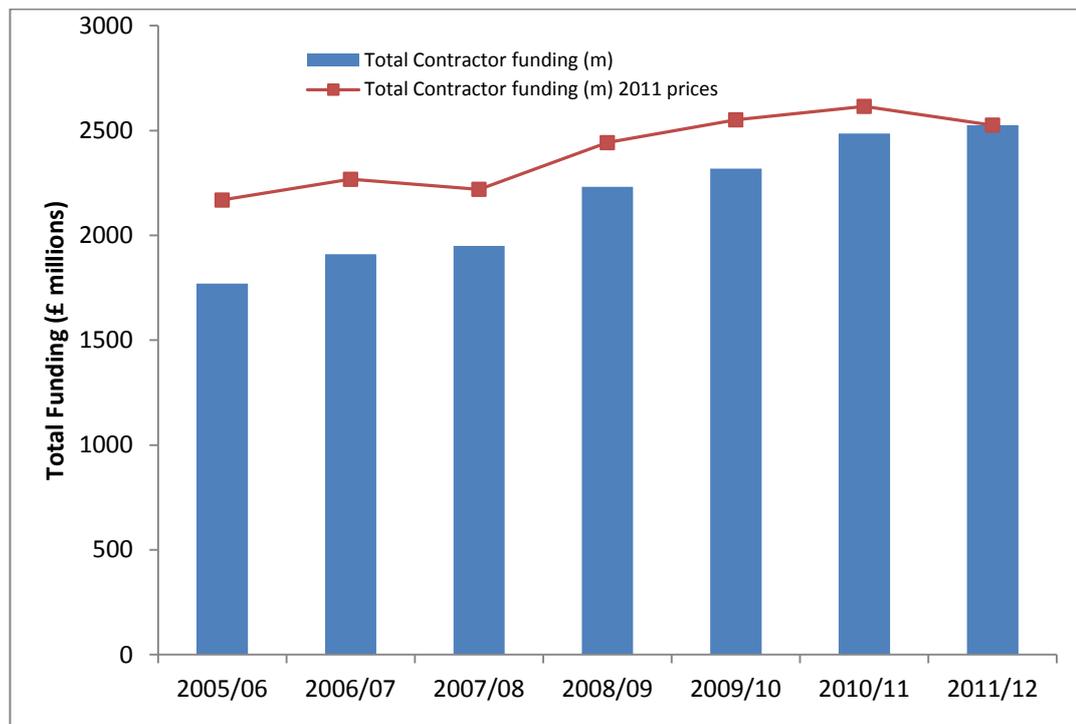
National Contractual Framework

Each year since 2005, the Pharmaceutical Services Negotiating Committee (PSNC), made up of representatives from the Company Chemists Association (CCA), independent contractors, and national representatives for pharmacists, has negotiated with the Department of Health and the NHS Employers²⁴ (a group representing about 95% of NHS organisations) for pharmaceutical services in England and Wales. This nationally negotiated framework represents a significant source of income into community pharmacies. The negotiations agreed £2.562bn for contractors nationally for 2011/12 (Pharmaceutical

²⁴ As of March 2013 the National Commissioning Board will have the responsibility for deciding upon the national contractual framework for community pharmacy.

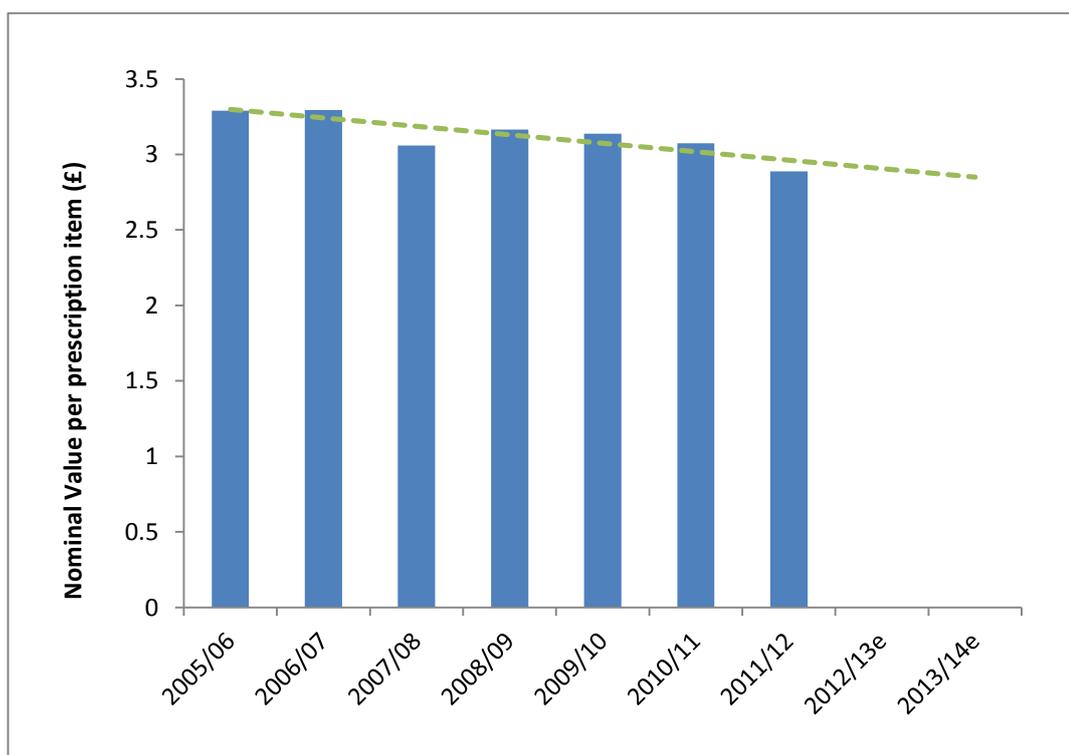
Services Negotiating Committee, 2011d). The total budget has increased year-on-year since 2005. However, in absolute terms - taking inflation into account at composite price index at 2011 prices - the trend ceases to remain positive after 2010, and has a far shallower gradient (figure 3.3.).

Figure 3-3– Agreed total contractor funding in England 2005-2012 (with and without inflation)



Taking into account the increase in volume, and the increase in total contractor funding, then the notional value of total contractor funding for each prescription item has in fact decreased since 2005 as shown in figure 3.4.

Figure 3-4 – Nominal Funding per item*



*Nominal Item value is calculated from the total contract budget divided by prescription item volume. This is non-inflation adjusted.

The effect of this decrease in overall nominal funding per item at 2011 prices is suggestive of a squeeze on overall margins for pharmacy contractors. This indicates a decrease of 1.9% in the nominal value of a prescription item each year. Overall national funding for community pharmacy as a proportion of NHS expenditure has remained fairly static, at just under 2.5% (table 3.3).

Table 3.2– Pharmacy expenditure as proportion of net NHS spend

Year	NHS net expenditure in England (£m)	Agreed pharmacy contract funding (£m)	Percentage of Total Expenditure
2005/06	73,203	1,770	2.42%
2006/07	76,831	1,910	2.49%
2007/08	83,223	1,950	2.34%
2008/09	89,927	2,231	2.48%
2009/10	97,130	2,318	2.39%

Source: NHS Net expenditure in England from the Public Expenditure Statistical Analyses 2011.

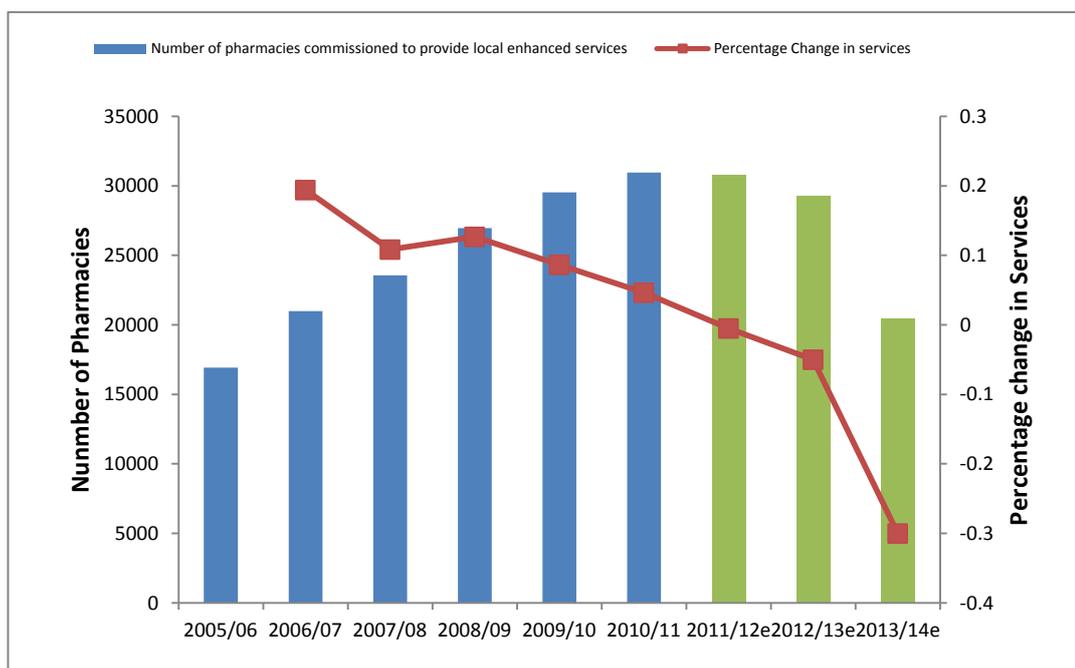
<http://www.nhshistory.net/parlymoney.pdf>

Within the national funding negotiations, there is a negotiated budget for advanced services. About 2.5 million MURs were conducted last year, equivalent to £70 million, and NMS has been budgeted at £55 million, (AUR and SAC represent a marginal additional income stream). Therefore advanced services represent about 5% of the national contractual framework.

Enhanced services are negotiated locally, and represent £4,977 per pharmacy per annum (Hall, 2012), contributing about £0.05bn across the sector. However, this is not homogenous, in City and Hackney PCT nearly £2.5m was spent on enhanced services, compared to just £250 in South Gloucestershire PCT. For the average community pharmacy with a turnover of several hundred thousand pounds, enhanced services represent a negligible income stream.

The current outlook for services is particularly uncertain. The trend in the number of services commissioned has increased by 45% since 2005. Yet the rate of growth is decreasing, possibly indicating that the capacity to deliver services has become saturated. On the one hand policy initiatives suggest that this sector will develop, but on the other reconfigurations within the NHS suggest that widespread commissioning of pharmacy services will not be actively purchased by clinical commissioning groups. Therefore the estimations of this area as a source of income suggest that it will decrease in the future (figure 3.5).

Figure 3-5– Number of Pharmacies commissioned to provide local enhanced services



OTC Pharmaceuticals

Over the counter pharmaceuticals (OTCs) are categorised into ‘P medicines’, which must be sold under the supervision of a pharmacist, and GSL medicines, which can be sold from any retail outlet. The sale of these products accounts for a significant proportion of turnover in community pharmacies. Until 2001, pharmacy profits in medicines sales were maintained by a resale price maintenance (RPM) scheme. When this scheme was removed the profits of many independent community pharmacies fell, but consumers enjoyed cheaper medicines and better access through supermarkets.

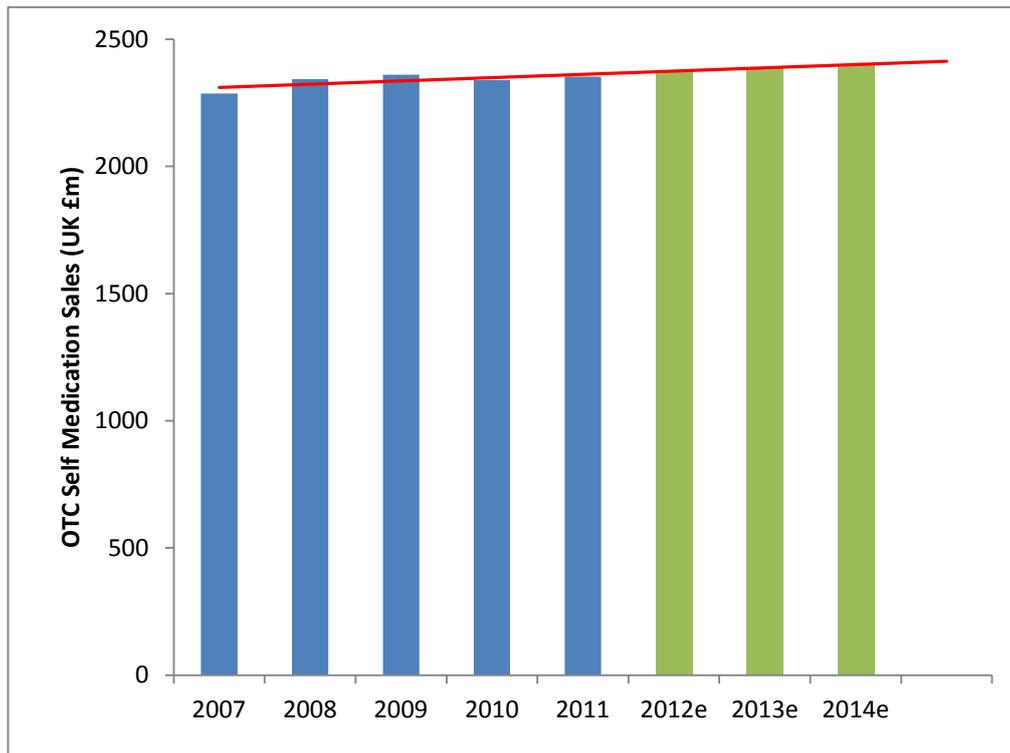
Despite the reduction in pack prices, the UK market for non-prescription medicines supplied without a prescription, as shown in figure 3.6, has continued to grow by 2.8% over the five years between 2007 and 2011 (AESGP, 2011). The market is currently valued at about £2.4bn (The Proprietary Association of Great Britain, 2010; AESGP, 2011; Keynote Report, 2011a). Including those non prescription medicines supplied on a prescription increases this market to approximately £3.4bn (at retail selling prices²⁵). This suggests that about £1bn of OTC medicines are supplied on prescription²⁶ (AESGP, 2011).

²⁵ Note that supplied on prescriptions, these medicines are zero rated for VAT.

²⁶ Conversion based on 2010 average of 1.17 Euro equal to 1GBP. Based on x rates.com

<http://www.x-rates.com/d/EUR/GBP/hist2010.html>

Figure 3-6 -UK OTC self medication sales



Source: AESGP, author estimations. Trend line in red. Forecasts in green.

In 2008, for the first time ever, globally the growth of sales of OTCs surged significantly ahead of growth of sales of prescription medicines. Now worth €73bn globally, the OTC market continues to outgrow the pharmaceutical sector by a clear and consistent margin (Keynote Report, 2011a).

Yet independent community pharmacy is less likely to capitalise on this growth due to the large mass market sector. The United Kingdom is often considered the most developed OTC market in Europe, in light of its progressive regulatory system, its heavy advertising spend, its highly active POM to OTC switch environment and its large mass market sector. While the wide availability provides benefits in exposure, the existence of such a prominent non-pharmacy sector has created a highly competitive pricing environment. Such competition has only intensified in the current economic environment, with community pharmacies suffering. According to estimates by Keynote the share of total sales in retail pharmacies declined from 17.1% in 2005 to 16.4% in 2010 (Keynote Report, 2011b). The increasing number of supermarket pharmacies has contributed to this trend, undermining the number of OTC pharmaceuticals that are sold on high street pharmacies (Keynote Report, 2011b). By volume, Tesco now represents the largest supplier of non-prescription medicines

(Chapman, 2011b) taking the title from Boots, who by value remain the largest supplier of OTC medicines to the public (Boots UK, 2012).

One of the factors driving the shift of supply away from pharmacies is the increasing deregulation of medicines. The switches are part of a national policy that drives collaborative care, whereby consumers rely heavily on the advice of pharmacists in making their OTC purchases. For manufacturers within this saturated market creating innovation by switching medicines from POM to OTC is the surest way to stimulate market growth. On this basis, many new products and indications are likely to become available OTC. A centralised procedure for POM to OTC switches has opened a gateway for switches to take place simultaneously across all 27 EU member states. The first two products to move through this process were orlistat 60mg (marketed as Alli) for weight loss and pantoprazole 20mg for acid reflux. Although these were categorised as P medicines in the UK, the future outlook suggests more medicines will be deregulated to GSL status, where pharmacies will be competing with other mass market outlets for sales. The combination of these factors has resulted in 55% of OTC medicine sales being made in community pharmacies down from closer to 70% a decade ago (IMS Health and Tisman, 2011). Therefore the remaining medicines that are supplied tend to be 'P' (pharmacy only) medicines which require more advice and time to be spent with the consumer. Indeed, increasingly complex sales protocols for new POM to P medicines, such as lengthy questionnaires, are being blamed as one of the most common factors in the 'failure' of a switch (PAGB, 2012).

In 2011, the estimated total OTC market in England at retail selling price was £2.77bn²⁷, of which £2.01bn was supplied without a prescription. Community pharmacy represents 55% of this market, therefore approximately £1.1bn OTC medicines are supplied without a prescription by community pharmacies²⁸.

While the overall market will grow the extent to which community pharmacy will benefit from this growth is limited. Nowhere else in Europe is there such a breadth of product types available for self service selection though supermarkets and impulse outlets. Grocery and discount stores have been increasing their market share, and therefore the growth in sales will likely benefit these alternative providers. Therefore the anticipated 0.5% growth expected in this market is unlikely to be realised by community pharmacy contractors.

²⁷ Includes VAT payable on OTC medicines of 20%.

²⁸ There is an additional £0.7bn in OTC medicines supplied on prescriptions in England, however these are accounted for in the NHS prescription figures.

Private Income

Pharmacies offer services that provide them with additional income, such as travel clinics or nurse led clinics. Taken as a whole the market for private healthcare is expanding with approximately 15% of the population in possession of some form of private healthcare insurance (Office of Fair Trading, 2012). The total market for acute private healthcare in the UK was approximately £5bn in 2010 (Laing & Buisson, 2012). The penetration of community pharmacy into this market is limited, with the main income arising from the supply of private prescriptions. Some pharmacies have embraced private travel clinics or fee based services, such as hair retention or weight loss. The estimated total revenue from this source is less than £0.2bn per annum across the pharmacy sector.

The income from private sources is likely to remain relatively static. Some contractors may partner with other private healthcare providers, such as Virgin Activ or BUPA to expand into this sector. Although currently, the degree to which it influences the overall viability of the market is marginal.

Health and Beauty Retail Sales

The total health and beauty market in the UK in 2010 was £17.9bn and is estimated to have increased to £18.5bn in 2011 (Verdict Retail Futures, 2012). Despite an economic downturn, this market has expanded, driven by the need for small luxuries in everyday life, especially at a time of reduced spending. The bounce back seen in 2011 led this sector to become one of the fastest growth channels in store based retailing, with health and beauty specialist retailers increasing by about 4% in current value terms going into 2011 (Verdict Retail Futures, 2012).

The health and beauty market is likely to remain resilient and continue to grow, especially as providers continue to push into underserved markets such as male health and beauty products. Between 2002 and 2007 sales by health and beauty specialists collectively increased by 18.5%, showing the beginning of a slow down on the 29.5% growth seen across the previous five years (Verdict Retail Futures, 2012). This slow down was exacerbated by the economic recession, leading to a predicted growth from 2008 to 2013 of 16.8%. However these still represent an overall per annum growth of 2.7%.

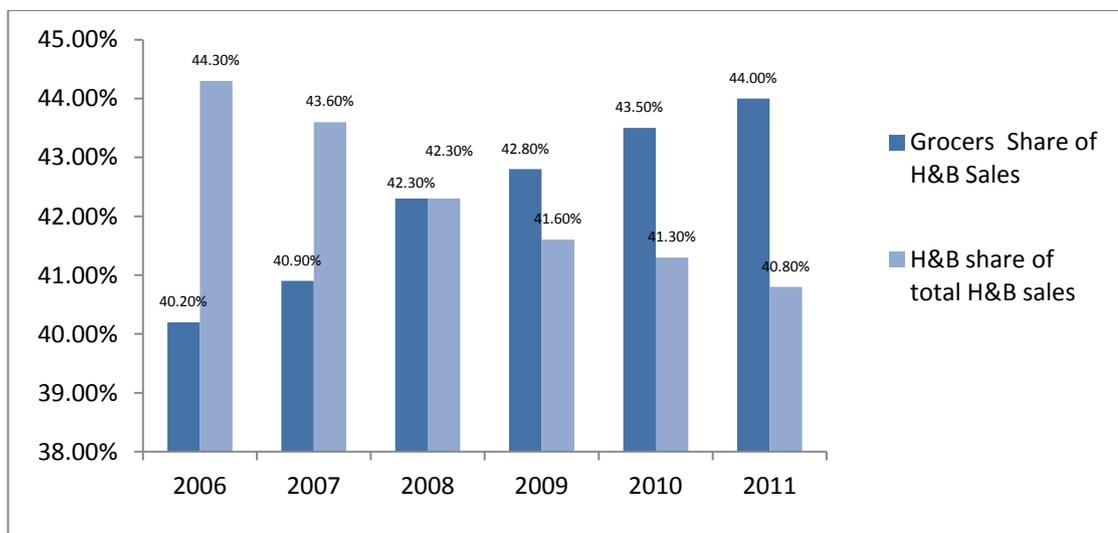
Boots lead health and beauty retailing, with annual health and beauty sales of over £3.984 billion, representing 62% of their revenue in 2010/11 (Alliance Boots, 2011). Recently there has been a loss in their market share due to strong competition from Superdrug, which

launched a beauty card scheme, and the major grocers, which are becoming a popular channel for health and beauty products.

The changes in pharmacy market entry have led to a significant shift in focus from retailers placing attention on dispensing as a driver of footfall. Therefore Boots and Superdrug have continued to expand their pharmacy networks at the expense of their para-pharmacies²⁹. Companies, such as Savers, a discount health and beauty supplier, have experienced a big decline in sales, largely as a result of its parent company Hutchinson Whampoa diverting resources to its sister brand, Superdrug (Verdict Retail Futures, 2012).

Skincare has continued to expand as a component of the health and beauty market. The aging population and the higher proportion of women with disposable income is driving this growth, meaning that skincare may overtake OTC as the largest component of the market. Although the sector will see growth, pharmacies and specialist health and beauty retailers will continue to see loss of market share (figure 3.7) because supermarkets are continuing to aggressively develop their offering.

Figure 3-7 – Changes in UK Health and Beauty Market Share



Source: Keynote Market report 2011

Supermarket chains have also expanded their pharmacy offering as well as creating in the region of half a million sq ft of additional health and beauty retail space in 2011. These rapidly growing pharmacy portfolios, and highly promotional pricing, including round pound and multi-buy deals in the grocery sector add pressure to stretched health and beauty specialists. Grocers represent approximately 44% of all health and beauty products

²⁹ Those operating as drug stores, sometimes without a pharmacy/pharmacist.

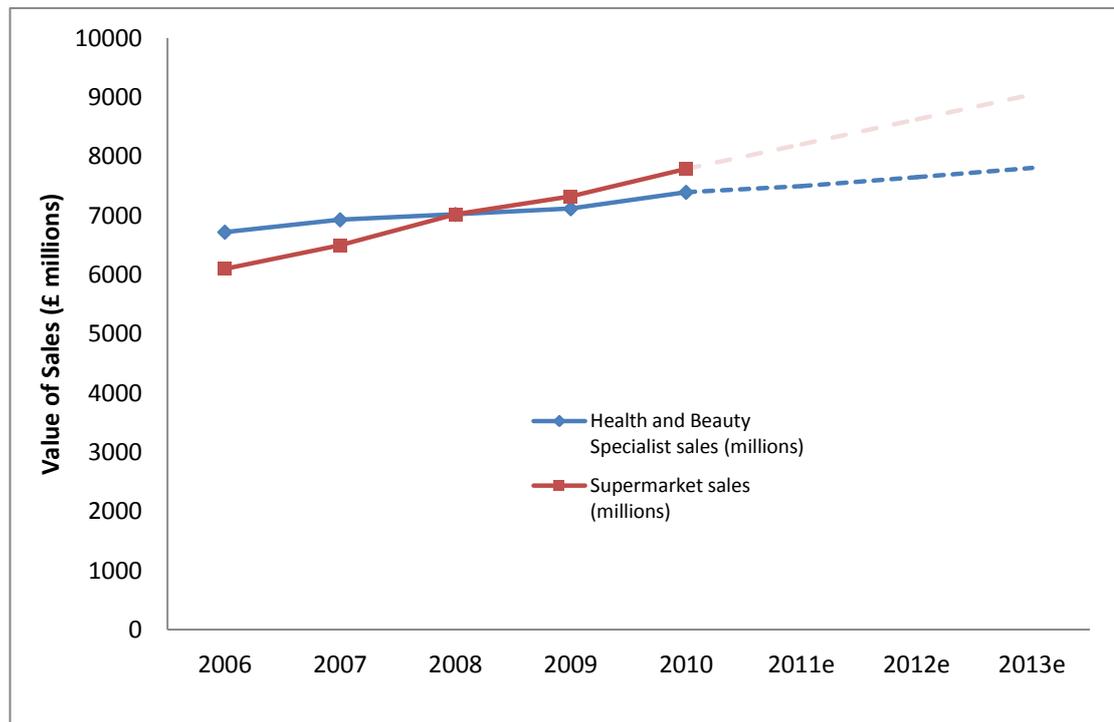
sold in 2011 (Verdict Retail Futures, 2012), taking market share from specialist health and beauty retailers. As a result the market leader, Boots, continues to lose market share down to 22.1%. Boots have attempted to react to this by cutting costs and raising margins, which has ultimately improved their profitability (Alliance Boots, 2011). These tactics have driven down prices in the sector and consequently the margins available to smaller pharmacies are likely to decline.

Overall growth in health and beauty specialist retailers outside of pharmacy is likely to be minimal as a result of saturation and increasing competition. Budget retailers such as B&M Bargains, Poundland, 99p stores and Wilkinson are also competing with community pharmacies for market share and are opening more stores as high street properties becomes vacant. These retailers are changing their image to attract mid market shoppers who, in times of economic recession, are trading down.

Particular aspects of community pharmacy sales are being hit. The fragrance market, which once showed significant profitability for pharmacies, is suffering from competition by The Perfume Shop and The Fragrance Shop. These providers are rapidly expanding by offering discounted designer label fragrances to price conscious consumers.

In total the English market for health and beauty products is about £16bn. Of this, health and beauty specialists, which include pharmacies, represent about two fifths of market share. Excluding the other health and beauty specialists and the £1.1bn spent on OTC Medicines in community pharmacies. This suggests that health and beauty sales in community pharmacies in England are worth approximately £5bn.

Figure 3-8 - Value of the UK Market for Health and Beauty specialist retailers and Supermarkets



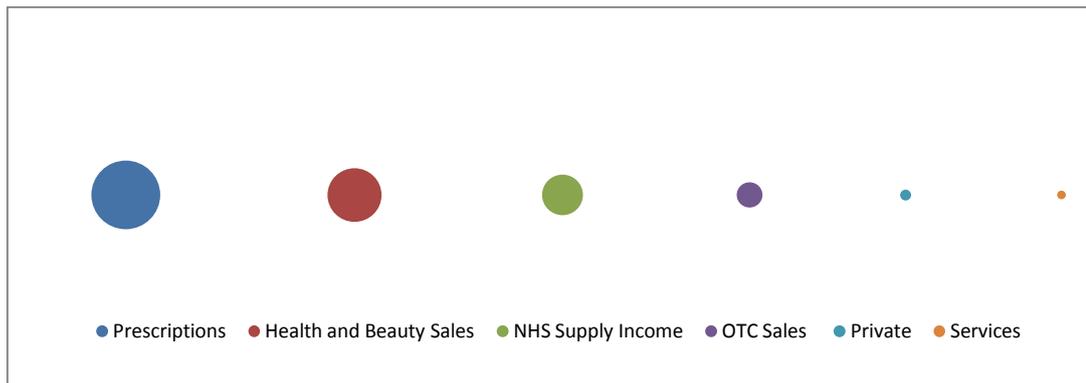
Source: Verdict Health and Beauty Retailers 2011.

The dashed line in figure 3.8 shows the forecast growth in the UK market. The year-on-year increase from 2012 onwards is forecast to be 2% growth. This figure relates to all health and beauty specialists, including pharmacies, and is UK wide. In reality, the real terms increase in market value for independent community pharmacies is likely to be minimal.

Overall Community Pharmacy Market in England

Considering the four different income streams identified above, the community pharmacy market can be represented as shown in figure 3.9 below, where the size of the circle is proportional to the value of the market. It is evident from this diagram that the main income streams are prescription supply and health and beauty products. Services provision represents a small fraction of overall income in the community pharmacy market in England. Overall, these six revenue streams combined to represent an estimated total market income available to community pharmacies in England of £16.3bn in 2011.

Figure 3-9 - Market Size for Community Pharmacy by Area



While accepting that there are a variety of business models that operate across pharmacy, in general terms independent pharmacies operate in an environment where the majority of their income is derived from the NHS. It was suggested in 2003 that approximately 80% of the average independent community pharmacy's turnover is generated by NHS business (Office of Fair Trading, 2003), a figure which has more recently been estimated to be closer to 90% (South East Local Pharmaceutical Committee Forum, 2005). Therefore typically prescription dispensing accounts for about 80-90% of revenue, retail sales accounts for 10-20% of revenue and pharmacy services represent about 5%.

In a business environment, workload will inevitably be focused towards those activities that secure the greatest income. In the case of pharmacy this is the supply of prescriptions and the sale of health and beauty products (including OTC medicines). The provision of community pharmacy services provides a minimal income, and although a possible income stream, it is not the main priority of the businesses. To some extent this explains the observation that pharmacists continue to spend the majority of their time on supply of prescription medicines (chapter 2).

Average 'Ideal Type' pharmacy? – a simplistic model.

Against these trends, the average community pharmacy: supplies 6,300 prescription per month; provides 192 MURs per year³⁰; completes 54 NMS per year³¹; and receives £4997 for enhanced services. At £9.04 per prescription item, NHS revenue is £683,424. Including fees, total NHS revenue per annum is £896,591. The average pharmacy is independent,

³⁰ Based on 2011 data: 203,628 MURs divided by 10, 951 pharmacies.

³¹ Extrapolated based on limited March 2012 data

therefore total non NHS revenue is 20% of this total, or £179,318. Removing purchase costs, gross Non NHS income is £17,931. Therefore average pharmacy income³² is £231,098

For an independent the average property costs are £26,058, depreciation is £13,000, other costs, £17,767, head office Costs £2,600 and cost of capital is £39,983. The staff costs are £152,660. This totals a cost of £252,069.

A full explanation of this model and the relative figures for each of these averages is provided in the appendix B. As with any model there are several simplifications and assumptions, based on the readily available data.

Therefore, by the average of averages, the average pharmacy is not profitable, making a loss each year. It is evident from reality that the average pharmacy does not make a loss. In fact far from it, the vast majority of pharmacies operate a profitable business. What this suggests is that the data is either falsely increasing the costs, or there is additional income that is not accounted for in this model.

The model of the average 'ideal type' pharmacy is one that is fictitious in its existence as the numbers provided are averages across a range of variables. As already described, there is no such thing as the average pharmacy, with pharmacies adopting different business models. However, what this exercise shows is that the national data sets used and the actually income streams into community pharmacy are not transparent. It is likely that retained buying profit and wage transfers exist which are not accounted for in this model.

Section Conclusion

The main income stream into a community pharmacy business is generated from the supply of prescription medicines. The margins for these medicines and the relative values of each prescription have decreased over the past decade. This is a trend which, under times of economic recession, looks set to continue.

Sales of OTC medicines and allied health and beauty products from independent community pharmacies have suffered as a result of the expansion of supermarkets into this sector. While the large health and beauty retailers have been able to compete, smaller independent pharmacies have suffered a considerable loss in their market share.

³² This makes the Pharmacy Income = £201,444 + (£5376 + £1350 + £4997) + £17,931.

Further revenue can be generated by extended pharmaceutical services. Yet at present the scale of funding for these services is erratic and unpredictable. At present such services do not represent a viable business opportunity for pharmacies. Without sufficient assurances of returns there is unlikely to be future investment by businesses in these services.

Against this, it is unsurprising that pharmacists have focused their attention on prescription supply, and spend a large proportion of their time assembling and labelling products. Despite the workload challenges created by the growth in prescription items and the decrease in relative margins, dispensing continues to represent a guaranteed income stream.

The rest of this chapter seeks to understand why there has been such an increase in prescribing volume, and to explore strategies that can be taken to address this workload by focusing on the relationship between prescription durations and volumes.

The Increases in Prescription Volume

[The data report reported in the section formed the substantive part of a paper published in Primary Health Care Research and Development under the title "Individualisation or standardisation: trends in National Health Service prescription durations in England 1998–2009".(Davies and Taylor, 2012)]

The increase in prescriptions seen over the last decade is a reflection of the changing mantra of the health service as it moves from acute healthcare towards preventative health and the management of chronic disease. The literature suggests that the increasing age of the population; the increased use of secondary preventative technique (as well as an increase in the prescribing of preventative medicines, such as low cost statins, for cardiovascular diseases); the dominance of the unhealthy lifestyle which have driven up prescription use (obesity, etc); and finally the increase in evidenced based medicine driving national guidelines for prescribing (e.g. NICE guidelines), are all factors that have led to rising prescription volumes (Davies and Taylor, 2010a).

Undoubtedly, the Quality and Outcomes Framework (QOF), introduced in 2004 as a reward programme for GP practices, has led to the increase in prescription volume through its incentivisation of prescribing for primary prevention, particularly in cardiovascular disease. As the background prevalence of chronic disease increases, this (and other national prescribing frameworks such as NICE guidance and National Service Frameworks) has led to an increase in prescription items for other prevalent chronic diseases, such as asthma and diabetes.

All of the reasons provided above suggest that prescription volumes are a factor of health, and are driven by health targets. However, other subtle factors may be at play. Some have hypothesised that the duration of each prescription has also influenced the observed increase in prescription items (York Health Economics Consortium and School of Pharmacy University of London, 2010). The authors suggest that pharmacists have actively encouraged shorter prescription durations, using evidence that longer prescription durations result in increased medicines waste to artificially increase their income. However, there is little published evidence to prove whether this is the case.

In order to strategise ways for pharmacists to manage the increasing number of prescriptions, as well as to understand processes that led to the increase in prescription

volume, an evaluation of the NHS prescribing data was undertaken to discover the extent to which the shortening of prescription durations has affected prescription volumes.

Background to Prescription Duration

During the 1990s, several studies explored the opportunities available for reducing the drug stocks held by patients at any one time, and where possible aimed to prevent the potentially hazardous and wasteful stockpiling of medicines. Reducing the duration of the average prescription emerged as a possible means of achieving this end. For example, an influential investigation published in 1996 of unused medicine returns made to thirty community pharmacies over a one month period (Hawksworth, 1996) found a positive correlation between prescription lengths and the volume prescribed, with the cost of the drugs brought back to pharmacies. The authors of this research claimed that if all prescription supplies could be limited to 28 days then wastage would be reduced by a third, albeit that they did not offset the financial savings implied by the possible cost increases involved in the associated fees to pharmacies.

It is worth noting at this point that several initiatives were taking place in community pharmacy. The Nuffield report on community pharmacy had been published less than a decade before and was still very much in the minds of policy leaders in pharmacy. Those within the policy elite in the profession could see that the increasing genericisation of medicines and developments associated with reducing the supply costs of pharmaceuticals were likely to impact upon the future income of community pharmacies. Therefore they began to think strategically about how pharmacy could look elsewhere to gain both professional support and alternative income streams (chapter 1).

One of the leading actors involved in these studies was Gillian Hawksworth, who was a member of the RPSGB council between 1992 and 1998. As an independent pharmacy contractor, Hawksworth began to realise the economic and business constraints likely to affect the future of community pharmacy, and as such sought to demonstrate the positive effects of community pharmacy through research. Her work promoting the idea of large scale medicines waste suggested short prescriptions and community pharmacy as the solution.

Following such research, a significant proportion of prescribers were advised to reduce the length of their prescriptions in order to curb medicines wastage. This practice was supported by the Pharmaceutical Services Negotiating Committee (Pharmaceutical Services

Negotiating Committee, 2007), the Department of Health (Department of Health, 2004d) and the National Prescribing Centre (National Prescribing Centre, Undated). Since their formation in 2002, many PCTs have sought to restrict prescription lengths while also investing in awareness raising activities such as DUMP (dispose of unused medicines properly) campaigns. Even if the latter did little directly to curb ongoing waste, they may encourage and/or legitimate other interventions (York Health Economics Consortium and School of Pharmacy University of London, 2010).

Certain medicines, most notably the combined oral contraceptive pill, have been excluded from such restrictions on the grounds that they are relatively inexpensive long term use products that normally require limited follow up care. As well as the fact that healthy young women wishing to use 'the pill' might be expected to oppose robustly the inconvenient imposition of unduly short supply durations.

The provision of levothyroxine for conditions associated with thyroid deficiency offers another example of a medication that might rationally be expected to be supplied via long duration prescriptions. Yet research conducted by the British Thyroid foundation (Mitchell et al., 2009a; Mitchell et al., 2009b) found that in 2008/09 about a third of Primary Care Trusts were seeking to apply a 28 day limit on all levothyroxine prescriptions. In other parts of the country PCTs were 'allowing' 2, 3, or even 6 month prescriptions. But in more restrictive areas it appears that many GPs accepted that 28 day prescribing rules should apply to all medicines being taken for long term conditions (White, 2010).

The extent to which this policy has in fact reduced the cost of medicines waste and other problems is difficult to estimate, not least because of the growing use of relatively low cost generic medications (The NHS information Centre Prescribing Support Unit, 2010). The latter has likely been partly responsible for a fall in the (non-inflation adjusted) net ingredient cost³³ per prescription item to £9.04 in 2011, from £9.99 in 1999 (The NHS Information Centre, 2011). It is important to note that while drug reimbursement costs are based on the actual quantity of medicine supplied, the professional fees paid to pharmacy contractors are on a per item basis, meaning that contractors receive the same professional fees for supplying 28, 56 or 84 tablets. Therefore, an active reduction in prescription length will increase the number of prescriptions and the remuneration associated with them.

³³ The net ingredient cost refers to the cost of the drug before discounts and does not include dispensing costs or fees.

A number of studies conducted outside the UK environment highlight the potential importance of such observations. For example, in 2004, US researchers investigating medicines supply via Medicaid concluded that restricting prescriptions to less than 100 days would not be cost effective, as the savings made via wastage prevention would be outweighed by increased pharmacy service costs (Domino et al., 2004). Similarly, a New Zealand project which increased the length of prescriptions from around 30 days to 90 days indicated a saving in excess of NZ\$100m. This occurred because the resultant pharmacy cost reductions were greater than the increase in medication wastage observed.

It should not be assumed that such conclusions necessarily apply to the British setting. However, there is a clear case for believing that such a possibility might exist. Furthermore, the British Thyroid Foundation⁸ revealed that nearly two thirds of patients were dissatisfied with 28 day prescriptions for levothyroxine. This calls into significant question the desirability of trends observed in this context (White, 2010).

A recent Department of Health funded review of medicines waste found that in England alone in 2008/09 some £300 million worth of NHS community supplied medicines were disposed of unused, and that up to £150 million of this inefficiency is cost effectively avoidable. This last figure is equivalent to about 2 per cent of the cost of all medicines supplied, and a little under 10 per cent of the cost to the NHS of community pharmacy services. This study also presented evidence that the inappropriate imposition of restrictions like 28 day prescribing in some circumstances reduces adherence in medicines taking and can lead to other forms of perverse consumer reaction. At the same time some of the GPs and pharmacists interviewed expressed concerns about the quality of personal care being provided to vulnerable NHS patients living in the community. They noted that the amount of time being spent on activities such as dispensing by pharmacists, as opposed to understanding and meeting patients needs in a flexible and individually tailored manner, was to the detriment of patient care.

Against this background a brief analysis was undertaken to see if nationally collected data showed any changes to prescribing lengths as a result of the original research (Hawksworth, 1996) and the policy suggestions that developed from it.

Methodological Approach

Each year the Department of Health (DoH) publishes a set of Prescription Cost Analysis (PCA) statistics. These data provide details of the number, content and costs of all the

prescription items dispensed in the community in England. This data are based on information systems at NHS Prescription Services, part of the NHS Business Services Authority. The data are collected as part of the process of reimbursing for medicines supplied³⁴.

The analysis offered here relates to the period of January 1998 to December 2009 inclusive. The numbers used includes all relevant items supplied in the community. The vast majority of prescriptions included are written by General Medical Practitioners in England, but the analysis includes prescription written by dentists and hospital doctors that were dispensed in the community, as well as prescriptions written in Wales, Scotland and Northern Ireland, but dispensed in England.

The information available allows for the calculation of the average quantity of dosage units (tablets or capsules) supplied per prescription item in each year, which serves here as a proxy for prescription duration. Liquid and injectable formulations of these medications were excluded, as comparable volume data is not easily accessible. In total eleven drugs, available as 34 different dosage and strength presentations and in over 60 forms (i.e. different brand and generic items) were included in the sample analysed. They were selected due to featuring in the 'top twenty' most frequently prescribed agents in 2009 for which dosage units could be considered an appropriate proxy for prescription length. Nine long-term medications used in chronic conditions (simvastatin, levothyroxine, ramipril, bendroflumethiazide, amlodipine, atenolol, atorvastatin, aspirin and citalopram) were selected, in part because of the high volume of these products dispensed. Other selection criteria included the characteristic of being taken via a specified dosing schedule (i.e. they are not PRN or 'take as required' medications) and their availability in countable dosage forms and data being available for the period analysed.

Due to the fact that prior investigations indicated that PCT prescribing advisers usually accept that contraceptive products should be exempted from 28 day supply requirements, Microgynon – the most commonly prescribed combined oral contraceptive was also included for comparative purposes. Finally, antibiotics are subject to different prescribing restrictions compared to chronic medications as they are usually prescribed for a short defined period of time. Therefore, amoxicillin capsule supply duration was interrogated as a comparator to the chronic medications because it is the most commonly prescribed

³⁴ Due to the complex automated and manual processes involved in capturing this data, inaccuracies may occur. Currently internal audit suggests the data is 97.5% accurate.

antibiotic in the community setting³⁵. This would aid the assessment of the *a priori* hypothesis that prescription durations had decreased in the past decade. A full list of the presentations analysed is shown in table 3.4. In combination they accounted for 194 million of the prescription items dispensed in 2009, representing approximately 20% of the prescription items supplied.

Data were extracted from the Department of Health published tables. For each drug, all data relating to branded and generic formulations was extracted from the published Prescription Cost Analysis (PCA) tables. Data extraction was checked manually to ensure accurate extraction and formatting. Preparation data was then collated to provide values for each drug. This was subsequently analysed using Microsoft Excel 2010 and SPSS V16. Trends in the average number of unit doses (tablets or capsules) supplied per prescription were analysed using Pearson r and linear regression analysis. The complete data set is summarised in Table 3.5.

Table 3.3 – Presentations Analysed

Drug	Presentations analysed (Generic and Branded)
Simvastatin	10mg tablet, 20mg tablet, 40mg tablet, 80mg tablet.
Levothyroxine	25mcg tablet , 50mcg tablet, 100mcg tablet
Ramipril	1.25mg tablet, 2.5mg tablet, 5mg tablet, 10mg tablet, 1.25mg capsule, 2.5mg capsule, 5mg capsule, 10mg capsule
Bendroflumethiazide	2.5mg tablet, 5mg tablet
Amlodipine	5mg tablet, 10mg tablet
Atenolol	25mg tablet, 50mg tablet, 100mg tablet
Atorvastatin,	10mg tablet, 20mg tablet, 40mg tablet, 80mg tablet
Citalopram	10mg tablet, 20mg tablet, 40mg tablet
Aspirin	75mg tablet, 75mg E/C tablet
Combined Ethinylestradiol	Microgynon 30mcg tablet
Amoxicillin	250mg capsule, 500mg capsule

³⁵ In the strictest sense amoxicillin could not be used as a control, but it offers some insight into the differences between acute and chronic medication supply.

Table 3.4– Prescription Length Comparison

	A	B	C	D	E	F	G	H				
	Prescription items dispensed in 1999 (thousands*)	Total volume of doses (e.g.tablets, capsules) supplied in 1999 (thousands*)	Mean number of doses per prescription in 1999 (B/A)	Prescription items dispensed in 2009 (thousands*)	Total volume of doses (e.g.tablets, capsules) supplied in 2009 (thousands*)	Mean number of doses per prescription in 2009 (E/D)	Number of additional Prescriptions items created by change in mean number of doses (D – (E/C)	Percentage change in mean number of doses per prescription ((C-F)/C)		Pearson r (YEAR/ AVERAGE LENGTH)	R Squared (YEAR/ AVERAGE LENGTH)	P (YEAR/ AVERAGE LENGTH)
Amoxicillin 250mg Capsules	6496	126825	19.52	3508	70549	20.11	-105.8	2.9%		0.862	0.743	<0.001
Amoxicillin 500mg capsules	2791	55122	19.75	6175	127102	20.58	-260.4	4.1%		0.929	0.863	<0.001
Atorvastatin 10mg Tablet	1201	48566	40.43	2856	104097	36.45	281.5	-10.9%		0.991	0.983	<0.001
Atorvastatin 20mg Tablet	392	16396	41.8	3396	123570	36.39	440.2	-14.9%		0.998	0.996	<0.001
Atorvastatin 40mg Tablet	111	5007	45.31	3560	125580	35.27	788.4	-28.4%		0.986	0.972	<0.001
Atorvastatin 80mg Tablet	x	x	x	1037	33842	32.64	x	x		0.999	0.997	<0.001
Simvastatin 10mg Tablet	2195	94164	42.89	2834	103806	36.63	413.7	-17.1%		0.999	0.998	<0.001
Simvastatin 20mg Tablet	1289	54870	42.55	11010	405262	36.81	1487.1	-15.6%		0.988	0.976	<0.001
Simvastatin 40mg Tablet	103	4298	41.65	22981	829109	36.08	3073.3	-15.4%		0.955	0.912	<0.001
Levothyroxine 25mcg Tablet	1842	122439	66.49	6706	295111	44.01	2267.3	-51.1%		0.933	0.986	<0.001
Levothyroxine 50mcg Tablet	3099	228595	73.76	7066	306141	43.32	2915.9	-70.3%		0.991	0.982	<0.001
Levothyroxine 100mcg Tablet	3290	192292	58.44	8129	352648	43.38	2095.0	-34.7%		0.994	0.989	<0.001
Atenolol 25mg Tablet	1981	89185	45.02	4436	182561	37.85	380.9	-9.4%		0.998	0.995	<0.001
Atenolol 50mg Tablet	5467	248842	45.52	9707	408695	38.69	728.0	-8.1%		0.998	0.996	<0.001

Atenolol 100mg Tablet	2571	116759	45.42		3167	132944	38.35		239.8	-8.2%		0.998	0.996	<0.001
Citalopram 10mg Tablet	199	6646	33.4		2681	85273	31.80		128.1	-5.0%		0.945	0.893	<0.001
Citalopram 20mg Tablet	959	32958	34.36		6344	213459	33.65		132.0	-2.1%		0.849	0.721	<0.001
Citalopram 40mg Tablet	56	1766	31.71		1421	44294	31.18		24.0	-1.7%		0.631	0.399	0.28
Ramipril 1.25mg capsule	269	11175	41.6		1613	53114	32.93		336.5	-26.4%		0.999	0.998	<0.001
Ramipril 2.5mg capsule	515	23605	45.85		4313	154869	35.91		935.5	-27.7%		0.988	0.975	<0.001
Ramipril 5mg capsule	725	38950	53.75		5154	203288	39.45		1371.8	-36.3%		0.955	0.912	<0.001
Ramipril 10mg capsule	31	1292	41.16		7477	277020	37.05		746.1	-11.1%		0.957	0.916	<0.001
Ramipril 1.25mg Tablet	x	x	x		71	2353	33.34		x	x		0.966	0.933	<0.001
Ramipril 2.5mg Tablet	x	x	x		161	5714	35.40		x	x		0.962	0.925	0.001
Ramipril 5mg Tablet	x	x	x		188	7396	39.33		x	x		0.916	0.839	0.004
Ramipril 10 mg Tablet	x	x	x		272	9757	35.92		x	x		0.546	0.298	0.205
Bendroflumethiazide 2.5mg Tablet	7850	363738	46.34		18206	698946	38.39		3122.4	-20.7%		0.992	0.983	<0.001
Bendroflumethiazide 5mg Tablet	1760	78668	44.71		632	24386	38.56		86.9	-15.9%		0.991	0.982	<0.001
Microgynon Combined Ethinylestradiol 30mcg	2554	253331	99.2		2238	220466	98.51		15.4	-0.7%		0.647	0.419	0.023
Amlodipine 5mg Tablet	3260	139585	42.82		10122	377313	37.28		1309.5	-14.9%		0.995	0.99	<0.001
Amlodipine 10mg Tablet	1607	67950	42.28		6320	235311	37.23		755.5	-13.6%		0.998	0.997	<0.001
Aspirin 75mg tablet	11618	646766	55.67		26647	951342	35.70		9558.2	-55.9%		0.99	0.981	<0.001
Aspirin 75mg E/C Tablet	2227	114854	51.58		6748	230794	34.20		2273.4	-50.8%		0.999	0.997	<0.001

*rounded to the nearest thousand X – product not available in 1999.

Results

All of the long term use medications analysed showed a clear trend over time towards a reduced number of doses being supplied per prescription. Typically, on average, the mean quantity supplied fell by five doses on each prescription over a ten year period (table 3.5).

To illustrate the nature of the calculations made, the PCA data showed that in 2009 7,066,184 prescriptions were written for levothyroxine 50mcg tablets (Figure 3.10), and that overall 306,141,376 tablets were supplied in that year. This equates to an average of 43.32 tablets per prescription. By contrast, in 1999 3,099,000 prescriptions were written for Levothyroxine 50mcg tablets, and 228,594,600 tablets were supplied. This equates to an average of 73.76 tablets per prescription. If all the tablets supplied in 2009 had been supplied via prescriptions written to the 1999 mean, this would have resulted in 4,150,282 prescription items, rather than the 7,066,184 actually dispensed. The close to three million item discrepancy between these totals is indicative of the scale of the dispensing workload that could have been avoided if the number of tablets per prescription had not been reduced.

Other than in the case of amoxicillin where the correlation was positive, the majority of the drugs included showed a strong, statistically significant ($p < 0.001$), negative correlation between the year of prescribing and the mean number of doses per prescription item. The exceptions to this were citalopram 40mg tablets ($r = 0.631$, $p = 0.28$), ramipril 10mg tablets ($r = 0.546$ and $p = 0.205$) and the combined oral contraceptive, Microgynon ($r = 0.647$, $p = 0.023$, see figure 3.11). The mean number of doses per prescription decreased by approximately seven tablets over the last decade for atenolol, bendroflumethiazide and amlodipine (Figure 3.12), which are commonly used to treat hypertension in primary care. However, ramipril tablets were not widely available until 2003, which may well explain the non-significant trend observed in this context. The ramipril capsules show an average decrease of nine capsules against a typical initial volume of 50 across all the different strengths in the period assessed.

The mean number of statin doses per prescription reduced by about six tablets against a starting total of just over 40 in the period concerned (Figure 3.13). The 80mg atorvastatin presentation did not enter the market until 2000, and is only featured in the data available from 2001. Similarly simvastatin 80mg does not feature in the data until 2000.

It was anticipated that there would be no significant change in the mean number of doses for amoxicillin capsules. However, these capsules showed a shift towards increased prescription duration. In overall (population level) volume use terms the number of 250mg capsules supplied has also decreased, while the volume of 500mg capsules prescribed has markedly increased (table 3.5).

The reduction in prescription item volumes observed in the decade 1999-2009 varies considerably between the different medicines analysed. The observed range was from an increase of 4.2% in the case of amoxicillin 500mg capsules to a fall of 41.3% in that of levothyroxine 50mcg tablets. The prescribing of aspirin 75mg tablets also reduced markedly (circa 35% in volume per item terms).

The results shown suggest that overall, if the average prescription length had been kept the same as in 1999 then some 35 million fewer prescription items would have been dispensed in 2009 than was actually the case for the preparations included in this sample.

Figure 3-10 - Average Levothyroxine prescription durations (1998-2009)

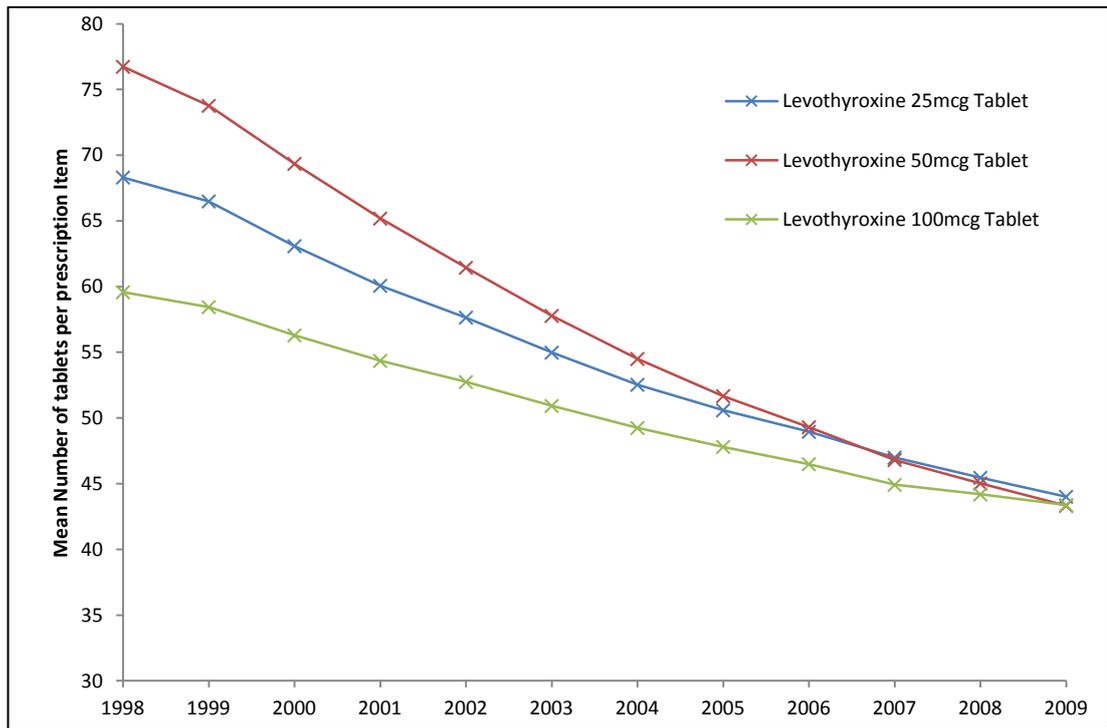


Figure 3-11- Microgynon Combined Ethinylestradiol 30mcg, prescription duration (1998-2009)

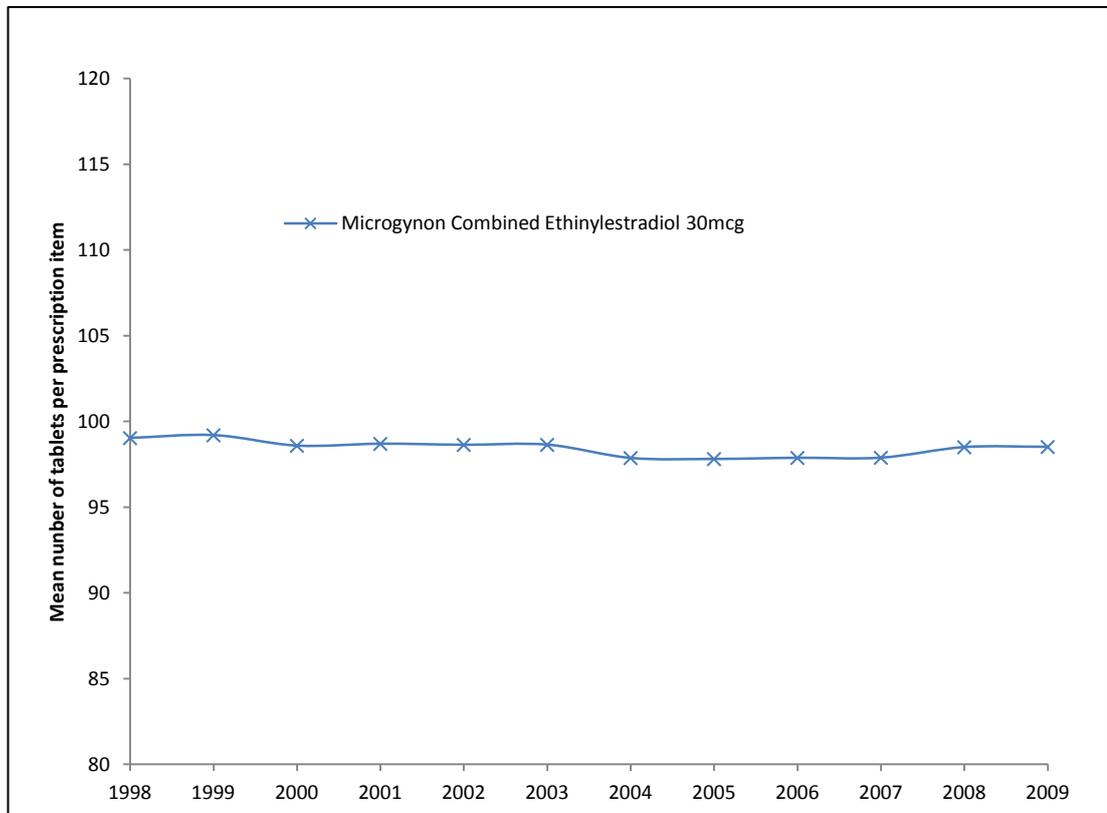


Figure 3-12– Anti-hypertensive prescription durations (1998-2009)

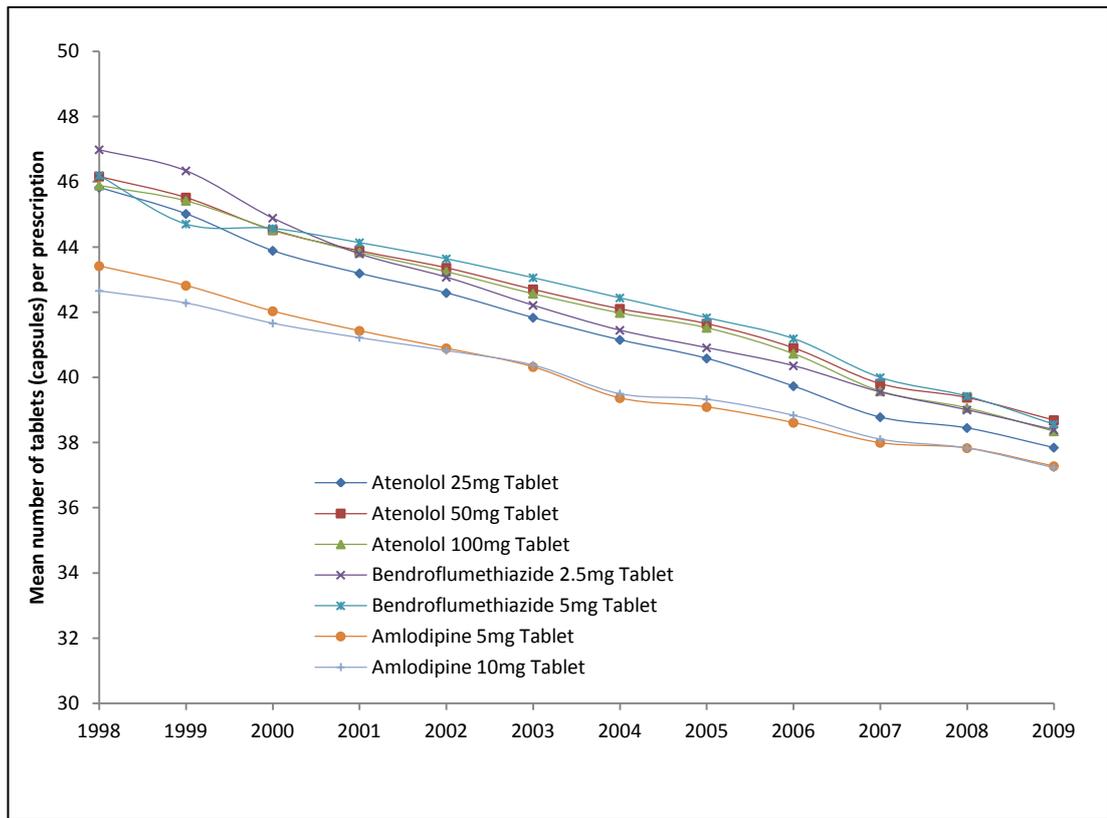
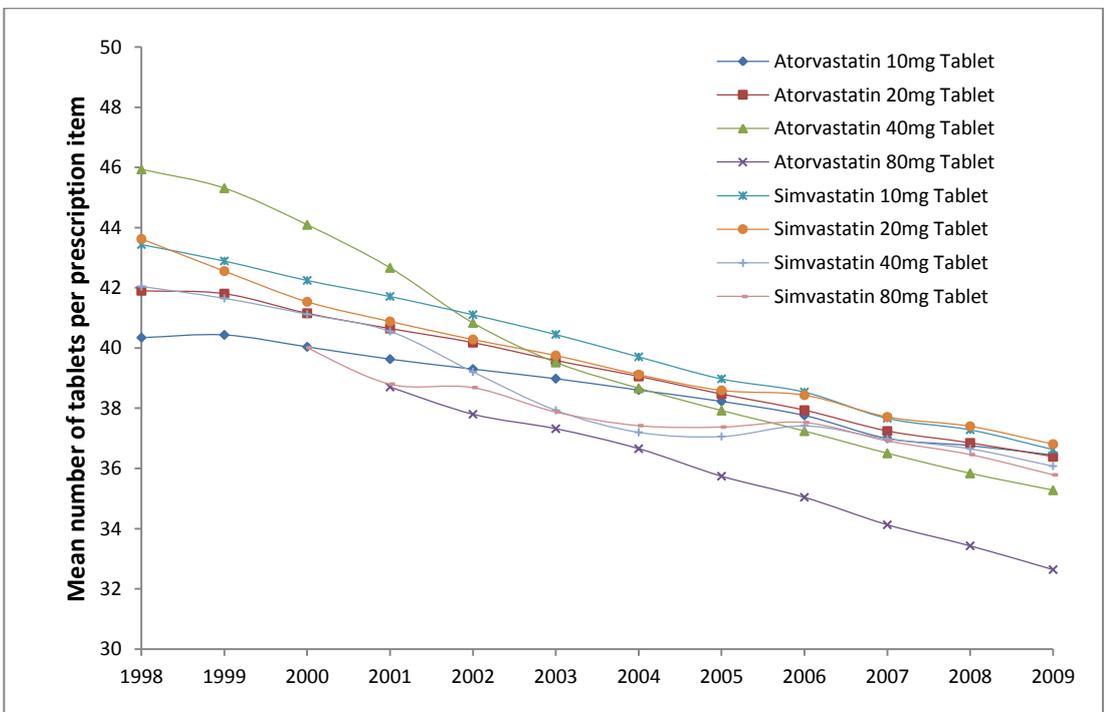


Figure 3-13– Statin prescription durations (1998-2009)



Towards shorter prescriptions? A Discussion

This shift across a range of medications suggests a generalised change in prescribing behaviour, associated with both local and national policies and interventions. Amoxicillin showed an opposite trend to the chronic medications, with longer prescription durations and a greater volume of higher strength capsules. This could in part be explained by concerted national and international campaigns over the last decade to change prescribing behaviour for antibiotics to optimal doses, however it is unclear from this data as to why prescription durations for amoxicillin have increased.

One of the most striking differences is observed in aspirin, which may in part be related to changes in the pack sizes available. Aspirin was once commonly supplied in 100 tablet bottles. It is now more often presented in boxes of 28 tablets. The trend shown here may also have been affected by a shift away from 150mg (2x75mg) daily dosing to 75mg daily dosing. The move towards the common supply of original pack dispensing, as seen with Aspirin, was partly the result of a European Community Directive (92/27/EEC) which requires all dispensed drugs to be accompanied by a Patient information leaflet (PIL). Therefore, it has been law since 1998 for all UK medicinal products to be supplied with an authorized PIL. The requirement for a PIL to be provided spurred the development of patient ready packs leading to an increased number of products being packed and supplied in a patient ready format. This suggests one of the limitations to the analysis performed above. In most cases, and certainly for the preparations analysed, items are supplied in patient ready packs. This would suggest that prescription length is not a continuous variable, but instead a dichotomous one (i.e. 28 days or 56 days) as dictated by patient pack size. However, evidence from pharmacists suggests that prescribers are often unaware of pack sizes and therefore supply quantities of 28, 30 or 32 days, which causes pharmacists to 'snip' packs. This results in additional time consuming processing steps (Pharmaceutical Services Negotiating Committee, 2007)³⁶. Therefore, a limitation of this data is that it does not allow for the evaluation of the spread of data behind each mean. A further limitation is that the drugs and formulations selected may not be fully representative of prescribing as a whole, despite their high prescribing volumes.

The combined oral contraceptive was one of the first products to be supplied in patient ready packs, and yet the view that contraceptives such as Microgynon should be excluded

³⁶ Consider the RPSGB Snipping campaign, or for example evidence presented to the APPG. <http://faculty.ksu.edu.sa/hisham/Documents/StudentsAll4/1/2/1a%20%2833%29.pdf> or more recently <http://www.pharmacy-life.co.uk/news/news/6/medicines-packaging-campaign-launched.aspx>

from prescribing length restrictions is supported by the data presented. No statistically significant change in prescription length could be observed.

For products where a significant decrease was not observed, several other factors may be important. For example, the discrepancy seen in Citalopram may be due to the supply of short term prescriptions due to the nature of the indications to which this is being used and the associated risk of suicide, coupled with possible prescriber concerns regarding self harm attempts.

However, despite the limitations acknowledged above and the limited number of medicines studied, there has been a general trend towards shorter prescription lengths. As prescription durations have reduced, the number of items dispensed has increased. It is not possible to extrapolate with full confidence the findings offered here to the entire range of medicines supplied in the community setting in England. Yet it is probable that if prescription lengths had not decreased over the course of the last decade the total number of items being dispensed via community pharmacies and other outlets would be about 10 per cent lower than is currently the case. A simple extrapolation would suggest a 175 million prescription item variation between 1999 and 2009, but long term use items subject to prescription volume declines were probably over-represented in the sample selected. If it were assumed that the total number of potentially avoidable items were only 50 per cent of the total implied by simple extrapolation, then it would stand at just under 90 million. Considering pharmacy fees, and all other things remaining constant, the increase in prescription numbers due to duration declines, cost the NHS in the region of £150 million in 2009. This is approximately 10% of the cost of the 2009 community pharmacy budget for medicines supply.

As previously noted, the overall increase in NHS prescription item numbers observed in England during the decade from 1999 to 2009 was over 300 million, a nearly 70% rise. The significance of prescription volume reductions alone should not therefore be overstated. The calculation of pharmacy fees is also linked to fixed, rather than variable, business cost assumptions, and should consequently over time take into account the marginal, rather than average, costs of activity rate increases. This implies that although community pharmacists will (unlike non-dispensing GPs) in the short term gain financially through supplying additional prescription items, their longer term returns will be ratcheted down.

In considering the public policy implications of growing prescription item numbers and their ongoing health and health care impacts, two initial points deserve emphasis. First, as already highlighted, growth in the overall volume of generic and other medicines being supplied to the population is a multifaceted phenomenon. It is taking place worldwide as relatively rich societies age and relatively poor ones benefit from globalisation and their populations gradually get better access to health care.

One particularly important driver in the last ten to twenty years has been the mass use of medicines to reduce the risk of, and to treat, vascular diseases. For example, a recent Canadian study showed a 165% increase in the total number of prescriptions for such drugs in the decade 1996-2006 (Jackevicius et al., 2009). There is substantive evidence that such changes in medical and pharmaceutical care have significantly benefited the communities being served, and have been encouraged by governments as well as by commercial interests. In Britain, for instance, the current general medical services (GMS) contract incorporates a points based Quality and Outcomes Framework (QOF) which incentivises improved chronic disease management (Alabbadi et al., 2010). One of its effects has been to encourage an increased use of medicines such as statins and anti-hypertensives.

Second, with regard to the reductions in prescription durations reported here, the arguments in favour of this strategy in England have related primarily to medicines waste prevention. In addition to evidence such as that published by Hawksworth et al in the 1990s, there are more recent studies that confirm that restricting periods of chronic/long term medicines supply to a period of 28 days should reduce the volume of NHS medicines that eventually have to be discarded. For example, a widely cited Bradford University study investigated two groups of 20 elderly patients receiving regular prescriptions for more than 3 medications. The first had 28-day prescriptions and the second 56-day supplies. It was found that the 56-day group had greater home stocks, and reported disposing of unwanted medicines more often than the 28 day group (Gatley et al., 1995). Suggesting that the rational application of 28 day prescribing policies appears to reduce medicines waste.

It would therefore be wrong to assume that the growing volume of NHS prescription items supplied by community pharmacies has been a negative trend in public health terms, and/or that reducing the length of the average prescription has during the past decade increased dispensing costs without conferring any counterbalancing benefit.

However, the possibility that therapeutic gain has been lost as a result of policies ostensibly aimed at medicine waste reduction should not be ignored. For example, evidence from Italy suggests that shortening prescription durations for patients being treated for hypertension reduced adherence rates in people who had previously been taking their medicines appropriately (Atella et al., 2006). In the American context Domino et al. (2004) recognised reducing duration decreased waste but this was not justified due to increases in dispensing outlays. Notwithstanding the dissatisfaction and inconvenience that these prescribing policies have for patients (Mitchell et al., 2009a; Mitchell et al., 2009b).

Such research suggests that the supply of medicines to people should be facilitated in ways which maximise customer satisfaction and minimise professional workloads, even if longer average prescriptions durations are associated with an increased risk of physical waste. The latter's cost might be successfully offset via greater concentration on identifying and effectively supporting patients at unusually high risk of experiencing problems with medicines taking. Lack of harmonisation when managing repeat pharmaceutical supply has been suggested to contribute to waste, highlighting perverse provider side incentives that produce system failings (Jesson et al., 2005). In this instance a balance should be struck between standardised prescribing terms and patient desires for individualised care, albeit that in situations where there are unusually high treatment costs or risks of non-consumption, safeguards should be instituted.

The findings reported here do not in themselves define the extent of avoidable waste or the effects of 28 day policies on clinical outcomes. But they do indicate a need for further evaluations. It is possible that a more flexible approach to regulating prescription lengths could increase service efficiency and effectiveness while also creating a more convenient system for some patients. International experience suggests that median community prescription duration periods of up to three months (that is, of around twice the current estimated length) may prove desirable (Domino et al., 2004) especially if community pharmacy and other resources released can be cost effectively re-deployed towards areas of higher gain.

Section Conclusion

The data presented in this analysis indicates that in the context of longer term medicines use, the last decade has seen a significant reduction in the duration of prescriptions supplied by the NHS. This may have been due to the encouragement of '28 day prescribing' which has been applied rigidly in some localities. While such policies may have brought

advantages in some contexts, they may nevertheless have imposed additional disadvantages elsewhere.

This study does not provide a definitive answer in favour of prescription duration individualisation as opposed to standardisation. Yet it does suggest that this is an area in need of further exploration aimed at discovering if the intelligent, 'customer needs' focused application of informed professional judgement to prescription duration determination should be preferred to blanket prescribing policies. As such there are potential opportunities for the community pharmacy profession to advocate increasing the duration of prescriptions. In doing so this would release some of the pharmacists' time, and would allow them to carry out therapeutics based interventions.

Chapter Conclusion

The productivity of pharmacists has increased over the last decade to manage the swell in prescription items created as a result of the new and innovative ways of using pharmaceutical therapies to treat diseases, particularly as preventative treatments for diseases associated with a western lifestyle. This trend looks only set to increase. Further administrative and regulatory changes, coupled with an increasingly competitive market, have all added to the workload pressures that pharmacists experience.

The main income stream into a community pharmacy business is generated from the supply of prescription medicines through the pharmacy contractual framework, and as a result it is understandable why this activity dominates so much of pharmacists' time. Yet the benefits of pharmacists supporting and overseeing the safe and effective supply of nearly a billion prescription items each year should not be underestimated.

Meanwhile the economic reward for each unit of work has decreased. This is a trend which, under times of economic recession, looks set to continue. This has been positively reinforced by the restrictions on dispensing income and retained buying profit imposed by the Department of Health as well as by the increase in prescription volume observed over the last decade. Such changes have added to the pressure that community pharmacists experience in their day-to-day working practice.

The evidence presented in this chapter suggests that the supply of medicines to people should be facilitated in ways which maximise customer satisfaction and minimise professional workloads, even if longer average prescriptions durations are associated with an increased risk of physical waste. The latter's cost might be successfully offset via greater

concentration on identifying and effectively supporting patients at unusually high risk of experiencing problems with medicines taking, a role that pharmacists are well placed to support. Indeed, such activities would make better use of their skills. Professional efforts ought also to focus on situations where unusually high treatment costs are involved, and/or where failures to take medicines as recommended are most likely to lead to lost health gains.

Additional commercial pressures have been generated by competitive practices in the sales of OTC medicines and allied health and beauty products, which have shifted custom away from high street locations towards large scale grocers. Retail led health and beauty retailers have robustly competed, but all the signals indicate that smaller independent pharmacies will continue to suffer a considerable loss in their retail market share.

At present the current structure of the pharmacy business is pulling the workforce in several different directions. Pharmacists are struggling to decide what their core purpose and responsibility should be within the health service under challenging economic conditions. The economic and practical viability of extended 'clinical' roles appears doubtful. At present the scale of the funding for community pharmacy based services is erratic and unpredictable, which in turn prevents future investment and innovation. The combination of these factors has led to several obstacles to the further development of for the pharmacy profession, including stress, workload fatigue and general disillusionment. Unless the underlying issues of workload are suitably managed or resolved, community pharmacy practice is unlikely to be able to embrace the clinical mantle that government policies are suggesting it take³⁷.

Given this background, the next chapter goes on to explore the development and implementation of policies related to advanced community pharmacy services, to establish if there are strategies that both pharmacists and policy makers can adopt to help manage these workload issues.

³⁷ Further discussion of this is provided in Appendix A

Chapter 4. Implementing Policy in Community Pharmacy

Chapter Introduction

The previous chapters have established that community pharmacists spend the majority of their time on activities related to the dispensing and supply of medicines (chapter 2). One of the main drivers of this trend was the therapeutic revolution of the second half of the twentieth century which provided doctors with a wider range of medicines to prescribe. Coupled to this, the increase in the occurrence of unhealthy lifestyles as a result of the 'western' diet has driven up prescription use in chronic diseases, such as obesity and type II diabetes. The ageing population has also given rise to the better use of secondary preventative medicines, supported by national evidenced based guidelines for prescribing (Davies and Taylor, 2010a). This has led to an increase in the number of prescription items, which have been further exacerbated by a reduction in the average duration of each prescription (chapter 3).

Guaranteed income streams from dispensing have also helped to ensure that medicines supply has come to dominate pharmacists' work even if it is at the cost of reduced professional contact with medicine users (chapter 3). Yet despite the dominance of the supply of prescription medicines, community pharmacy policy (as described in chapter 1) has shown a desire for pharmacists to be 'utilised to greater effect' through 'clinically' focused services.

The evidence gathered so far in this thesis proposes that the implementation of services into community pharmacies has been slow. On this basis, the aim of this chapter is to understand and interpret the process of service implementation into community pharmacy through two case studies, and discover if any lessons can be learnt for future pharmacy, and wider healthcare policy, implementation.

A structured overview of the barriers and facilitators to implementation from the Medicines Use Review and prescription intervention (MUR) literature is described here. This is succeeded by an analysis of the most recent service to be implemented in community pharmacy - the New Medicine service (NMS). Through the use of the Kingdon model of the policy process (Kingdon, 1984), the development and implementation of a community pharmacy service is recorded and captured by analysis of qualitative interviews

with key stakeholders involved in the services' implementation. This provides insight into the challenges and complexity associated with bringing community pharmacy policy to fruition. This chapter concludes by comparing MUR and NMS implementation with an interpretation of the challenges that future services in community pharmacy are likely to face.

The implementation of Medicines Use Reviews

The Medicines Use Review (MUR), implemented through the 2005 pharmacy contractual framework, is a documented, face-to-face consultation between a patient and a community pharmacist that takes place in a pharmacy consultation room. The aim of this advanced service is to improve a patient's knowledge, adherence and use of medicines by ascertaining their understanding and experience of medicines taking (Pharmaceutical Services Negotiating Committee, 2012).

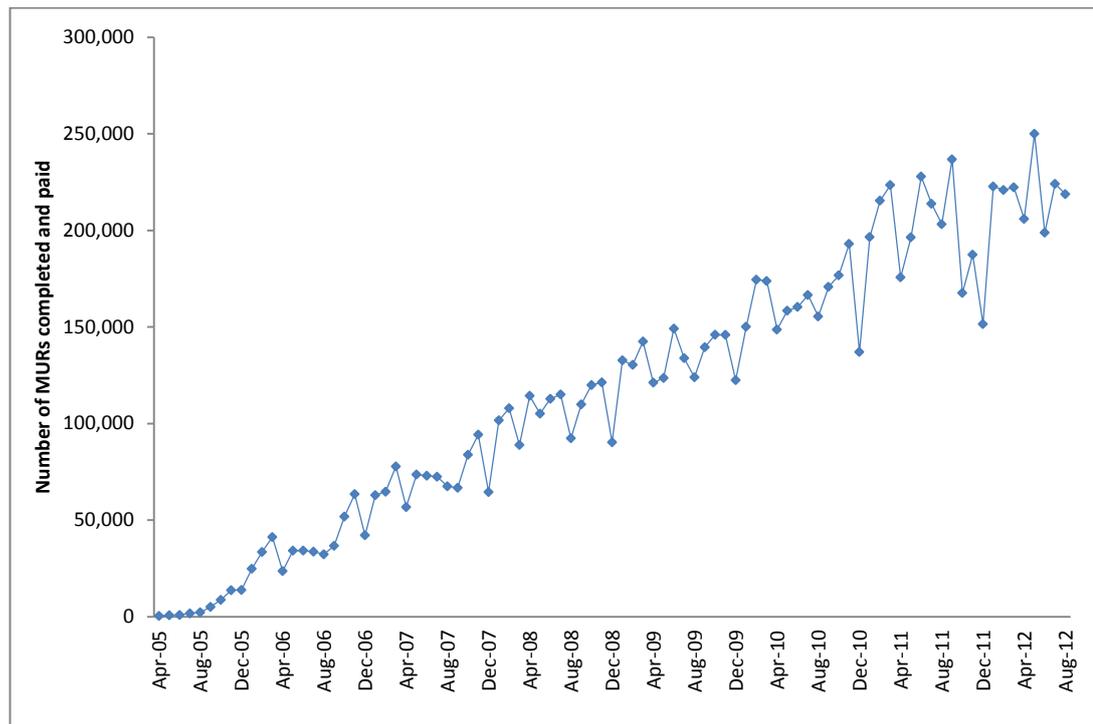
During this documented consultation the pharmacist may identify ineffectual or poor medicines use, side effects, or therapeutic drug interactions, which are then resolved through discussion with the patient and, where applicable documented feedback, which highlights any medication related problems, is supplied to the patients' GP on an approved form. Beyond clinical governance requirements, any community pharmacy in England and Wales can offer this service as long as the pharmacist wishing to provide the service has completed a nationally accredited training program, and the premises has a private consultation area deemed fit for purpose by the contracting local primary care organisation.

Although this was the first nationally advanced service to be offered free to patients in community pharmacy, pharmacists are not obliged to offer MURs. They can claim reimbursement (currently £28) from the NHS, subject to a maximum of 400 MURs per pharmacy per year (Department of Health and the Welsh Assembly Government, 2012) which can provide an addition £11,200 in income per annum.

Despite this service being heralded by the profession at its conception as a positive development, the widespread implementation of the MUR delivery was limited in the early years. The uptake was initially slow (figure 4.1), with only 7% of the available funding spent in the first year and only 38% of pharmacies claiming payment for MURs (Blenkinsopp et al., 2007a). However, recent data shows that nearly nine out of every ten community pharmacies in England have provided and been paid for providing an MUR (The NHS

Information Centre, 2011), with a peak of 249,986 MURs completed in England during May 2012 (equivalent to about 20 MURs in a month per pharmacy). Figure 4.1 shows the steady increase in MUR numbers since 2005. There are observable drops in the number of MURs completed in December, attributed to the effect of the festive period which limits the number of working days in which MURs can be provided coupled with attention being focused on retail sales, and observable peaks in March as contractors aim to reach their target of 400 MURs before the end of the financial year.

Figure 4-1– Number of MURs completed in England per month (2005 –2012)



Source: NHS Prescription Services

The uptake and delivery of MURs from community pharmacies across England has been far slower than originally anticipated and is believed to be a result of implementation problems. Given the importance placed on pharmacy services by the government (Department of Health, 2008a), it is vital for their future delivery that the factors that have limited implementation are understood.

The overview provided here offers a structured review of the published literature relating to the implementation of MURs by community pharmacists in England and Wales. The aim of this was to discover the barriers recorded during the implementation of MURs to see if these can be learnt for subsequent policy implementation.

Methodological Approach

PubMed, International Pharmaceutical Abstracts and CINAHL were searched for the term “Medicines Use Review” or “Medicines Use Reviews”, between 2004 and 2012. Studies were limited to English language and based in the United Kingdom. This revealed 33 abstracts, of which only 22 were deemed relevant from analysis of the title.

In addition the abstracts of the British Pharmaceutical Conference (BPC - now known as the RPS conference) and the Health Services Research in Pharmacy Practice Conferences (HSRPP) databases were interrogated for articles relating to Medicines Use reviews between 2004 and 2011. This revealed 44 abstracts that contained the words “Medicines Use Review” or “MUR”.

In conjunction to this, all of the references of the papers identified were interrogated for relevant research articles relating to Medicines Use reviews. This strategy helped to highlight research that had been published in the Pharmaceutical Journal. The majority of the references identified were conference abstracts, but where applicable full copies of these papers were sourced.

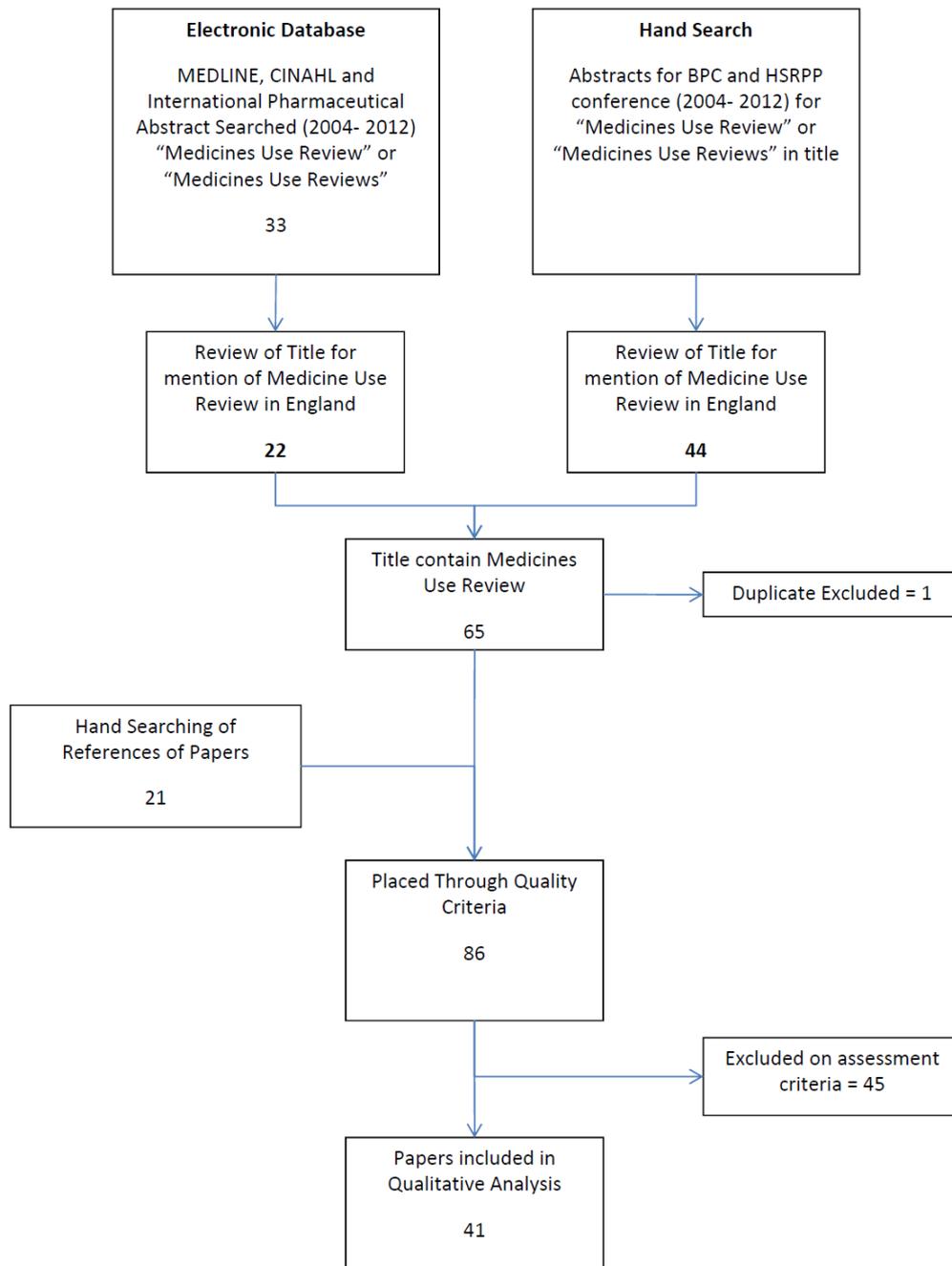
These abstracts and full papers were assessed against three criteria:

- Does the study describe its methods clearly?
- Does the study describe or investigate perceived or real barriers or facilitators to the implementation of MURs?
- Was the study conducted in the United Kingdom?

Against these criteria, papers were only included if they made a mention of barriers or motivators that support the implementation of Medicines Use Reviews in community pharmacy in the United Kingdom. Most of the excluded papers lacked a description of a method, often due to being editorial in nature. Several of the excluded articles looked at patient perceptions or disease outcomes from MURs in specific disease groups and therefore did not describe or explain barriers or facilitators to implementation. Two papers were excluded which related to Medicines Use Reviews in New Zealand.

This left 41 abstracts, articles and papers to be included in the review (figure 4.2). Each of these was thematically analysed and cross-examined for barriers and facilitators to the implementation of MURs. The findings of which were tabulated for analysis.

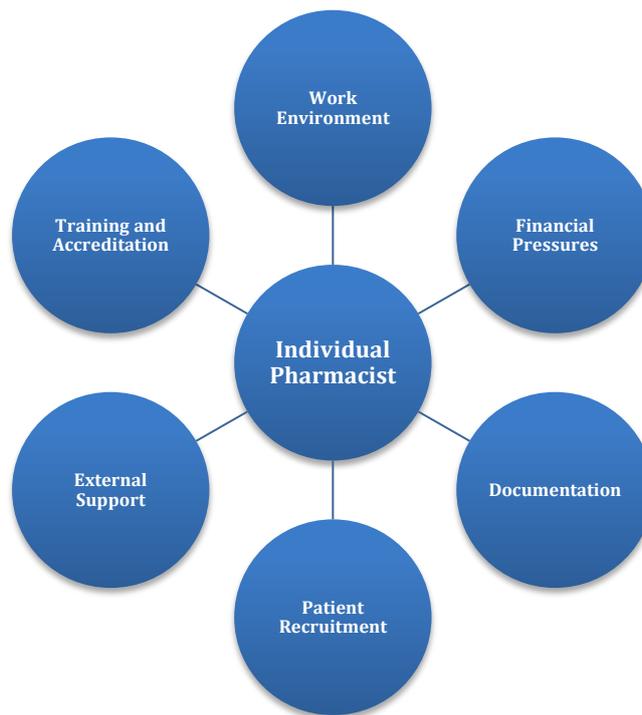
Figure 4-2– Flow Chart of Literature review



Results and Discussion

Thematic analysis of the literature, which is a qualitative method used to analyse classification and present themes, revealed seven overarching themes (figure 4.3) that affected the implementation of medicines use reviews, namely: Work Environment; Financial Drivers; Accreditation and Training; Patient Recruitment; External Support; Documentation; and Individual Practitioner.

Figure 4-3– Barriers and Driver to MUR implementation



Work Environment

The work environment of community pharmacy was commonly reported to be a barrier to the implementation of MURs. In particular time pressures, additional workload and lack of sufficient staff prevented MURs from being delivered. The reforms to the pharmacy contractual framework effectively represented an increase in workload without additional resource (Blenkinsopp et al., 2009; Cowley et al., 2010). Although the majority of pharmacists absorbed Medicines Use Reviews into their daily practice without additional pharmacist cover (Boardman et al., 2011; Blenkinsopp et al., 2007b), over half of pharmacists in a survey reported lack of sufficient staff as a barrier (Ewen et al., 2006), which resonates with findings elsewhere (Blenkinsopp et al., 2007b; Latif and Boardman,

2007; Rosenbloom et al., 2005). However, staffing is not solely a factor of the number of staff present, but also the ability of pharmacists to delegate their work effectively to those staff present (see chapter 2). It was suggested that other environmental factors are important, with the initial low volumes of MURs performed also reflecting resource pressures on space in small dispensaries (McDonald et al., 2010b).

Pharmacists have reported that the reduction in the reimbursement of drugs has increased the pressure to focus on dispensing volumes (McDonald et al., 2010b; Rosenbloom et al., 2005). Many expressed difficulty in managing time spent between the dispensary areas and the consultation room (McDonald et al., 2010b) making it difficult to maintain normal pharmacy services at the same time as an MUR service (Hilton et al., 2007), with opportunities for activities such as patient counselling at the last stage of the dispensing process being reduced (McDonald et al., 2010b). Many pharmacists felt that MURs only increased the pressures on their time (McDonald et al., 2010b) and therefore lack of time was a commonly reported barrier to providing the MUR service (Ewen et al., 2006; Latif and Boardman, 2007).

As a result the importance attached to performing MURs appears significantly lower than routine activities. The pressure to manage patients who either wished to speak to a pharmacist or have their medicine checked, compared to providing an MUR, resulted in reviews being abandoned when the pharmacy became busy (Boardman et al., 2011). In some cases time management issues were such a challenge that they led several pharmacies to cease providing the service (Rosenbloom and Graham, 2008).

Such pressures are understandable when the mean time to complete an MUR is 51 minutes, of which just under a half (22 mins) is spent with the patient, the rest spent on paperwork (Blenkinsopp et al., 2007b). As a result pharmacists were observed doing MURs at times that were convenient to them and the workload in the pharmacy (Boardman et al., 2011), which may not necessarily be the most convenient time for the patient.

While some strategies, such as a support tool developed by the NPA and the PCPA are reported to improve pharmacists time management skills (Kaulbach et al., 2010), other strategies such as formalised appointment based system have been implemented. Although appointments allow pharmacists to regulate their work, they reflect a more formal approach to accessing pharmacists advice, which encourages the view that

pharmacists' time is more valuable than patients (McDonald et al., 2010b) and changes public perception of pharmacists as an accessible healthcare provider.

Financial Pressures

Across any business, finance is a motivator of practice. MUR delivery remains financially driven with quantitative rewards based on number performed as opposed to their quality (Latif and Boardman, 2008). The remuneration system has resulted in what some argue is a prioritisation of income targets over patients (Bassi and Wood, 2009; McDonald et al., 2010b) and therefore requires reform (Cowley et al., 2010). For example, financially driven company policies were cited by two-fifths of pharmacists as a key driver for providing the MUR service (Blenkinsopp et al., 2007b) rather than patient need. Many pharmacists, particularly those working in multiples, have reported being under pressure from head office to deliver target volumes of MURs (McDonald et al., 2010b; Rosenbloom and Graham, 2008) regardless of whether patients require the service, leading these organisations to be depicted as large, impersonal and solely driven by profit (McDonald et al., 2010a; McDonald et al., 2010b).

It is these motives that are argued to have increased MUR provision from multiples (Blenkinsopp et al., 2009; Latif and Boardman, 2007; Bradley et al., 2008; Elvey et al., 2007). On one hand, it is believed that this observed pattern was due to organisational pressure within multiple pharmacies and the forceful implementation of targets. On the other hand, independents suffer from a relative lack of staff capacity (Bradley et al., 2008). This creates a challenge in fitting MURs into their daily activities, coupled with the additional costs associated with employing locums to increase capacity (Elvey et al., 2007). This is in contrast to the predictions made over a decade ago that extended roles for community pharmacists would be of greater benefit to independently owned pharmacies (Edmunds and Calnan, 2001a). Indeed, the demands of contract implementation reportedly fall more heavily on independents. In contrast to multiples they do not have well established management systems to streamline paperwork which reduce the effort required at an individual pharmacist level (Blenkinsopp et al., 2007a).

While organisational pressures and company policies may have indeed led to an observed increase in the number of MUR completed, they have also shaped what has been described as the "McDonaldisation" of MURs (Latif et al., 2011c). These pressures have been implemented in undermining MUR quality (Elvey et al., 2007) and have forced pharmacists to compromise their professional judgement and autonomy (Harding and Wilcock, 2010;

Wilcock and Harding, 2008). For example, pharmacists reported performing MURs that they felt to be less resource intensive, of limited benefit and cursory in nature in order to reach their targets (McDonald et al., 2010b). Indeed, some reported gaming the system by choosing patients with fewer medications, despite acknowledging that those taking more drugs would benefit most from the service (Latif et al., 2011b). Even though the pharmacists acknowledged that this was likely to have a detrimental effect on the public's perception of MURs and the pharmacy profession, they persisted in targeting the least complex patients (McDonald et al., 2010b).

Training and Accreditation

MUR training itself is believed to be a motivating factor for implementation (Elvey et al., 2006). The small number of pharmacists accredited in the early stages of service implementation contributed to the initial slow delivery of MURs (Blenkinsopp et al., 2007a). The Department of Health insisted MUR accreditation be conducted by higher education institutions that were required to assess the competence of pharmacists against a national framework. Ideally, professional competence should be assessed through observation. However, the practicalities of achieving this in a cohort of 12,000 pharmacists meant that questioning and portfolio work were used as the assessment of choice, which some argue contributed to questionable MUR quality (Alexander, 2006).

On one hand, time and financial pressures are forcing some pharmacists to game the system are implicated in decreasing the quality of MURs. On the other hand, such decreased quality may instead be a manifestation of poor training and implementation. Indeed, there is evidence of deficiencies in the training of pharmacists, particularly around communication (Kaulbach et al., 2010). Such deficiencies are exemplified by accredited pharmacists who reported not feeling confident enough to perform MURs after training (Rosenbloom et al., 2005; Davies and Pugsley, 2006; Khideja, 2009) and therefore wanted further assurance of their own competence (Davies and Pugsley, 2006; James et al., 2009). However, this may be a manifestation of the cultural change that MURs created. Some pharmacists expressed trepidation and uncertainty providing MURs, despite being perceived as a core feature of their professional activity now and in the future (Harding and Wilcock, 2010; Wilcock and Harding, 2008). Other pharmacists revealed that they had an aversion to speaking to people who took psychiatric medication because they were anxious about prying into 'sensitive' issues (Latif et al., 2011b), although there was also an

assumption that these patients were under specialist care and so were perceived to be in less need of an MUR (Latif et al., 2011b).

Various education focused strategies have been suggested to improve service implementation. These include training opportunities provided by PCTs (Bradley et al., 2006), providing direction and ongoing training with respect to the content of the MUR (Khideja, 2009), using supported peer review of MURs (Harding and Wilcock, 2010; Kaulbach et al., 2010), providing opportunities for pharmacists to practice MURs with constructive feedback on performance (Kaulbach et al., 2010), demonstrating good practice (Davies and Pugsley, 2006) and adopting key quality indicators of MUR action points (Harding and Wilcock, 2010). Yet despite this evidence few of these have since been incorporated into MUR accreditation.

However, it is not solely the accreditation of the pharmacists, but also the accreditation of premises that has been shown to be a barrier to fast service rollout (Latif and Boardman, 2007; Elvey et al., 2006; Blenkinsopp et al., 2007b). Two years after implementation, a fifth of community pharmacies did not have a private or semi-private consultation area (Blenkinsopp et al., 2007b), of those that did, some patients reported them being too small or claustrophobic for practical use (Iqbal and Wood, 2010).

A further barrier to implementation was created by a misunderstanding of the intended purpose of MURs. Initially it was designed to improve patients' concordance and understanding of medicines. Yet pharmacists have interpreted the MUR to be an extension of their role by including advice giving and knowledge of drug interactions in the consultations (McDonald et al., 2010a; McDonald et al., 2010b). While some have taken this further and conducted a full clinical medication review. The lack of uniform service objective has resulted in MURs of differing detail and quality. Given this ambiguity it unsurprising that many patients and health care professionals are unaware of the purpose of an MUR (Iqbal and Wood, 2010).

Patient Recruitment and Education

Many papers have reported patient uptake and interest as a barrier to implementation (Elvey et al., 2006; News Team, 2006; Hall et al., 2006). Although strategies, such as a dedicated MUR facilitator in the pharmacy, can help to improve patient recruitment problems (Rosenbloom and Graham, 2008), nearly half of a randomly selected sample of community pharmacies in England and Wales believed that poor recruitment was due to a

lack of patient knowledge of the service (Ewen et al., 2006; Thomas et al., 2007b). Patients seldom asked for MURs themselves, instead being selected and persuaded by the pharmacy staff (Latif et al., 2011b). Indeed, poor service uptake can be compounded by patients who initially accepted an MUR but failed to attend the subsequent appointment (Blenkinsopp et al., 2007b).

Some attribute the poor uptake of patients to the language that has been used in the recruitment materials which describe the process inconsistently, with interchangeable use of formal, (review meeting), and informal 'friendly' terminology (Van den Berg and Donyai, 2007). One small explanatory study suggested that native language may also play a role in patient engagement, as the MUR form is only available in English (Hughes et al., 2009). However, interviews with patients declining MURs suggest that their reasons for lack of uptake are often more complex (Urban et al., 2008). It was found that patients main reason for accepting the offer of an MUR was simply because they had been asked, but only agreed if they had time (Latif et al., 2010). Latif et al (2010) suggest that some patients felt obligated to have an MUR to help the pharmacist. Such reasons do not suggest that patients are strongly motivated by self interest or the prospect of personal benefit to have the service (Latif et al., 2010), instead acting because of a moral obligation.

It has been suggested that improving patients' understanding of the service could be a key facilitator to future service delivery (Rosenbloom et al., 2005; Bassi and Wood, 2009; Davies and Pugsley, 2006). Suggested strategies to achieve this are national advertising campaigns and clearer explanations from individual pharmacists (Iqbal and Wood, 2010).

External Support

External support, either from Primary Care organisations (PCOs) or General Practitioners, was seen as a core factor in the effective implementation of MURs. In a telephone interview survey most pharmacists felt they did not receive sufficient support from PCOs (Hall et al., 2006) which limited their ability to provide the service. Blenkinsopp et al (2007) found that just under half of all primary care organisations had no strategy for MUR service delivery (Blenkinsopp et al., 2007a). This suggests that in the early years, PCOs may not have been able to think strategically about MURs for local healthcare needs (Blenkinsopp et al., 2007a).

In England PCT leads blamed the lack of support from General Practitioners as the number one barrier to implementation of MURs (Elvey et al., 2006). They believed that MURs had

done little to improve integration (Elvey et al., 2006). The lack of effective working between GPs and community pharmacists has been reported elsewhere as a factor for the poor uptake of MURs (Ali et al., 2011; Latif and Boardman, 2007; Blenkinsopp et al., 2007a; Ewen et al., 2006).

Although some PCOs reported creative ways to incentivise GP participation through the GMS Quality and Outcomes framework (Blenkinsopp et al., 2007a), most were unsuccessful. This may be because GPs view MURs negatively (Wilcock and Harding, 2007), by and large, describing MURs as a waste of time and money (McDonald et al., 2010b). This general lack of support may be a product of a limited understanding of the service itself (Davies and Pugsley, 2006). Hilton *et al* (2007) found that inadequate information had been provided to general practitioners and other health professionals about the purpose of MURs (Hilton et al., 2007). James *et al* (2007) reported that GP were unaware of their role in MURs. Indeed a lack of central guidance may have contributed to this (Thomas et al., 2007b).

As a result of this misunderstanding of purpose, community pharmacists, pharmaceutical advisors, and local pharmaceutical committees have expressed concern that MURs are making clinical recommendations when this was not their primary intent (Hilton et al., 2007). This ambiguity of purpose has led some pharmacists to call for clarification about the extent of their clinical input and responsibilities following an MUR (Latif and Boardman, 2008). This has not been aided by the low levels of communication between local pharmaceutical and medical committees (Blenkinsopp et al., 2007a) and the lack of general communication between community pharmacists, GPs and primary care organisations (Davies and Pugsley, 2006). This suggests that inter-professional dialogue is limited in primary care and may act as a barrier to the effective implementation of future services (Kaulbach et al., 2010).

Documentation

The presentation and transfer of information from pharmacies to other primary care providers contributed to the lack of external support for MURs. The documentation format has partly been blamed for this because it was confusing, complex, of poor design and difficult for GPs to use (Blenkinsopp et al., 2007a; Hilton et al., 2007; Thomas et al., 2007a).

A redesign of the MUR paperwork was conducted after the initial implementation in an effort to address some of the documentation problems (Latif and Boardman, 2008). This

new design was found to be more user friendly and time saving (Bassi and Wood, 2009), making it clear when GP action is required. Yet despite the changes the form is still considered unnecessarily bureaucratic (Cowley et al., 2010). The structured format, which, when coupled with standardised procedures and routines, is seen to limit professional autonomy of pharmacists and their decision making abilities (Latif et al., 2011a). Some argue that a review of the formulaic approach to the MUR is required so that the complex ways patients take their medicines can be understood (Latif et al., 2011a). At present the model of MUR delivery treats individuals as passive recipients of expert knowledge, which appears to be an inappropriate response to inspire confidence to meet the changing needs of patients. However, without such standardisation, the resulting output from MURs around the country would be even more diverse.

The documentation of the MUR consultation was found to be incompatible with computer systems and therefore regarded as a barrier to effective inter-professional communication (Rosenbloom and Graham, 2008). Changes have since been introduced which link MURs to patients records on the pharmacy computer, although some suggest this could be improved further by sharing across NHS IT systems (Thomas et al., 2007b). However, even with these innovations the variable quality of pharmacists' written communication remains a problem (Kaulbach et al., 2010).

Furthermore patients are required to sign MUR forms that are subsequently submitted for payment. This act creates a visible link between payment and service, which some argue alters patient perceptions of this being altruistically motivated as opposed to a financially driven (McDonald et al., 2010a). Such acts are believed to be a barrier to future recruitment of patients to pharmaceutical services.

Individual Pharmacists

The individual motivation of pharmacists was seen as one of the main drivers that enabled the implementation of MURs to progress in a locality (Elvey et al., 2006). The literature suggests that the vast majority of pharmacists welcomed the intention of the new contract to encourage a move away from dispensing towards other cognitive based roles (McDonald et al., 2010b; McDonald et al., 2010a; Bradley et al., 2008). In general, MURs were viewed positively by community pharmacists who perceive this service as an opportunity through which the profession can evolve (Ewen et al., 2006; Latif and Boardman, 2007; Hughes et al., 2009) and enhance its relationship with patients (Cowley et al., 2010).

Yet despite this optimism, the delivery of advanced services is not homogenous across the profession. In general terms owners struggle to conduct MURs while maintaining an economically viable dispensing volume, locums reported little desire or motivation to conduct MURs, whereas salaried pharmacists experienced varying degrees of pressure and motivation to deliver this advanced service (McDonald et al., 2010b). Coupled with this, those pharmacists working 'full time' performed significantly more MURs than part time pharmacists, and store based pharmacists performed significantly more than 'relief' pharmacists (Ewen et al., 2006; Latif and Boardman, 2008; Latif and Boardman, 2007), which some suggest is a reflection of their dedication to the profession.

For locums, factors of familiarity, such as working with staff who were strangers and unfamiliar settings, procedures, policies and equipment were reported to be the main factors limiting the number of MURs that they are able to deliver (McDonald et al., 2010b). This literature suggests that individual professional priorities influence the extent to which advanced services are provided. In turn, these priorities are influenced by all of the other factors outlined above.

Policy Lessons

This literature review has exposed the main barriers and motivators to the implementation of the Medicines Use Review and prescription intervention service into community pharmacies, which have been grouped together into seven broad themes: **Work Environment; Financial Drivers; Accreditation and Training; Patient Recruitment; External Support; Documentation; and Individual Practitioner Motivation.**

Policy leaders working from the 'top down' can manipulate the macro, contextual environment, of the organisational system within which individual pharmacists operate. However, ultimately, implementation relies on the practice habits of the individual pharmacists at the local level.

Encompassed within these individual practice habits is the organisational culture of the pharmacy, which is commonly understood to be integral to the way in which organisations function, as an influence of behaviour. It has been broadly described as "*the way we do things around here*" as well as the way things are judged, valued and understood (Schien, 2004). Pharmacists as the individual leaders of a pharmacy at the micro level have a key role to play in re-defining the culture of each pharmacy. Yet despite its importance, cultural

leadership has been largely ignored in pharmacy practice research (Roberts et al., 2003; Clark and Mount, 2006).

Understanding the thoughts, actions, beliefs and values that drive behaviour and the everyday assumptions that influence how an organisation functions can provide a powerful insight into service implementation. Under an organisational paradigm the values and beliefs that people hold individually as members of the organisation are thought to collectively influence how they act, and therefore influence the behaviour and function of the place in which they work (this is explored further in chapter 5). What this review suggests is that while the six contextual factors identified are important for manipulating the environment, it is ultimately the individual pharmacist's professional cultural identity in the pharmacy that drives service implementation. It is argued here that future service implementation needs to empower change in the professional cultural identity of pharmacists if it is to succeed (Roberts et al., 2003; Roberts et al., 2006; Roberts et al., 2008; Scahill, 2008; Scahill et al., 2009). As leaders of the premises they will then influence the culture of the community pharmacy, and eventually the profession. In many respects this is an argument in favour of professional empowerment and a 'bottom up' approach to policy implementation.

The individual interpretation and professional empowerment of service delivery at the local level has been recognised within the policy arena under the framework of 'street level bureaucrats' (Lipsky, 2010). Lipsky contests that individual autonomy at the consumer facing level influences who benefits from policy initiatives (Lipsky, 2010). Kelly (1994) suggests that due to their responsibility as the final implementers of policy, street level bureaucrats find their jobs inherently discretionary. This is exacerbated by a knowledge asymmetry between street level bureaucrats and the public (Hupe and Hill, 2007)³⁸.

Pharmacists display the characteristics of a 'street level bureaucrat' through their agency status which allows them to decide who is offered the service; for example pharmacists excluded those with mental health medications (Latif et al., 2010). Some might argue that this is a manifestation of professional autonomy, yet this discretion results in a gap between the objectives of policy and the observed outcomes³⁹. As demonstrated by the literature review, pharmacists, like all street level bureaucrats, have incentives to pursue their own ends that are at odds with the interests of management (Ricucci, 2005). Moore

³⁸ This is a manifestation of the agency relationship outlined in chapter one.

³⁹ Note the conflict here between professionalism and managerialism/bureaucracy.

(1987) suggests that in negotiating ambiguous work settings, street level bureaucrats create conflict between themselves and management - something that was observed in community pharmacy settings (Latif and Boardman, 2008) - in order to exert their own autonomy and identity.

Citing Hill (1997), Walker and Gilson (2004) argue that there is often a disjuncture between what senior level management prescribes and what actually happens at the 'street level'. In their analysis of nurses they argue that this 'bottom up' approach subverts the 'top down' discourse that rationalists believe is central to policy formulation (Walker and Gilson, 2004). They argue that this bottom up perspective, "emphasises the need to understand implementation systems and the actors responsible for implementation" (Walker and Gilson, 2004: p1215). Such arguments suggest that implementing services and policies into community pharmacy require a clear understanding of individual pharmacist's culture as they are the actors responsible for implementation.

Walker and Gilson (2004) suggest that policies should be created in ways that are inclusive of the street level bureaucrats discretion, which in the case of pharmacy should take into account the individual pharmacists' professional cultural identify. What this literature review reveals is that the process of MUR implementation relied heavily on the decisions made in the planning and delivery of a service, as a 'top down' approach, as opposed to a flexible 'bottom up' approach required by pharmacists. While the objectives may be clear at the early stages of the service, it is only when the pharmacists act as street level implementers of the service is it possible to assess the outcomes.

Section Conclusion

The analysis presented in this section revealed seven broad themes about service implementation. These are: Work Environment; Financial Drivers; Accreditation and Training; Patient Recruitment; External Support; Documentation; and Individual Practitioner Motivation. The last of these was the most influential in deciding on the implementation of services locally.

The literature in chapter 2 describes the general willingness of pharmacists to provide extended services. Yet despite this, the results here suggest that individual practitioner willingness is the biggest driver of service implementation. Individual resistance to change is not a new phenomenon and a well reported in the wider implementation literature. But clearly overcoming the barriers described here requires more than and motivating

individual pharmacists to change, or remunerating them to provide a service. Wider external and organisational factors are important.

Change is always a difficult process. And while this literature identifies the barriers to successful change, its focus has been limited to the individual pharmacist as the unit of analysis. Indeed, the facilitators of change suggested in this section mainly relate to the behaviours of individual pharmacists. This 'bottom up' interpretation of policy implementation negates the 'top down' effects of these policies. Few studies have considered the 'top down' effects of MUR implementation with the whole profession as the unit of analysis. Less focus has been placed on the collective profession (the organisation) that influences implementation at the local level.

It is for this reason that the next section of this chapter considers the 'top down' implementation of the New Medicines Service in England. Such research will help to discover if the lessons of MUR implementation have been learnt and whether the same barriers persist.

Implementing the New Medicines Service

The literature review of MUR implementation revealed that the organisational culture of the community pharmacy is an important element in service implementation. Involving street level operators early in the planning and development of the process is hypothesised to increase the effectiveness of the service when implemented at the local level. This builds upon the differences between ‘top down’ and ‘bottom up’ approaches to policy implementation. In this section the development and implementation of the most recent advanced service – the New Medicines Service- is explored as a case study to assess if ‘grass roots’ pharmacists were involved in the initial development of this service and to discover if lessons have been learnt following the implementation of MURs. These were analysed to provide a background to future policy implementation.

The New Medicines Service (NMS)

Consider a consumer buying a new piece of technology, a camera for example. They take it home, they experiment with using it, and in some cases they attempt to read the information manual provided. However, after a few weeks, the consumer may have developed problems that the manual fails to address. They may require some additional expert advice to obtain the full potential of a technology. This consumer follow up is the underlying concept behind the New Medicines Service (NMS), which was rolled out in England on 1st October 2011.

The way that patients interact with medicines, another technology, is no different. Patients experiment with their medications. They get used to taking them and fitting them into their daily routine. In some cases patients read the patient information leaflet (the instruction manual) provided. After a few weeks some patients may experience side effects or problems, which they want to discuss with an expert. In the case of medicines this ‘expert’ is the community pharmacist whose body of knowledge is centred on medicines and their use⁴⁰. Although pharmacists have always offered advice, they have historically recouped the economic cost of advice from healthcare products and prescriptions supplied. This new nationally advanced service allows pharmacy contractors to be directly remunerated for providing expert advice, either face to face or via the phone, to help patients get the full potential benefits out of their newly prescribed medicines.

⁴⁰ However this expert can often be other health care professionals, particularly the GP or the practice nurse.

On initiation of a new medicine for one of four therapeutic areas (Asthma and COPD, Hypertension, Type II Diabetes, and anti-platelet or anticoagulation therapy) patients are enrolled to the service by their pharmacist or by GP referral. After two weeks, patients return to the pharmacy where problems with medications are discussed. A follow up consultation typically two to four weeks later is made to ensure no further medication problems persist. It is suggested that this service will help patients with their medicines, reduce waste, improve adherence and increase pharmacovigilance (Pharmaceutical Services Negotiating Committee, 2011b). The case study described here explores the political process that led to the development of this new advanced service.

Theoretical Framework

In the social sciences theorists seek to develop models and theories that explain the world around them. All theories and concepts are contestable, meaning that they are part of an ongoing controversy. There are some concepts that are contestable but for which we have no way of resolving competing arguments. Therefore we can note the rival positions, but we cannot evaluate them in terms of principles that command general agreement. This is the very nature of politics, in that all political concepts are inherently contestable.

Deciding on a framework that can be used to analyse a policy problem is itself a contestable argument and therefore a decision that requires explanation. A multitude of theoretical models exist to describe the policy process (Sabatier, 2006), each with their own merits and drawbacks. Models, by their very nature, involve degrees of abstraction and idealisation that act as both their strengths and weakness. On the one hand these theories abstract certain features of reality, that is, they pick up aspects of reality and ignore others in order to simplify the focus. On the other hand, models add to our perception of reality by repressing the complex and entangled nature of the world being studied.

Until the mid-1980s the Stage Heuristic Model was the most influential framework for understanding the policy process. The model comes under the rationalist school of thought. It suggests that policymaking is a rational linear process separated into agenda setting, policy formation and legitimation, implementation, and finally evaluation (Sabatier and Jenkins Smith, 1993).

This 'stages' model describes 'implementation' as a separate stage in a rational sequential approach. In reality, policy formation is often non-sequential and may develop during

implementation. Therefore such an approach underestimates (and fails to capture) the importance of non-formal processes such as the disagreements between different advocacy positions or groups. It also ignores the 'bottom up' effects and conflicts involved in policy implementation, the links between several policies, and ignores the fact that policies are not created in isolation (see MURs above). As such rational models of policy development were deemed inappropriate for this study.

John Kingdon (1984) developed the multiple stream model, which is primarily concerned with the timing and flow of policy action as opposed to its components steps. As a model it fits closely with the narratives approach adopted here and therefore was used as the 'theoretical framework' for this section⁴¹.

The starting point for Kingdon's work was the 'garbage can model' developed by Cohen and colleagues (1972), which attempted to describe the ambiguous behaviours that contradict the classical rational behaviour perspectives (e.g. stages approach). The model was influenced by the observation that under great uncertainty, responses from decision makers would appear, when viewed from a distance, to be irrational. The 'garbage can model' was formulated in the context of universities where interdepartmental communication problems helped to support the model. This conjecture separates problems, solutions and decision makers from each other. It suggests that *problems* require attention, *solutions* are answers looking for a question, and *choice opportunities* are where organisations are expected (or they think they are expected) to produce a decision. In this model *participants* vary between problem and solutions. It was named the 'garbage can model' because it was believed that organisations produce many solutions that are discarded due to lack of appropriate problems. However, problems may eventually arise that have a solution in the 'garbage can'.

Kingdon (1984) attempted to reflect the complexities and realities of the policy making process by focussing on *policy entrepreneurs* who take advantage of agenda setting opportunities – named *policy windows*. The changing nature of the flow and timing of policies can lead to the opening and closing of windows of opportunity that allow policies to reach the agenda. Building on the garbage can approach, this model suggested that three streams or processes exist – the problems stream, the policy (solutions) stream and the

⁴¹ In the strictest sense of the word this is not a theoretical framework. However it is a model around which the narrative presented here can be explained.

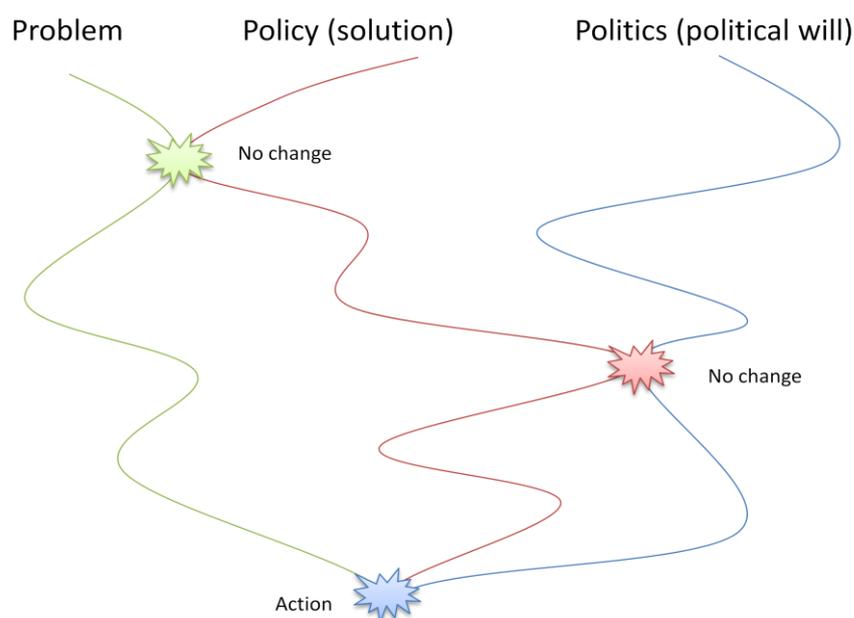
politics (political will) stream (figure 4.4). All three streams must meet at a policy window for a policy to progress.

Problems stream consists of various conditions that citizens and policy makers want addressed. These may come from indicators, (such as nationally collected statistics or specific studies), focusing events (such as riots or earthquakes), feedback (evaluation of previous policies) and load (the extent that other events preoccupy the minds of policy makers).

The Policy (or solution) stream is generally an output of mid level government officials, policy advocates, think tanks and academics. These ideas compete to win acceptance in policy networks. Ideas are considered in policy circles through papers, hearings and conversations. Some ideas survive, yet others are combined and still more disappear. As such, these policy solutions are subject to sensitive development of sequence, content, timing and translation to become action. It is worth emphasising that Kingdon's model does not suggest that solutions are built to resolve given problems, but instead that they float in search of problems to which they can be tied.

The Politics (or political will) stream explains changes in national mood as to what is acceptable, pressure group campaigns to change events and the turnover of the government, which all influence the desire of politicians to act on any given problem.

Figure 4-4 - Multiple Stream model of agenda setting and policy process (adapted from Buse et al., 2005)



The model suggests that while each of these streams move and 'flow' independently, it is only when they run together at critical moments in time that the policy is taken seriously. These opportunities are known as *policy windows*. Policy entrepreneurs may be individuals or corporate actors who attempt to couple the three streams together. The relative skill they have in doing this increases the chances of a policy being adopted.

This model differs from the other frameworks because it adopts the logic of political manipulation, whereby policy entrepreneurs couple the streams together. The power of this model is that it accepts that the policy process is non-linear and involves a numerous actors and forces.

Other lenses, such as rationality, fail to address this political manipulation. Rationalists assume individuals adopt the utility maximising concept of *Homo economicus*, they suggest that every individual has a clear and consistent way of arriving at a final decision. While this may often be the case, the multiple streams approach *reveals* rationality as opposed to assuming it exists. On the other hand constructivists see policy making a driven by persuasion and social construction. In reality it is more than just persuasion, it involves generating facts that can change people's minds. Constructivist approaches specify how identities are constructed but fail to sufficiently explain the fluctuations seen in policy over time.

The New Medicines Service has come into practice as a result of themes being coupled within the policy process. This case study uses the multiple streams model of policy development (Kingdon, 1984) to analyse the expansion of what some within the pharmacy profession see as a major stepping-stone for community pharmacist development and a path to pharmacy's clinical future (Richardson, 2011).

Method – Case Study Approach

This study applied a mixed method single case study approach. Despite the beliefs of some that case study research is the 'weak sibling among social science methods' (Yin, 2009: p xiii), case studies continue to be used extensively in a variety of academic disciplines, including political science and public policy research. The case study approach allows for an explanatory as well as a descriptive approach to understand complex problems and social developments (Yin, 2009: p5).

This case study used a purposive sampling methodology to identify policy entrepreneurs who were involved in the development and implementation of the new medicines service. A 'snowball technique' was used with an initial core of interviewees to identify other relevant people to be interviewed. All those interviewed were directly involved in the policy negotiations and had intimate knowledge of the service. Sampling ceased once no new streams were identified from the narratives. A semi-structured qualitative research instrument was piloted and developed to support a series of interviews with stakeholders who were known to have played a key role in the development of the NMS.

The interviewees were from the following groups: Academics (2); Pharmacy Voice (1); PSNC (2); Department of Health (1); CPPE (1); NHS Employers (3); Royal Pharmaceutical Society (3); GPhC (1); PCT Representatives (2).

The average interview duration was just under an hour. Participants were guaranteed confidentiality. In most cases the interviews were digitally recorded alongside summary notes that were made during the interview. The interviews were subsequently transcribed. Where recording equipment was not used, or where it failed, a summary of the researchers notes was formally written up. The transcriptions or notes from the interviews were shared with the interviewees for confirmation and clarity, as well as to ensure that their views were not misrepresented. The researcher was satisfied that he had sampled to saturation, in as much as later stage interviews did not reveal new streams, albeit that they added to his understanding. The interviews were analysed using a descriptive framework that allowed this case study of NMS implementation to be understood.

A descriptive strategy may be considered less preferential than a theoretical proposition, but serves the purpose required here. The technique is not guided by any preconceptions, but instead by the content that is recorded. Therefore this method allowed for the extraction of the descriptive narrative that underlay the development of this service. Due to the nature of this research institutional ethical approval was applied for and received from the School of Pharmacy Ethics Committee (Ref B-10-12).

The interviews were supported by a wealth of information about the service from academic literature as well as grey literature sources, such as trade magazines, community pharmacy blogs and internet discussion boards.

Systematic searching of the Pharmaceutical Journal for all mentions of the New Medicines Service (NMS) was performed, as were searches of the Chemist & Druggist Magazine. Websites of key pharmacy bodies, including the NPA, PSNC and RPS were also analysed alongside key documents and reports.

Interview transcripts were compared to the NMS implementation documents provided on the Pharmaceutical Service Negotiating Committee (PSNC) website (www.psnc.org.uk). Where decisions about the implementation of the NMS were not clear from the available documents and transcripts, employees from the PSNC, Department of Health and NHS Employers were contacted and invited to provide additional clarity.

All statements and observations made below are qualitative in nature. As far as possible dates, times and the sequence of events were confirmed by triangulation with the literature and the interview responses. However, in some cases discussions and conversations as part of the policy development process were not written down or formally recorded. These cases therefore rely solely on the memory of the interviewees. Although efforts were made to access minutes of significant meetings, confidentiality and commercial sensitivity restricted access to these documents.

Results - Narrative Findings

The results of this case study are organised in a narrative approach that adopts the multiple stream model of the policy process. Each of the streams is analysed in turn. Areas where these streams overlap are narrated, before being analysed. For ease of understanding these results have been summarised in the timeline shown in figure 4.5.

Figure 4-5 – Timeline of the NMS Development

	Problem Stream	Political will	Solution (Policy)
1997	Early 1990s – Problems with adherence first identified 1995 – WOSCOPS Study 1997 RPSGB Report on adherence November 1997 RPSGB receives support from Secretary of State	3 May 1997 – General Election (Tony Blair, Labour) 1997 New NHS, modern, dependable 3 May 1997 Frank Dobson Secretary of State for Health	
1998			1998 – NHS Direct Telephone service launched 1998 – Moss Pharmacy and SOP discuss use of Moss pharmacy network
1999		11 October 1999 Alan Milburn Secretary of State for Health	
2000		16 th January 2000 – Tony Blair Announces increased funding for the NHS 1 July 2000 – The NHS Plan: a plan for investment a plan for reform September 2000 – NHS Plan for Pharmacy	2000 - Stevenson et al. publish research on Doctor patient communication of drugs
2001		7 June 2001 – General Election (Tony Blair, Labour)	2001? – DHSC London provide funding for pharmacist intervention research
2002		18 April 2002 – Delivering the NHS Plan: next steps on investment, next steps on reform	2002 onwards – Medicines Partnership Program
2003	2003 – WHO Report on Adherence to Long Term Therapies	13 June 2003 John Reid Secretary of State for Health	2003– Pharmaceutical Care Award for 'Hello it's the pharmacist calling'
2004		2004 – New Contract for General Practice	2004– Barber, Parson et al. publish original research
2005	2005– Concordance, Adherence and Compliance in Medicines taking, NCCSDO 2005– DH asks NICE to investigate medicines taking	2005– Healthcare commission report April 2005 – New Pharmacy Contractual Framework 5 May 2005 – General Election (Tony Blair, Labour) 5 May 2005 Patricia Hewitt Secretary of State for Health	
2006			2006– Clifford, Barber et al. publish proof of concept research
2007	2007 – National Audit Office Report into Prescribing in Primary Care July 2007 – Ara Darzi asked to conduct review of NHS	27 June 2007 – Gordon Brown prime minister 28 June 2007 Alan Johnson Secretary of State for Health	2007 – Galbraith review of pharmacy contract
2008		Early 2008 – Darzi meetings for pharmacy contract 2008 – Pharmacy in England: Building on Strengths, delivering the Future. A white paper for community pharmacy July 2008 – Ara Darzi reports the next stage review of the NHS	2008– Elliott, Barber et al. publish economic evaluation
2009	2009– NICE guidelines on Medicines Adherence 8 June 2009 New Pharmacy Minister – Mike O'Brien August 2009 – David Nicholson sends letter announcing QIPP	5 June 2009 Andy Burnham Secretary of State for Health	Early 2009 – NHS Employers and PSNC given mandate to begin discussions on NMS
2010	2010 – YHEC/ SOP waste study published 6 May 2010 New Pharmacy Minister – Earl Howe 12 July 2010 – Liberating the NHS white paper November 2010 – Earl Howe announces support for NMS at PSNC dinner	6 May 2010 – General Election (David Cameron, Con-Lib Coalition) 11 May 2010 Andrew Lansley Secretary of State for Health	7 Sept 2009 – Andrew Lansley speaks at BPC 21 July 2010 – Earl Howe announces discussion on NMS to restart at APPG meeting
2011		15 March 2011- NHS Employers & PSNC announce introduction of NMS 11 May 2011 – Outline service specification released, stakeholder meeting begin 1 st October 2011 – New Medicines Service goes lives across England	

The Problem Stream – Adherence to Medicines

The challenge of getting patients to use and take medicines as prescribed by their doctors has been described in the literature for centuries. However, it was not until the development of modern mass scale factory produced pharmaceuticals in the Western world, that the problems of non-adherence to medications became contextualised as a problem. This was particularly brought to the fore from 1987 onwards by the introduction of statins to prevent chronic heart disease. Despite statin use increasing rapidly across Europe during the 1990s, the anticipated benefits of the drugs to prevent and manage cardiovascular diseases was not being observed in the population. It was postulated that compliance with medication regimes was the reason for this. Trials in the early 1990s, such as the West of Scotland Coronary Prevention Study (WOSCOPS) confirmed this belief by finding that adherence to statins of over 75% reduced the risk of death from any cause by one third (Shepherd et al., 1995).

Pharmaceutical companies began to recognise the importance of considering what happened to their medications after they had been dispensed. In early 1996, a working party of the Royal Pharmaceutical Society, with financial support from Merck Sharpe and Dohme Ltd (MSD), who at the time were the biggest supplier of branded medicines to the NHS, began to investigate the potential challenges associated with getting patients to take their medicines as prescribed. The group, which included doctors, pharmacists, nurses and social science researchers, produced a literature review that developed the terminology of 'concordance'. This assembly recognised that the culture of society had moved away from medical paternalism that defined 'compliance' in the 1940s, towards a more proactive patient centric system (The Royal Pharmaceutical Society, 1997). Not only were issues of medical paternalism (and patient non-adherence) highlighted in this report, but also the pharmaceutical waste and lost therapeutic outcomes that result from poor medicines adherence. This captured political attention, and on 13th November 1997, the newly elected Secretary of State for Health, attended a conference at the RPSGB to discuss how best to develop the concept of 'concordance' into the health service (News, 1997).

The next decade of research, mainly supported or sponsored by the pharmaceutical industry, analysed the issues, approaches and challenges related to taking medicines as advised. This issue was brought to the international stage in 2003 when the World Health Organisation (WHO) reported that action was needed to address the costs and safety aspects of poor medicines adherence (World Health Organisation, 2003). Such a report

failed to significant impact in primary care, with pharmaceutical waste and shared prescribing decisions remaining a problem (National Audit Office, 2007).

On 5th April 2005 the government formally asked the National Institute of Clinical Excellence to prepare clinical guidance on Medicines Concordance. The groups remit was *“to prepare clinical guidelines for the NHS in England on involving patients in decisions about prescribed medicines”*. These guidelines were published in January 2009, under a changed title - Medicines Adherence (NICE, 2009). This report described the ‘under-utilisation’ of pharmacists (see chapter 1) and pharmacy resources in combating poor adherence (Department of Health, 2008a). They suggested that pharmacists should be empowered to help create ‘behavioural change’ in medicines taking.

Poor adherence continued to feature in government sponsored research. A 2010 Department of Health funded report further showed the costs associated with non-adherence in primary care (York Health Economics Consortium and School of Pharmacy University of London, 2010). It suggested that non-adherence was costing in the region of £100 million per year. The government was keen to act partly because such significant sums of money at a time of economic recession and constrained spending are politically unpalatable. The stage had been set for the problem stream.

The Policy (Solutions Stream)

The documented loss of therapeutic benefit in the 1990s from non-adherence prompted both the pharmaceutical industry and Department of Health to fund further research to understand the problem. At the same time health services research, and in particular pharmacy practice research, was beginning to be accepted as an academic discipline. A pharmacist, Nicholas Barber, sought to establish and develop the concept of pharmacy practice research from a base within the School of Pharmacy, University of London. He built links with those in the developing field of health services research. There was an increasing recognition that understanding systems and processes within healthcare could help improve patient care, but also politically this could be used as a tool to influence service developments and assist managers within the NHS. From this base Barber became part of a Department of Health Prescribing Research initiative. The group investigated the dynamics of communication between doctors and their patients (Stevenson et al., 2000). They discovered that shared decision making and medicines information were poorly tackled during general practice consultations. Barber realised the potential benefits that

pharmacists could offer in assisting patients in the understanding of their medicines. He set about trying to establish whether this potential could become a reality.

Rob Darracott, who had been the Principal Pharmaceutical officer at the Department of Health since 1991, left in 1995 to join Moss Chemists, which at the time had in the region of 350 outlets. Darracott became the Professional Services Manager with a remit to expand the services component of the community pharmacy business. Darracott recognised that the chain had the potential to be used as a research network. He capitalised on such a network by exploring the factors influencing consumer choices into OTC medicines with academics from Manchester University (Payne et al., 1997; Payne et al., 1998).

During this period Darracott had been aware of Barber's work on shared decision making because of mutual professional and social friends. This precipitated discussions into how they could work together to utilise the Moss pharmacies as a potential research network. Barber developed their idea into a research proposal in the late 1990s. However, finding a sponsor for a project, which aimed to investigate the effects of community pharmacists' advice on medicines adherence, proved difficult.

At the time the Directorate for Health and Social care (DHSC) London had a research budget set aside to support innovative practice. Yet the DHSC, when presented with this research proposal, were reluctant to acknowledge the existence of non adherence as a problem in primary care. It was believed that acknowledging the existence of non-adherence in primary care would undermine the perceived effectiveness of medical interventions. Eventually, at the turn of the millennium, Barber received financial support from DHSC, but only to investigate if such an adherence problem existed.

Sarah Clifford - a health psychologist - was recruited to the School of Pharmacy to replace Jim Parsons (who for the first twelve months had been the main research assistant supporting this project). Clifford set about supporting and developing a research program that would identify non-adherence in primary care. After an initial slow engagement from community pharmacies, 258 patients who were aged over 75 and beginning a new medicine for a chronic condition were recruited to interview. Sixty-seven (30%) of the 226 people still taking their medicine at 10 days and 43 (25%) of the 171 people still taking their medicine at four weeks were found to be non-adherent. The research team, which included Rob Horne - a pharmacist and health psychologist from Brighton - found that 61% of

patients reported a substantial and sustained need for information ten days after starting a new medication (Barber et al., 2004).

On the back of this evidence the DHSC funded a subsequent intervention study to evaluate if a community pharmacy based intervention could improve adherence. At the time this represented the largest ever grant given by the Department of Health to community pharmacy research.

A randomised controlled trial of a pharmacist-delivered intervention to improve adherence using a centralised telephone service to patients at home was developed. The methodology was progressed to incorporate an economic evaluation with the assistance of Rachel Elliot, a health economist from Manchester University⁴².

In the wider society public acceptability of health services via the telephone was increasing (e.g. Hallam, 1993). In 1998 NHS Direct, a national nurse led telephone advice service, was created to help manage the demand for out of hours primary care in the UK (Munro et al., 2005). This service built upon the use of telephone technology in this way.

The pharmacists in the study were trained in 2000, with an initial pilot from October 2000 to May 2001. The main study, conducted between June 2001 and October 2002, found that the telephone intervention improved adherence. Their results won the runner up prize in the Pharmaceutical Care Awards 2002⁴³ (PJ, 2003) under the title of *“Hello, it’s the pharmacists calling” – how telephoning patients improves adherence*. The research team were also highly commended in the 2003 Primary Care Report best practice award. The research was formerly submitted for publication in 2005 and printed in 2006 (Clifford, Barber et al. 2006), with the economic evaluation following in 2008 (Elliott et al., 2008).

Despite the awards and media coverage of this research, the service received limited attention outside the profession, and failed to gain political attention. Moss business managers experimented with a telephone service targeting osteoporosis patients in collaboration with the pharmaceutical industry and tried selling a redesigned service to Primary Care Trusts. However, these small private schemes had limited commercial success and were quickly scrapped.

⁴² In late 2000, Elaine Hartley assumed the lead for this project at Moss Pharmacy. Darracott- who had previously been the key liaison - moved internally as result of a takeover of Moss by Alliance UniChem.

⁴³ This was presented in July 2003.

The problem stream of non-adherence received political attention in the middle of the decade, but this solution failed to be coupled with the problem until 2008. Even the National Co-ordinating Centre for NHS service Delivery and Organisation R&D (NCCSDO) commissioned research, *Concordance, adherence and compliance in medicines taking* (Horne et al., 2005), failed to effectively couple the telephone based study and the problem stream together despite a crossover of authors between the projects. It is postulated by some of those interviewed that the lack of political penetration of this study was part of a wider inability of pharmacists to effectively lobby and influence public policy.

Political Will

In May 1997, Tony Blair became the new labour Prime Minister. He took office with a large majority, popular support and a manifesto pledge to 'save and modernise the NHS' (The Labour Party, 1997). This pledge was implemented through a 1997 White Paper (Department of Health, 1997). Such investment was announced on January 16th 2000 (BBC News, 2000). This financial support provided a platform on which Alan Milburn - the secretary of state for health (previously Frank Dobson's deputy) – could bring about reform. The July 2000 publication of the *NHS plan: a plan for investment, a plan for reform* (Department of Health, 2000a) set out the government's modernisation program for the NHS. This aimed to move away from the paternalism of professionals towards greater active patient involvement through a quasi-market and greater patient choice in healthcare decisions. Revelations from the public inquiry into children's heart surgery (Kennedy, 2001) highlighted the lack of information provided to patients and carers by overbearing paternalistic doctors. This helped to spur public support for change.

The government publications (analysed in chapter 1) show a 'political will' to 'utilise' community pharmacists to help patients get the best out of their medicines. Such documents acknowledged the previous work of the Royal Pharmaceutical Society advisory committee on 'concordance'. A commitment of more than one million pounds over two years was provided by the government to support a national strategy for integrating partnership in medicines taking. This investment led to the foundation of the Medicines Partnership Program, which was established in 2002 to promote the concept of shared decision making and concordance.

Given the new investment and political rhetoric towards greater patient choice, the government was keen to develop "*modern contracts for both GPs and hospital doctors*" (Department of Health, 2000a: p15) to make best use of the new investment in the health

service. A new contract for community pharmacists followed in April 2005, a year after the successful implementation of the new GP contract. This contract attempted to address the 'under-utilised' of pharmacists by shifting "*away from being paid mainly for the dispensing of individual prescriptions towards rewarding overall service*" (Department of Health, 2000a: Para 9.8). Although previously there had been services provided in community pharmacies, this new contractual framework created a system for services to be commissioned nationally. The first of these was the Medicines Use Review (MUR) implemented with political support from Patricia Hewitt, the Secretary of State for Health.

Some of those involved in the negotiations at the time have implied that they regret not being radical enough in using the contractual negotiations to create a seed change in pharmacy practice. They believe that opportunities were missed. For example, the chairman of the PSNC, Barry Andrews, was at the time working for Moss Pharmacy. In this role he had oversight of the telephone intervention service, but failed to suggest it as a possible service during contract negotiations.

The lack of seed change created by the new contractual framework was reported in a Department of Health commissioned review of the new pharmacy contractual framework (Galbraith, 2007). This spurred pharmacy organisation to create 'political will' for further change. In June 2007, the All-Party Pharmacy Group (APPG) published a report that made a series of recommendations about the future development of community pharmacy (All Party Pharmacy Group, 2007).

Despite investment and improvements, reports that patient services across the NHS appeared fragmented and designed '*more to suit the needs of those delivering them than using them*' (The Healthcare commission, 2005: p9) persisted. The government commissioned Ara Darzi - a world leading cancer surgeon and confidant of Tony Blair - to undertake a systematic review of the NHS. His review presented an opportunity for pharmacy organisations to emphasise the role that community pharmacists could play in aiding patient care.

The combination of the 2007 AAPG report, the Galbraith review of the contractual framework, and Darzi's review of the health service, persuaded ministers to write a White Paper for pharmacy. The evidence gathering for this pharmacy White Paper was conducted alongside events to inform Ara Darzi's review.

In wider politics, Alan Johnson had taken the helm as Secretary of State for Health, and there had been a change of leadership at the top of the labour party, with Gordon Brown the prime minister.

The separate problem stream of pseudoephedrine misuse enters the narrative. In 2007, the Medicines Healthcare and Regulatory Agency (MHRA) was consulting on proposals to restrict pseudoephedrine to a prescription only medicine. This was due to concerns over the availability of pseudoephedrine, which can be converted into methylamphetamine - a drug of misuse. The Company Chemists Association (CCA) - a trade body representing the interests of nine large pharmacy chains⁴⁴ - had recently instated their new chief executive, Rob Darracott in January 2007. The CCA developed a concerted communication campaign, in conjunction with the RPSGB, to make pharmacists aware of the potential risks associated with pseudoephedrine misuse.

The CCA gained positive support for their campaign from the Department of Health for the effectiveness of this intervention. This helped the CCA to get a 'foot in the door'. They were subsequently encouraged by Mark Britnell, the then Director General for commissioning and service management, to feed into Darzi's review of the NHS. They were invited to hold a meeting in which they could present the contribution that pharmacy could play to future the development of the NHS. Various stakeholders from across Pharmacy, including hospital pharmacists and notably Professor Barber, were invited by the CCA to this meeting in March 2008. Mark Britnell was only in attendance for the final few minutes of the meeting and therefore Dr Keith Ridge – the chief pharmaceutical officer - chaired the meeting.

A literature review on pharmacy services commissioned by the Department of Health for the upcoming pharmacy White Paper had not been captured this pharmacy based telephone intervention study. Therefore this meeting allowed the telephone adherence service to be raised formally as part of the policy process. Britnell was impressed with the evidence and the potential value of this service as it appeared to meet policy objectives regarding adherence, waste medicines, and also supported clinical roles for community pharmacists. Officials were asked to explore this service in more detail.

The publication of a pharmacy White Paper was due in a matter of weeks. Therefore officials quickly began to investigate if this service could be set into the context of the

⁴⁴ equal to about half of all pharmacies in the country

'Darzi reforms' and if it could be included in the pharmacy White Paper. Several conversations (facilitated by the fact that Ridge and Barber had previously worked closely together during Ridge's time as an MSc and PhD student at Manchester University in 1998) between Ridge, Darracott and Barber followed in both formal and informal settings. The reaction was positive given the strong evidence. This quickly resulted in the service being drafted into the pharmacy White Paper.

The Streams Coalesce

In April 2008 the three streams (policy, politics and problem) coalesced with the publication of the Pharmacy White Paper (Department of Health, 2008a). This linked non-adherence – the problem stream, research – the policy stream, and the political will stream together by making a commitment to help patients with newly prescribed medicines.

“The Government will therefore discuss with the PSNC and NHS Employers how such a support service may best be introduced within the community pharmacy contractual work” (Department of Health, 2008a: Para 4.56).

Barber's initial research into non-adherence in primary care was described in this White Paper. Yet there was no direct reference made to the successful telephone intervention service. The incorrect reference citation was used in the internal partial impact assessment. It referred to the problem of non-adherence rather than the telephone intervention. This is possibly a reflection of the rush to include this service in the White Paper.

Despite the streams coalescing, the pharmacy led service to help patients with newly prescribed medicines was only a White Paper recommendation, which would require funding, further negotiation and implementation to become a reality.

In the summer of 2008 Ara Darzi published the findings and recommendations of his review of the NHS. In this he described a role for pharmacists in public health. This was interpreted by some as a signal to pharmacists that they should stop trespassing in to general practice territory.

The 2008 pharmacy White Paper made NHS Employers (NHSE)⁴⁵ the lead for negotiating service developments in community pharmacy. Yet their negotiations were bounded by a 'mandate' from ministers provided to them by officials in the Department of Health.

The NHSE mandate 2008/09 instructed them to negotiate with the Pharmaceutical Services Negotiating Committee (PSNC - a membership group that represents NHS pharmacy contractors) over MUR service developments, relationships between pharmacists and GPs, and aspects of service quality. It was funding reasons that prevented the inclusion of a service for patients on newly prescribed medicines in this mandate. Although the partial impact assessment had indicated a positive economic benefit, initial implementation funds were required to commission any new service.

Barber, whose research included aspects of medicines safety and service quality, was invited to discuss the service quality aspects of community pharmacy in early 2009. By chance one of the lead pharmacy negotiators for NHS Employers struck up a conversation with him about his research. This conversation helped to bring their attention to the telephone based intervention, which they had previously been unaware of.

Ministers could either fund the service with a new budget form elsewhere or source the funds directly from savings made within the pharmacy contractual framework. It was the latter of these options that prevailed. The medicines margin of 2008/09 allowed the service to be included in the 2009/10 mandate.

Throughout the autumn of 2009, NHSE and PSNC met on four occasions to negotiate the development of a service to support patients taking new medicines. It was only after the second of these meetings that PSNC representatives became fully aware of Barber's research that underpinned the service. Towards the beginning of winter of 2009 Barber was invited to present to the negotiating teams and explain his research. Eventually at the end of 2009, after much negotiation, these discussions culminated in a mutually designed 'heads of agreement' document⁴⁶. This described a 'first prescription service' which was to be implemented into practice in the financial year 2010/11.

On 15th September 2008 the collapse of the Lehman Brothers signalled the beginning of a global economic downturn. In August 2009, to help manage this situation in the NHS, David

⁴⁵ A group representing over 90% employers in the NHS. NHS Employers is part of the NHS Confederation. Their vision is to be the authoritative voice of workforce leaders, experts in HR, negotiating fairly to get the best deal for patients.

⁴⁶ The 'heads of agreement' is the outcome of the negotiations between the NHSE and the PSNC. This document is passed to the officials within the Department of Health to receive government ratification.

Nicholson - the chief executive of the NHS - sent a letter to chief executives setting out a policy for Quality, Innovation, Productivity and Prevention to help improve the NHS in times of financial austerity. This called for wide spread 'efficiency savings' to be made across the health service.

In wider politics it was rumoured that a general election would be called in May 2010. Consensus was leaning towards a likely change of government following significant losses for the labour party in local and European elections in the summer of 2009. Gordon Brown reshuffled his cabinet in June 2009 replacing Alan Johnson with Andy Burnham as secretary of state for health. This reshuffle made Mike O'Brien the minister responsible for pharmacy, a post previously held by Ben Bradshaw. In doing so, Mike O'Brien assumed the responsibility for signing off the 'heads of agreement' document. This policy window was open and the streams of 'problem' and 'policy' were aligned. All that was required was 'political will' to provide ministerial agreement for this service.

The Streams Come Apart

In January 2010, the All Party Pharmacy Group brought adherence to medicines back into the spotlight, calling for a universally designed service to support adherence. This was an attempt to create some consensus surrounding a pharmacy based adherence service.

The proposal for the 'first prescription service' sat with O'Brien until the early spring of 2010 awaiting ministerial assent. When the minister spoke at the PSNC conference on 1st March 2010, it became apparent that a ministerial decision had been made not to pursue the service – The 'political will' had departed.

Those interviewed postulated several possibilities for this verdict. Firstly, considering that there was likely to be an election in May, the commitment to this service was unlikely to provide the labour party with any political gain. Secondly, the responsibility for pharmacy funding negotiations was spread between several ministers, increasing the complexity of the decision. Thirdly, being new to the role, O'Brien may not have truly understood the complex nature of community pharmacy funding. Under pressure to make financial cut backs in the wake of wider external events it could be speculated that he did not believe community pharmacy required this funding. Further it may have been a more fundamental ideological position that he believed pharmacists should focus on medicines supply. These postulations all represent conjecture and the real reasons may never be publically known.

However advocates of this service persisted in keeping the service on the agenda. Following the announcement of the election, the APPG produced a 'policy action plan' that called on any new government to launch "a national First Prescription Service" in community pharmacies (All Party Pharmacy Group, 2010).

A new government formed in May 2010, but unusually for British politics this was a coalition between the conservatives and the liberal democrats. As widely predicted Andrew Lansley became Secretary of State for health⁴⁷. However, as a result of the coalition agreement Mark Simmonds, who had been expected to take forward the mantle for pharmacy services, failed to gain a ministerial position. The responsibility for pharmacy was passed to Earl Howe.

At the time of its publication the 2008 pharmacy White Paper had received cross party support. Yet with a new government the previous pledges were no longer policy creating a blank sheet in terms of policy. Therefore there was no guarantee that this new government would support a pharmacy service.

The 'first prescription service' heads of agreement that had been presented to Mike O'Brien was passed to the ministerial office of Earl Howe where it remained unsigned. Those interviewed suggested that this was because it had been gifted from the previous government, and because large scale reforms were planned for the NHS. Indeed, two months after being elected, the new government issued *Liberating the NHS*, a wide ranging White Paper that proposed large scale reform of the health service (Department of Health, 2010: Para 3.22).

The Streams Realign

On 21st July 2010, the same month that *Liberating the NHS* was published, Earl Howe announced at the APPG summer reception that he would be asking negotiations on the 'first prescription service' to restart. This was a positive sign for the service, but the financial climate had resulted in a reduced funding envelope.

NHS Employers received a new mandate in August 2010. Using the previous heads of agreement document as a base, the negotiators set about realigning the service in light of the financial climate and the policies of the new government.

⁴⁷ Lansley has been the shadow health secretary for the last 12 years.

Between September and early November 2010, the groups negotiated to form a new 'heads of agreement'. It was during these discussions that the name of the service formally changed from 'first prescription service' to 'my new medicine', and then to 'New Medicine Service'. The latter was believed to be less antagonistic to the medical profession and to sound both professional and descriptive. Also, it was postulated that this created a visible separation between this service and the name used by the previous government.

Positive ministerial support came later that year, when Earl Howe spoke at the PSNC dinner on 17th November. He made a public commitment to the introduction of a New Medicine Service.

"I am an advocate of the new medicine service being mainstreamed within community pharmacy" (Howe, 2010).

However, in this speech he alluded to the challenges of the economic climate and the need for appropriate funding.

The economic evaluation carried out by Rachel Elliot as part of the original research (Elliott et al., 2008) provided a solid grounding for the impact assessment and helped to persuade officials of the economic benefits that this service provides. Pharmacy contractors waited four months for internal Department of Health scrutiny, and a revised impact assessment before the agreement could receive ministerial support.

However, on 15th March 2011 NHS Employers and PSNC were able to announce that a new medicine service (NMS) would be introduced. A funding letter from Bob Alexander - the Director of NHS finance – confirmed this to PCTs on the 17th March. It described how the service would be supported by a maximum investment of £55 million per annum in 2011/12 and 2012/13 recovered from medicines margin adjustments. The trade press viewed the service development as a significant event for the profession, despite the associated reduction in category M funding.

The challenges of getting from ministerial approval and commitment to a service on the ground should not be underestimated. While at this point all of the streams were aligned there were many rocks on which the service implementation could become snagged.

The Path to Implementation

The NHS employers and PSNC (with oversight from the Department of Health) set about developing the service specifications. These discussions were held confidentially, and

therefore the main source information as to what the service might entail came from the gesticulations of the pharmacy press.

On 4th April 2011, in advance of the specification's release, representatives of Pharmacy Voice⁴⁸ met to discuss the implementation of this service. Barber was invited to present the research underpinning this service. Pharmacy contractors began planning what they could do ahead of the release of the service specification. Some argue that early transparency in the design of the service specification would have helped improve implementation – an argument in favour of 'bottom up' policy design. They believed that the only way that this service could be implemented effectively was through a cultural shift in the hearts and minds of contractors. Such a shift would require a lengthy process and therefore early engagement was needed.

However this engagement did not materialise until 11th May 2011, two months after the initial announcement. NHS Employers and the PSNC released an outline specification of the new medicines service at a large stakeholder meeting. Department of Health representatives urged for a structured implementation process in order to achieve the planned -1st October- service delivery date. NHS Employers, on behalf of DH were given the responsibility for service implementation, working with the PSNC (News Team, 2011).

Following the stakeholder meeting, a New Medicines Service Requirements and Development group was convened. Its remit was to confirm the knowledge and skills that pharmacists require to deliver the NMS. The first meeting of this group, on the 1st June, discussed topics such as self-accreditation, outcome measures, training and the interview schedule for this service. Several tensions were exposed when the group began to discuss the delivery of the service. The choice of membership of this group may have contributed to those tensions. NHS Employers acknowledged that they do not necessarily know the best way to deliver any service, and therefore rely on expert groups to develop service specifications.

The first tension was finding a suitable compromise between the professional opportunities of individual pharmacists and the commercial needs of the pharmacy business. The second tension concerned the extent of training and expertise that might be required to deliver the service. The third tension can be described broadly as theoretical differences of opinion

⁴⁸ Pharmacy voice is a group that comprises of the three largest community pharmacy associations. The members of Pharmacy Voice are the Association of Independent Multiple Pharmacies (AIMp), the Company Chemists' Association (CCA) and the National Pharmacy Association (NPA).

in tackling non-adherence. The fourth relates to outcome measures and implementation and the fifth to the funding model. The final tension was the short timescale in which decision had to be made and the service implemented.

Education and Training

Tensions pertained to the service training requirements were exposed early in the discussions. Publically the PSNC had suggested the service would have an accredited training requirement (Chapman, 2011a), but there was no indication what this would entail. There were concerns that a formal assessment of knowledge followed by certification could not be feasibly achieved for 20,000 pharmacists in the time available. After much discussion, a decision was made that pharmacists should be allowed to self-assess their competence, as long as they had already completed MUR accreditation. The Centre for Pharmacy Postgraduate Education⁴⁹ (CPPE) and the regulators of pharmacy championed this focus on outcomes as opposed to tick box criteria. Yet several in the group were uncomfortable with this move to self declaration. They preferred some external assurance of the pharmacists' ability to provide the service⁵⁰.

The role of training coordinators became important because educational materials were developed alongside service negotiations. CPPE given their close links with the DH, were both influential and pivotal in the development of training materials for pharmacists seeking to deliver this service. They had been given a green light to start developing training in early June ahead of a formal service announcement on 16th June at a Stakeholder engagement event at the Ambassadors Hotel in Bloomsbury. They worked as part of the review group to help develop training materials for national dissemination. However, they could only prepare the finer details of training materials once they had received decisions and approvals from NHS Employers and PSNC, often at the last minute.

Pharmacy or Pharmacist

The accreditation process was complicated by a need to separate the responsibilities of individual pharmacists from those of pharmacy contractors. For example it was initially stated that it was the responsibility of the pharmacists to ensure that a consultation room was present, when this is actually the responsibility of the contractor. As a result it took until the end of June for the content of the self-assessment accreditation forms to be

⁴⁹ CPPE are a not-for-profit, Department of Health funded group who provide continuing professional development training materials and support for pharmacists and pharmacy technicians providing NHS services in England

⁵⁰ Indeed, many pharmacists wanted this themselves. The CPPE reported that after the service was launched they received phone calls asking them to formally accredit people to offer the service.

finalised. It was eventually release publically on 2nd August alongside the funding structure (Chapman, 2011c).

Theoretical Approach

Equally contentious was the development of the interview schedule. One of the principles of the service is that it is patient led, allowing patients to raise and discuss issues regarding their new medicines that they feel are important, necessitating a free flowing, semi-structured approach. Pharmacists' traditional responsibilities concern supply, following standard operating procedures, and protocols. As such, an unpredictable free flowing service was perceived by some to be both difficult and a potential threat. Therefore the interview schedule went through several iterations based on both theoretical and academic viewpoints as well as preliminary pilot work, before a degree of consensus was reached in early July. However, the schedule still required ratification by DH, PSNC and NHS Employers.

Outcome measures and Documentation

This group had to determine the records and outcome data that pharmacists would be required to collect. They also had to decide how this should be transferred to primary care organisations. This was an urgent issue because outcome measures required a full impact assessment and secondary legislation. *Liberating the NHS* was in a process of being developed into the Health and Social care bill. Because of this, operational responsibility for community pharmacy was being shifted between primary care employees. This operational turmoil in primary care allowed the service to develop without overbearing opposition from primary care representatives. Several PCT representatives contributed to the stakeholder engagement. However, their offerings were easily side stepped (or as some claim ignored) in the development process. As a result some of those interviewed believe that the incorrect outcome measures were chosen for this service.

The PSNC developed a electronic platform to make the outcome measures operational and to support documentation and recording of this service. This platform was named Pharmabase. The tight budget for this service meant that the content, organisation and structure of this database took time to develop. As a result the system was only implemented as the service was launched.

Timescales

The final impact assessment was finished in early September. The secondary legislation that was required for this service to progress was only signed into law a week on September 22nd, a week before the service started nationally. Many contractors raised concerns about the tight turnaround of the service, which the PSNC blamed on the governments wider NHS reforms (Hunt, 2011).

Funding Model

The funding model was subject to much criticism when it was released. These arrangements were (to a large extent) decided in the negotiations that took place prior to wider stakeholder engagement. Given the previous experience of MURs (Latif et al., 2011b), concern had been expressed that this service may be used by contractors as a purely revenue generating activity. Early negotiations included such concerns by applying a “scum bag” approach to the service development specification to limit the ability of less professionally (more commercially) orientated contractors from producing low quality, poorly delivered services. This necessitated a movement away from a fee-per-service model towards a payment matrix that was intended to make NMS integral to daily practice.

As experienced in MURs, there was concern that this service may encourage employers to exert undue pressure on pharmacists. The introduction of written (as opposed to verbal) patient consent was also introduced to address quality, because it was believed that this would encourage pharmacists to explain the service to patients and would help reduce fraud⁵¹.

Collaboration

Learning from criticisms of MUR feedback, led the PSNC and NHSE to collaborate with the General Practitioners committee of the BMA to publish a standard feedback form for GPs, released jointly in August 2011. This communication to primary care and general practitioners was supported by a series of national road shows and engagement events in September that showcased the service.

It was on the 1st October 2011 that the service was finally implemented into community pharmacy, despite the final service specifications and data recording requirements not being published until November 2011. The importance of this service to pharmacy should not be underestimated, so much so that the Department of Health have funded an evaluation of this service to support future service negotiations.

⁵¹ This intent is reflected in the consent form that was published without piloting.

Purpose of the Service

The eventual NMS implementation was only possible due to the interlinking of multiple streams. Throughout, numerous justifications for this service have been used to rationalize its development. Indeed, the interviewees offered divergent opinions of which were most important. Some argued that the aim was: to assist people with their medicines; to improve adherence; to utilise pharmacists; to reduce waste; to empower patients; to preserve pharmacists' status; and to maintain contractors' income. Whatever the driver, their combined effects led to this service, which has been described as a turning point for the pharmacists.

The purpose of the multiple streams framework was to model the process that led to the implementation of the New Medicine Service. The streams that underpin the development of this service are extracted in figure 4.6 below to provide an overview to the descriptive narrative.

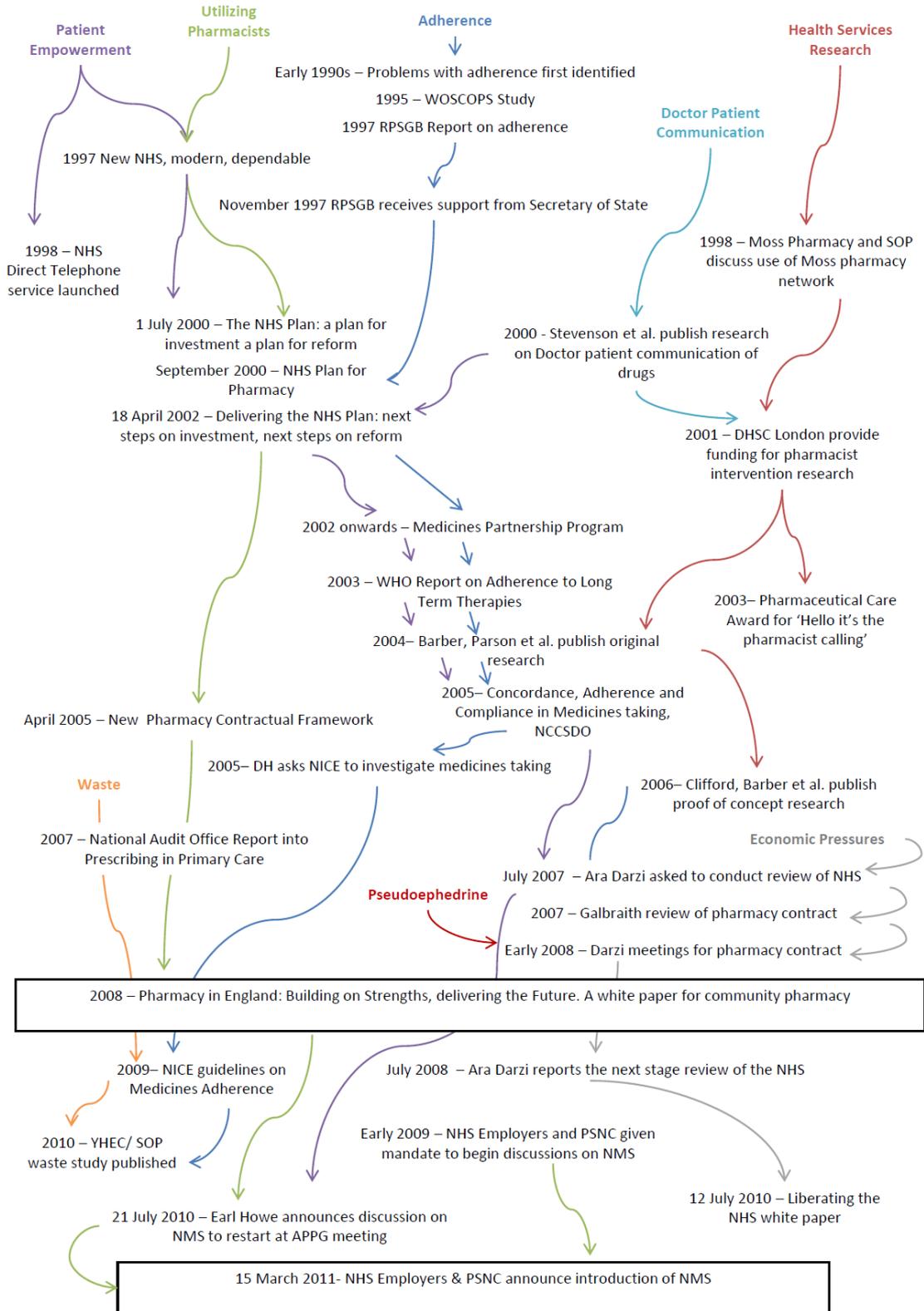
Limitations of the Multiple Stream Model

The multiple stream 'model' has been used extensively across the public policy literature. Models are expressions of the real world and as such contain assumptions and simplifications that make that the subject of denigration. Critics have attacked it for making a number of unrealistic assumptions because as a 'model' it fails to generate enough clear, falsifiable hypotheses. However this case study approach did not begin with an *a priori* hypothesis, instead it aimed to observe the process of policy development. This framework was used for its narrative as opposed to hypothesis generating qualities.

Such criticisms are often aimed at the origin of the model - the 'garbage can approach'. While the criticisms of the 'garbage can model' are valid, in so much that it works on the basis of fortune, it should be remembered that the Kingdon's model takes a different starting point and suggests that the coupling of streams is purposeful performed by policy entrepreneurs, rather than relying on chance.

Some critics legitimately suggest that the 'model' is invalid as the streams are not actually independent. It is argued here that the streams do not have to be independent in reality, but only need but they only need to flow as if they are independent. This is a subtle but important distinction. Therefore accepting that models are a simplification of reality and provide a tool for understanding the complex social world should be acknowledged as both a strength and a limitation.

Figure 4-6– Streams of NMS Implementation



Section Conclusion

This section has demonstrated that implementing a service into community pharmacy is a complex challenge. Political processes, when viewed from a distance, often appear confused and illogical. As such rational models of policy implementation fail to capture the subtleties involved in the development of real world policies. It is only when different streams are coupled together that 'policy windows' of opportunity are created. It is difficult to couple the stream together, but by contrast all too easy for them to come apart.

In this case, political will and political support for a service has been the hardest stream to maintain control over. On more than one occasion the development of the new medicine service was halted due to a lack of political support. This set back the development and implementation of this pharmacy service by several years. In the future pharmacy will need to be far more attuned to politicians if they hope to have further services implemented.

Even after ministerial support had been received internal tensions persisted. The profession failed to reach a consensus on various issues related to the service. The lack of unity and collaboration across the community pharmacy sector acts to hamper future service implementation. The service managed to be delivered on time because of several hard working people who sought to create unity.

Innovations in practice therefore take many years to achieve wide roll out. The origins of the New Medicine Service are in the late nineties, yet the service was not implemented into practice until two decades later. At this pace the research innovations being piloted in community pharmacy at present are unlikely to feature in practice before 2030.

Different groups have used different reasons to justify and explain the development of the NMS. The problem stream of adherence has been the most predominant, although issues of pharmacist 'utilisation', medicines waste and patient empowerment have all featured in the discussions and debates that led to this service being implemented. Such justifications create confusion as to the purpose of the service, but also allow the service to gain wider political support.

The service also had to contend with the challenge that the previous advanced service, MURs, had created. The next section of this chapter considers if any of the problems identified in the implementation of MURs were addressed in the development of NMS policy.

Were Implementation Lessons Learnt?

By the first of October 2011 the policy process had successfully managed to create a new advanced service for community pharmacy. Based on the MUR implementation literature there are seven main areas that need to be addressed in order for implementation to be successful, namely: Work Environment; Financial Drivers; Accreditation and Training; Patient Recruitment; External Support; Documentation; and the Individual Practitioner. The remainder of this chapter uses the policy documentation, news reports and interviews to analyse the implementation of NMS in relation to these seven barriers and discusses whether these challenges persist.

Work Environment and NMS

NMS arrived in October 2011 at the same time as a decrease in category M funding⁵², which further reduced the overall value of the average prescription and further raised the pressure on pharmacy contractors to increase prescription volume to counter a real terms loss in income (Pharmaceutical Services Negotiating Committee, 2011d). Therefore, an increase in additional staff to support the service was unlikely to be financially viable. As a result it is expected that (similar to MURs) time management challenges will continue, and indeed increase, as a barrier to service implementation. However, the NMS service intervention is generally a pre-booked appointment, thus allowing pharmacists the ability to regulate work responsibilities. The initial research that led to the NMS suggested that the median consultation time was about 12 minutes (Clifford et al., 2006), in contrast to the 51 minutes recorded for MURs (Blenkinsopp et al., 2009). By comparison NMS should be comparatively easier to fit into the working day. Also, follow up consultations can be completed by phone, which allows for greater flexibility in terms of timing and location. The lack of consultation rooms that plagued MUR implementation has been addressed as over 90% of community pharmacies in England now have one (The NHS Information Centre, 2011). Initial feedback suggests that these factors assisted in the completion of over ten thousand of NMS interventions in the first month of service roll out compared to only 373 MURs after launch (NHS Prescription Services, 2012).

The challenge of integrating the service into the workflow of the pharmacy persists. A reallocation of work responsibilities that allows the dispensing work to be carried out by non-pharmacists is yet to be resolved. Although legal barriers persist, the service may be

⁵² See Chapter 3.

used as a driver to relinquish pharmacists' control of the dispensary and delegate their responsibilities more effectively to support staff. But this is still to be seen in practice.

Financial Pressures and NMS

Pharmacists are paid a fee per service for MURs, whereas NMS is rewarded according to a payment matrix. The funding arrangements within the matrix are organised relative to a contractor's dispensing volume in banded prescription volumes. A target number of NMS cycles to be completed each month (Pharmaceutical Services Negotiating Committee, 2011a) is assigned based on the prescription volume (Pharmaceutical Services Negotiating Committee, 2011d). Feedback about inappropriate MURs, driven by organisational pressures precipitated this funding design. Negotiators conceded that this was designed specifically to prevent the cherry picking of 'easy' NMS patients at opportune moments. Instead pharmacists would be required to engage with all NMS opportunities, incorporating NMS into their working day.

The target band constantly changes for each contractor as dispensing volumes in the pharmacy fluctuate from month to month. Therefore, contractors may deliver the same number of NMS services in two consecutive months, but receive different levels of payments, or in some cases receive no income. Anecdotal evidence suggests that the unpredictability of the revenue prevented some contractors from offering the service. Instead they concentrated on aspects of the business where there was a greater certainty of economic return, such as dispensing.

However, policy implementation does not cease at service launch. After six months of complaints from contractors (Weinbren, 2012; PSNC News, 2011c), the negotiators produced a revised funding matrix which assured contractors a minimum income per service, but retained the banded matrix design. This was implemented in May 2012.

Extrapolation of the evidence from MURs suggests that NMS implementation is likely to be more prolific in multiples. Independents continue to suffer from a relative lack of time and staff capacity to implement services. Although several pharmacy organisations, including the National Pharmaceutical Association (NPA, 2011) and the Royal Pharmaceutical Society (RPS, 2011) have developed support materials designed specifically to help independents implement the service. The 'McDonaldisation' of service by multiples was raised as a concern in NMS negotiations, with fear that it would become a tick box exercise (Latif et al., 2011c). Therefore the training materials and interview schedule were designed to be open

and free flowing, with an emphasis on communication in the consultation - as opposed to following a rigid protocol (CPPE, 2011) - to try to overcome the weakness of a protocol based approach.

Financial rewards inevitably drive behaviour. The matrix design and the training materials have attempted to create a 'culture' that integrates the service into practice. However, while uncertainty persists contractors are likely to continue to focus on services that offer guaranteed income.

Patient Recruitment in NMS

The initial service design estimated that 0.5% of prescriptions would be eligible for NMS – the reality appears to be far lower⁵³. Therefore, contractors are not being afforded the anticipated opportunities to complete these services meaning they must recruit every eligible patient to meet the funding band requirements. However, patients are required to complete a consent form, which was designed with fraud prevention in mind. Completing an official form that was not properly piloted, instils a sense of formality and bureaucracy to which the service is explicitly designed to avoid. Therefore early indications suggest that the consent form is acting as a barrier to recruitment (Smith, 2011b). Explaining the empowerment and information benefits of the service to patient may improve service recruitment. Despite a national media promotion by the RPS in the early weeks of October 2011, general patient awareness of pharmacy services remains low (Coombs, 2011).

External Support for NMS

As shown in MURs, recruitment can be improved with external support. The service was cautiously welcomed by the Royal College of General Practice (RCGP) with their chair quoted as saying

“Patients do sometimes experience problems with their medicines and, through the New Medicine Service, GPs and pharmacists will work in partnership to ensure those that need support receive it”(PSNC, 2011).

Beyond this, a professional relationships working group, formed from the PSNC, NHS Employers and the General Practitioners Committee (GPC) of the British Medical Association, wrote to local medical (LMC) and pharmaceutical (LPC) committees to

⁵³ The exact proportion of prescriptions is still to be determined, but the national evaluation of the NMS should help to identify the true value of this figure.

encourage and facilitate local conversations about the New Medicine Service, with a focus on the immediate need for communication processes to be set up locally between pharmacists and GPs (PSNC News, 2011b). This working group published a guide for GP practices outlining the changes to the pharmacy contract recognising that service implementation relies on effective communication across primary care. Engagement with GPs was also incorporated into the self-assessment form for contractors in an attempt to improve dialogue. Despite well-intentioned support from the top, anecdotal evidence suggests that this has not been sufficient to drive referrals because GPs lack enough understanding and confidence to endorse NMS (Flynn, 2011). Indeed, during a busy clinic how many GPs will have the NMS in mind when issuing a prescription (De Simoni et al., 2012)? Primary care organisations were found to significantly influence MUR implementation (Ali et al., 2011; Latif and Boardman, 2007; Blenkinsopp et al., 2007a; Ewen et al., 2006). Their wider support is likely to be an important factor in the future commissioning of the service. Yet the current reorganisations in primary healthcare have acted to prevent their engagement with this service. As such its longevity is being brought into question.

Documentation and NMS

Some of the documentation problems observed with MURs have been addressed in NMS. For example, PSNC, NHSE and GPC produced a simplified one-page *NMS feedback form*. This form had active GP involvement and aimed to ensure that communication between GPs and pharmacy was standardised and simplistic. The MUR forms had been criticised for not clearly specifying where GP intervention was required. Therefore it was re-designed so that problems, which requires resolution, could be easily identified by GPs (Pharmaceutical Services Negotiating Committee, 2011c).

However, the biggest documentation development has been the creation of an information technology platform. Learning from MUR documentation, which was found to be time consuming to complete and incompatible with IT (Rosenbloom and Graham, 2008), the PSNC created Pharmabase, a web-based platform to support community pharmacy contractors in the delivery of their services. It provides an electronic storage format for entering and recording NMS interventions. It also produces reports for PCT audit purposes. While the intent is laudable, Pharmabase has been criticised for not integrating with Patient Medication Record (PMR) systems (Smeaton, 2011) and for lacking sufficient usability (Smith, 2011a).

Pharmacy software suppliers believe this could have been prevented if the PSNC had engaged them early. They believe that information was deliberately withheld from them to reduce competition in the market. Yet these suppliers began creating alternative recording systems, which has led to a loss of standardisation across the sector.

Training and Accreditation in NMS

Training coordinators were important in service implementation because they developed the educational materials alongside service negotiations. In doing so they were able to identify problems with the service specifications and feed these back into the discussions. Some believed that this led to a collaborative implementation process.

Negotiators chose a self-accreditation solution, learning that formal accreditation of 12,000 pharmacists created a barrier to service delivery. This approach was also adopted for premises. It allowed contractors to inform local primary care organisations that they proposed to offer the service, as opposed to waiting for an inspection visit. The result has been a rapid accreditation of pharmacies, with about of 70% of pharmacies able to offer NMS after the first month (PSNC News, 2011a).

Pharmacists who were accredited to deliver MURs have sufficient clinical knowledge to provide NMS. Therefore, the CPPE training materials that were sent to every pharmacist in England (regardless of sector of practice) focused mainly on the theoretical framework and evidence base underpinning the service as well as on communication skills. However, facilitating training with in a short timescale from service announcement to implementation proved difficult. Multiples that employ thousands of pharmacists had to begin training in early August prior to the full service specifications being released. Much of the support and training materials were only released a few week prior to launch. This gave contractors little time to prepare.

In contrast to MURs, alternative educational packages such as video training were also provided, but supported peer-to-peer review and simulations of consultations were not, despite these being called for in MUR training (Harding and Wilcock, 2010; Kaulbach et al., 2010).

Individual Pharmacists – NMS

As with other services, there will inevitably be variation between individual practitioners. The thoughts, actions, beliefs and values that drive individual implementation behaviour

have not yet been investigated in the context of NMS. Employment characteristics that influenced MUR delivery are unlikely to be different in NMS. Owners will seek to maintain an economically viable dispensing volume, locums have little desire or motivation to conduct services and salaried pharmacists will experience pressure to deliver services, unless the organisational culture of pharmacy changes (McDonald et al., 2010a).

Section Conclusion

Despite the criticisms of the PSNC, it should be recognised that many of the practical issues associated with MUR implementation were addressed in NMS. For example, documentation provided to GPs had a positive effect on service implementation. However, by not identifying and rectifying implementation problems early on, new problems were created. For example, the funding matrix, which sought to mitigate some of the negative behaviours observed in the implementation of MURs created further implementation problems. This, and the challenges of the timescale, dissuaded some contractors from providing the service.

Whilst it is evident that some lessons have been learnt, the cultural environment that underpins pharmacy continues to persist as a barrier to implementation. Organisational policies motivated by financial returns continue to place pressure on pharmacists' time. The widespread reallocation of responsibilities within pharmacy seems to be the most plausible solution. Changing this culture was something that pharmacy bodies called for prior to NMS implementation. They suggested early engagement as a solution. This was not realised and therefore cultural barriers to change persist.

The complexity of service implementation, evidenced by the two decades that it took for this service to develop (even without significant political opposition) tends to suggest that future services are unlikely to be implemented quickly. The policy commitment to full 'utilisation' of community pharmacy as primary care based clinical professionals seems unlikely to be fulfilled in the short term. Indeed, while funding structures fail to offer stable and predictable alternative income streams, it is unlikely that pharmacists will be able to relinquish their control of the dispensing process.

Chapter Conclusion

It is not solely good evidence that ensures that a 'problem' and its subsequent 'solutions' reach the policy agenda, but a subtle combination of factors. Policy entrepreneurs play an important role in helping to create policy windows of opportunity. This requires the alignment of multiple streams, which is achieved by contextualising the 'problem' and 'policy' and then engaging the required 'political will'. However, even after the streams have been aligned there is no guarantee that they will remain coupled or that the service development will not get smashed by the rocks of implementation.

Medicines Use Reviews suffered from several implementation difficulties. These can be described by seven overarching themes (Work Environment; Financial Drivers; Accreditation and Training; Patient Recruitment; External Support; Documentation; and the Individual Practitioner). Despite lessons being learnt, half a decade after MUR implementation the New Medicines Service (NMS) suffered from similar organisational challenges. It took over two decades to develop the service from initial inception and evidence gathering to full national roll out. Given this pace of change it is unlikely that the utilisation of community pharmacists described in policy (chapter 1) will be achieved in the short term.

While the six contextual factors identified above are important for manipulating the environment, it is ultimately the seventh, individual practitioner motivation that drives local service implementation. Encompassed within this motivation is the organisational culture of the pharmacy, understood as "*the way we do things around here*" which influences role assignment in service delivery. However, organisational culture has been largely ignored in pharmacy practice research (Roberts et al., 2003; Clark and Mount, 2006). Therefore understanding the future professional cultural identity motivating pharmacists forms the basis of the next chapter.

Chapter 5. Stakeholder beliefs on the Future of the Pharmacy

Chapter Introduction

In policy direction terms NHS community pharmacy appears to be going through a transformation which can be characterised as a shifting of its focus from medicines supply to 'clinical' service provision (chapter 1). This change in practice does not have a single clearly described goal, or policy aim. It instead relates to a philosophical approach which is arguably centred around the 'pharmaceutical care' concept (Hepler and Strand, 1990) and the development of 'cognitive pharmaceutical services'. These were defined by Cipolle et al as *"the use of specialised knowledge by pharmacists for the patient or healthcare professionals for the purpose of promoting effective and safe drug therapy"* (Cipolle et al., 1998).

This trend has the potential to fundamentally change the nature of pharmacy practice in England (and other UK nations) and with it community pharmacists' functional roles and professional standing within healthcare. Such policy objectives were implicitly if not explicitly embodied in the 2008 White Paper 'Pharmacy in England: building on strengths - delivering the future' (Department of Health, 2008a). However, this document is only one of many that together can be taken to represent a global policy direction in not only the UK (Community Pharmacy Scotland, 2010; Community Pharmacy Wales, 2011) but many other OECD nations, including not only English speaking nations like New Zealand and Australia but also in European States such as (and arguably most notably) the Netherlands (New Zealand Ministry of Health, 2007; Australian Government & The Pharmacy Guild of Australia, 2010; Bouvy et al., 2011).

Yet the path ahead for community pharmacy is unlikely to be a smooth one, for a variety of reasons. The previous chapter provided evidence indicating that there are seven main factors that influence policy implementation in the community pharmacy context. While the majority of these lie outside the direct control of individual community pharmacists, their collective preferences and linked behaviours inevitably play a key part in determining the rate and nature of practice and service changes. The organisational culture of the pharmacy and the wider professional community – which may be understood as 'the way we do things around here' – is a powerful determinant of not only current roles, but also

their future evolution. However, organisational culture has often been ignored in pharmacy practice research (Roberts et al., 2003; Clark and Mount, 2006). One of the aims of the research reported in this chapter was to contribute to knowledge the shared underlying identity of community pharmacists in England, and evaluate the views of stakeholders in primary care as to the future for community pharmacy within this social context.

From a role theory perspective (see below) the shifting objectives of community pharmacy (and wider health policy) reflect a change process in which both the external identity of pharmacists and the internal 'self' of group members must adapt. During periods of change ambiguity surrounding role identities can logically be expected to increase. New behaviours, skills and attitudes are required to enable actors to address new tasks and abandon redundant activities, and during major role adaptation processes there are almost certain to be conflicts within not only individuals but also between different factions within given communities.

In England the traditional function of community pharmacy as compounders of medicines for 'society' (and in certain instances a direct health care provider) was in the main lost in the first half of the twentieth century (Thum-Bonanno et al., 2012). It was replaced by a finished product supply function. Because this function has been delegated and partially mechanised, a mix of new professional services delivered via community pharmacy, broadly aimed at improving medicines use and 'improving' health related behaviours has risen to take its place. Yet there have been difficulties related to adopting new practices and demonstrating their value (as discussed in appendix C). As such there remain questions as to what the 'true' roles of community pharmacists are now and could and should be in the future. As already indicated, the goal of the observations and analysis provided in this chapter is to cast new light onto pharmacists' and other pharmacy sector stakeholders' beliefs about relevant issues.

Theoretical Framework

The research presented below is based on constructivist theory (and in particular social constructivism) and on role theory. The former in essence postulates that subjects from different social backgrounds have, because of their varying experiences of being, different notions of reality and that knowledge and truth are created, not discovered, via the mental states and processes of observers. Researchers working in this area have focussed a great deal of their effort developing understandings about the ways in which actors and groups

of actors participate, within their overall social context, in the construction of their perceived social reality.

This approach has been applied in the Danish context to the perceptions and future role of community pharmacists (Nørgaard et al., 2001). This work adopted the Social Construction of Technology (SCOT) theory to describe the development of Danish community pharmacists' professional role(s). SCOT theory requires the identification of a 'relevant social group' comprised of people involved in the development of an artefact, which is in this case the pharmacists' (clinical) role in the community setting. Examples of its membership include not only medicine users (patients) and pharmacists themselves but in addition medically qualified prescribers and other stakeholders such as politicians, journalists and consumer advocates. These sub-groups can be distinguished by their diverging interpretations of the role in question.

Over and above this, the classical definition of role theory is that it is centred on '*a triad of concepts: patterned and characteristic social behaviours, parts or identities that are assumed by social participants and scripts or expectations for behaviour that are understood by all and adhered to by the performed*' (Biddle, 1986). Role theory has underpinned a wide range of work on social identities, behaviours and expectations as they influence human interactions. Perceived roles can be taken to be key elements of any social structure because they define social identities. For example, it can be argued that most people hold preconceived ideas about the work and characteristics of secretaries as opposed to, say, plumbers or dentists. It is in this sense that the 'role' of pharmacists is explored below.

Role theory was developed from a theatrical metaphor, in which actors play their parts in social situations and follow relatively precise scripts (expectations). The extent to which such assumptions are realistic and defined in today's circumstances is questionable. However, for the purposes of this research it is accepted that expectations learned through life experiences generate perceived roles, and that these in turn can influence beliefs and attitudes. It is also accepted that changing perceived roles is normally a necessary requirement for behavioural and wider social change.

Broadly speaking role theory based research has in the past created five different perspectives: functional, structural, symbolic interactionist, organisational, and cognitive (Biddle, 1986). Each of these is described briefly below, although it should be noted that

terminological ambiguities may to a degree serve to exaggerate differences and conceal overlapping concepts.

The *functional* perspective presents roles as sets of expectations that given societies in effect place on the individuals within them. Certain behaviours are deemed appropriate for a given 'role' as a result of normative expectations about the function of a given category of person in society. For example, it is appropriate for a doctor to ask personal health questions, but not an electrician. The functionalist conception believes that roles create regular patterns and thus a measure of predictability. Functionalist approaches struggle to account for variability in roles and find it difficult to accommodate the fact that individuals conceive given roles in differing ways. For this reason the functionalist approach has been criticised for its static, relatively rigid, bias.

Research undertaken from a functionalist perspective has attempted to categorise the 'roles' of pharmacists in terms of their being business, clinically or professionally focused (Guirguis and Chewing, 2005). McCormack (1956) took a functionalist stance where discussing problems experienced by pharmacy students who displayed both a business and professional orientation. So did Kronus (1975), who found that regardless of their role orientation, pharmacists were motivated by both service and income values. Using this functionalist stance it was found that key actors in healthcare policy in Denmark had differing expectations for the role of Danish pharmacists (Nørgaard et al., 2001). It was concluded that such differences would limit the development of the profession.

Structural role theory gives cursory attention to the individual. It has been centrally concerned with the social environments and wider contexts in which actors play out their lives, and on social structures and institutions conceived as stable phenomena at any one point in time. In the case of pharmacy today this approach is likely to be of only limited value in casting light on how the profession can best adapt to social change, although it might be of more utility in understanding barriers to change within sections of the pharmacy community.

Symbolic Interactionist perspectives are by contrast more fluid in their approach. They suggest that a role is a conception that is constantly negotiated between individuals operating within determining social contexts. This approach lays emphasis on the creation and re-creation of roles via social interactions and through cognitive processes that are influenced by norms, attitudes and contextual cues. As such it may be of more value in

describing evolutionary role developments, albeit that this approach may be limited by, for instance, a tendency to under-estimate the significance of structural constraints.

Organisational role theory has typically been applied to understanding the social systems that exist in planned, hierarchically structured and task orientated organisations. Within these, formal roles are associated with identified social positions and strong normative expectations. However, individuals may question the values and 'official' demands of the organisations in which they work and also be subject to informal pressures from within the workforce they are part of, or through their membership of other communities that are important in their lives.

Research in this area has shown that individuals are often subjected to 'role conflicts'. In the pharmacy context 'role conflict' (see below) and 'ambiguity' have been found to relate to the professional orientation and expectations of pharmacists as compared to the day-to-day demands placed on them (Guirguis and Chewing, 2005). Mott et al (2004) also used this approach to elucidate the role stressors affecting job satisfaction in pharmacies. More recent work in this area has described how changing aims and expectations can cause 'role strain', and the importance of the strategies that individuals and groups adopt to resolve or at least contain such tensions.

Finally, *cognitive role theory* investigates the connection between personal level expectations and behaviour. Role expectations can be embodied in norms, preferences or beliefs. Research in this area has considered the potentially beneficial effects of role playing and developing anticipatory role expectations in relation to behavioural change. An example of pharmacy practice research conducted in this context was provided by Pendergast and colleagues (1995). They linked perceived role related factors to participation in research.

In addition to the above it is important in relation to the findings reported later in this chapter to define terms such as role confusion, role conflict, role strain, role distance and role embracement. Key points to be made in these contexts include:

- *Role confusion* (or ambiguity) describes a situation where individuals struggle to determine which role to assume. For example, if a student were to attend a celebration at a professor's house, should they assume a student role, showing deference and respect, or a role as a friend, displaying familiarity, equality and reduced social distance?

- *Role conflict* results when tension is encountered between incompatible roles. This has in the past been said to affect women conflicted between their roles as mothers and as employed workers. It might in the context of pharmacy today exist in the case of an individual wishing on the one hand to act as a clinician and recommend a relatively unproven and/or costly treatment, and on the other as medicines manager committed to therapeutic risk and cost minimisation.
- *Role strain* can be used to refer to difficulties experienced in meeting all the obligations of a single role with multiple dimensions. An academic may, for instance, struggle to conduct 'high level' research and at the same time deliver quality undergraduate teaching.
- *Role distance* exists in situations in which an individual attempts to separate or distance themselves from the role they are playing. It may be reflective of an inner conflict between personal values and aspirations and those associated with a given formal role or task, and/or of social situations such as disciplinary interventions in which it is valuable to emphasise the impersonality of an action.

As noted above, role theory has been applied in a variety of setting in pharmacy practice research (Guirguis and Chewing, 2005). Research from the symbolic inter-actionist and functionalist schools has drawn attention to the multiple roles of pharmacists, whereas organisationally oriented research has described instances of role overload, conflict and ambiguity (as discussed in the appendix). The work presented here relates to the future roles that pharmacists might pursue in the NHS, and the extent to which social constructs could help or hinder progress towards enhanced primary health care provision.

Research Objectives

In summary, the brief theoretical analysis above indicates that understanding roles and role change is a complex challenge, not least because although they may be formally delineated by statutory provisions and written job statements, roles are also defined by individual and group beliefs and informal human interactions. They are in part constructed by the social environment within which those who act them exist, and in part serve to form it. Changing 'objective' demands and the introduction of new technologies often serve further to increase such complexities. For example, while the incumbents of an established role may not wish it to change, the users and/or funders of their services may have differing expectations. Such phenomena lead to confusion, conflict and strain.

On the one hand, the functions of community pharmacy and pharmacists are well established. Their collective identity as medicine suppliers and advisors are generally well recognised and their activities are, from a role theory perspective, highly ritualised. A typical patient/pharmacist interaction follows a set 'script' through the application of which a pharmacist identifies a patient, provides information on medications and how to take them, and asks if the medicines recipient has any questions. The patient's 'role' is to respond to the pharmacist, ask clarifying questions and pay (where applicable) for the prescription. Local contextual cues may influence the application of the script, but its content is in the main universal. In some respects it is so ritualised that patients can pre-empt interactional stages with phrases such as "I have had this before". Much of what takes place in such interactions is defined legally, and/or within standard operating procedures or pharmacy regulations.

On the other hand there are significant ambiguities between pharmacy policies and pharmacy practices. Pharmacists are recognised by others or aspire themselves to be 'shopkeepers with degrees', business people, guardians of drug safety, clinicians and/or 'scientists on the high street'. Government policies and wider literature suggest a transition in the pharmacists' role from a product focus to a patient focus (as described in chapter 1), albeit that all but a few per cent of the typical community pharmacy's NHS revenue is derived from dispensing and associated fees (chapter 3). There is much evidence that this uncertain situation is linked to considerable levels of ambiguity and uncertainty concerning the status of community pharmacists and their role as health care professionals. Both internal and external forces are working to change the profession of pharmacy, against an incumbent population of community pharmacists whose current roles and identities are in the main defined by established practice behaviours (chapter 2).

Against this background social groups relevant to the future of community pharmacy include not only pharmacists themselves and their immediate representatives but the reforming political cadre (or informal leadership group) within the profession that has from the 1980s been attempting to introduce an extended role for community pharmacists, along with patients and consumer representatives, general medical practitioners and non-pharmacy political actors. Each has a perception about the role that community pharmacy practitioners should perform in health care.

The research reported in this chapter was designed to generate qualitative insights into both the current perceptions and future vision for the pharmacists' role that these actors

have. It was intended to promote understanding of not only conflicts and the problems facing community pharmacy as it seeks to adapt the business and professional practice models of the period 1950-2000 to meet the demands of the 21st century environment, but also of the opportunities and areas of agreement that may provide bridgeheads to change.

Methodology

A semi-structured interview guide was developed and employed as a research tool to facilitate increased understanding of the culture and beliefs underpinning community pharmacy practice, and the likely success of the current service focused strategy. Flexibly conducted semi-formal interviews permit, using a core set of open-ended questions as a basic template, the exploration of perceptions, meanings, attitudes and past experiences and allow people to offer their constructions of reality in a ways which other methods, such as structured questionnaires, are not able to emulate (Pope and Mays, 2006; Kvale, 1996).

A key aim of such interviews is to reveal and support the evaluation of new concepts and ideas proposed by the interviewees: interviewers must therefore be open-minded to the views expressed (Patton, 2002). To allow sufficient discourse flexibility, not all the questions can be predefined before the interviewing commences, and question order and style should be adjusted to reflect the direction that an interview takes (Silverman, 2010).

In this case the interviews were directed by a generic guide that covered some predefined areas based around the themes developed through the policy literature review (chapter 1) and earlier work that had investigated student perceptions of community pharmacy (Davies and Taylor, 2010b). This acted as a framework that allowed the interviewees to develop the conversation in a direction that they felt appropriate. As and when it was judged desirable questions were adapted to fit the expertise base of respondents. In addition the order of the questions asked was changed to meet circumstantial requirements and in some cases questions were omitted, due to the nature of the initial responses given by certain respondents. As the research project itself progressed interviews were also varied to accommodate the responses of previous interviewees. This allowed emergent issues and themes to be pursued in greater depth than would otherwise have been possible.

All the interviews opened with a general question about the role that community pharmacist's play. This was used to help establish interviewees' beliefs and attitudes prior to confirmatory interrogation and subsequent questions that explored their views and

feelings in the context of the aims and barriers to and facilitators of future pharmacy practice developments.

Seventeen purposively selected leaders of both the pharmacy and general practice communities were interviewed between November 2010 and February 2011 (see sampling strategy below). The interviews were normally conducted face-to-face and in a variety of locations, but most often in the interviewee's office. In two cases the interviews were performed in public places. It was anticipated that all interviews would have been completed by early January, but due to the weather being particularly bad during December 2010, a number of the interviews were postponed or conducted via the telephone. This last tended to limit discussions and did not permit observations of emotional expression via, for instance, body language.

The recorded interviews lasted between 30 and 65 minutes, with the average being 42 minutes. In most cases the interviewee had allocated 60 minutes for discussion with the researcher, and therefore when possible further data was captured manually before and after the digital recorder was turned off. When appropriate these notes were also included in the analysis. During these interviews the interviewees were asked to express their personal views, rather than speaking on behalf of the groups that they represented. However, it appeared that the positions of respondents as group representatives tended to influence responses.

In addition to a study explanation sheet all participants were given a preliminary introduction to the research before the interviews began. When face-to-face meetings took place the participants were asked to complete a consent form. In the case of telephone interviews verbal consent was given. All the interviews were digitally recorded with the interviewees' consent, either written or verbal. One interviewee asked for the recorder to be turned off at one point to discuss some personal information, but it was subsequently restarted. During all interviews written notes were also made, in part to help guide discussion and also to help capture important phrases and ideas in case of recorder failure. No recording failures in fact occurred.

After each interview the recording was checked and the process of the interview was reviewed to enable changes to be made in future interviews. With the exception of three interviews, these recordings were sent to a professional transcriptionist to be transcribed in a specified format. Three interviews were personally transcribed for various reasons.

Two were due to background noise, which the professional transcriptionist found to be excessive, and the third was because the interviewee specifically requested a section be removed that contained potentially sensitive information. All transcriptions were verified and in some cases this was done on two or three occasions as part of the familiarisation process.

Sampling Strategy

The sampling methodology used in this case was purposive. Building on the principles of the SCOT theory described above, the techniques of 'follow-the-actors' and 'snowballing' were used to identify additional interviewees. In accordance with 'snowballing' methodology, all interviewees were asked to provide names of other potential actors. The sampling continued until saturation: that is, until no new themes emerged in new interviews.

Interviewees were selected on the basis of their identification by other actors, their acknowledged influence and familiarity with the development of English community pharmacy and relevant policy issues and processes, as well as their observed standing in the primary healthcare domain. The sample included pharmacists and general medical practitioners, patient group representatives and individuals from the Department of Health and allied agencies. Overall, six of the respondents were pharmacists and or employees of pharmacy bodies, five worked within the Department of Health or in the wider public sector, four were general practitioners and two represented patient views. A brief summary of their roles is described in table 5.1 below. However, only limited detail is given in order to preserve anonymity.

In many cases, due to the variety of 'roles' that these stakeholders performed, there was overlap between categories. For example one pharmacist was also a representative of a patient advocacy group. Likewise one general practitioner was still involved in direct care provision but also served in a national policy related role. These overlaps helped to promote the exploration of emergent themes through different lenses. As shown in table 5.1 PH is used to denote pharmacists, DH represents Department of Health or public body representatives, GP denotes General Practitioners and PT indicates a patient representative. Although several of the interviewees could have been included in more than one group, only the role taking most of their time was used in the descriptor. The number that follows them serves as a personal identifier.

Table 5.1 – Brief overview of Participants’ Roles.

Identification Number	Role
DH1	Department of Health pharmacy official
PH1	Pharmacy body representative
PH2	Pharmacy body representative
PH3	Pharmacy body representative
DH2	Department of Health pharmacy official
DH3	Department of Health primary care policy
DH4	Senior manager of a public sector body with health responsibilities
PH4	Pharmacist primary care adviser working in general practice
GP1	GP and Department of Health role holder
GP2	Professor of general practice with primary care interests
GP3	Professor of general practice with primary care interests
GP4	General medical practitioner body representative
PH5	Pharmacy body representative
PT1	Patient group representative
PT2	Pharmacist working with a patient group
GP5	General medical practitioner body representative
PH6	Pharmacy body representative

Data Analysis

In much qualitative research the data analysis begins during its collection to allow early and emergent findings to help shape ongoing data collection. This study incorporated such an approach. The data was constantly analysed through a process of deduction and induction to search for apparent regularities and anomalies. Given the author’s identity as both the data collector and analyser it was impossible to separate these two processes and therefore data analysis and collection existed simultaneously. The identification of emergent themes was also in part guided by the previous literature review.

The use of interim analysis (Miles and Huberman, 1994) has the advantage of allowing emerging avenues of inquiry to be explored in greater depth than would otherwise have been the case, and for questions to be refined and hypotheses to be developed and tested.

It may be useful to note that the underlying approach adopted in the research presented here is based on a rejection of the so-called ‘realist’ view that qualitative research simply ‘gives voice’ to the views of the responding participants. Rather, it is assumed that giving voice, even at the most basic level, inevitably involves identifying and crafting ‘pieces of evidence’ which are then edited and deployed in order to project a coherent argument and to generate hypotheses which can only be verified via subsequent quantitative analysis. What is arguably most important in the qualitative research context is that the methods

used and the theoretical frameworks employed are both consistent with the questions being asked. This decision process necessitates that value decisions and associated elements of prior knowledge are added to the observed data. It is argued here that this is an appropriate research approach which adds to the meaning of data gathered, provided that it is clearly documented and acknowledged. This explains why in the results section below references are made to literature search based findings, alongside the original observations reported.

Approaches to analysing interviews

Following on from the above, for the sake of linearity data management and data analysis are normally identified as separate, distinct 'items' in theses such as this. But in reality they are not normally neatly sequential in nature. There is rather an iterative process between the stages of data management, description and explanation (Ritchie and Spencer, 1994). The choice of method of analysis of qualitative data lies on a continuum from inductive to deductive analysis (Pope and Mays, 2006). Inductive analysis, also known as 'coding up', identifies themes from the data. Deductive analysis, also known as 'coding down', draws from predefined or anticipated themes identified in the published literature or from elsewhere to structure the analysis. In combination both approaches allow new ideas, theories and hypothesis to be formed, as themes are formed from the research findings.

Methods of qualitative analysis are described in table 5.2 below. They can broadly be categorised into two different types. The first is tied to a particular method or theoretical position. Illustrations include conversational analysis (CA) or interpretative phenomenological analysis (IPA). Grounded theory and discourse (DA) or narrative analysis also lie within this camp. They are all methods which can be said to sit within a broad theoretical framework.

The second methodological type includes approaches which are essentially independent of theory or epistemology. Therefore they can be applied across a range of theoretical positions. Framework analysis and thematic analysis are located within this second group.

Table 5.2 – Methods of Qualitative Analysis

	Description	Suitability for this study
Content Analysis	A review of documents, newspapers, reports or narratives. Occurrences of words or themes are counted and subjected to statistical analysis.	This approach requires an a priori knowledge. However, this study began with as few preconceptions as possible and requires a deeper level of analysis of views and beliefs.
Discourse Analysis	This refers to a number of approaches to analysing speech series, propositions or sentences (discourses).	These approaches emphasise different aspects of language use, by viewing language as a social interaction, and are concerned with the social contexts in which discourse is embedded. This is not the central aim of this study.
Conversational Analysis	This technique is a distinct form of discourse analysis and seeks to uncover and explain the structure of communication in natural dialogue. It explores naturally occurring language use to examine the way questions, answers and statements are made in social interactions.	This is a method predominantly used by cognitive psychologists for detailed interactional analysis, which is again not the central aim of this research.
Narrative Analysis	This method focuses on the ways in which people make and use stories to interpret the world. It is not concerned with the specific stories per se, but with the social products that they help to generate.	The aim of this research is not to investigate the way people describe the social world, but the beliefs about future pharmacy practice.
Interpretative Phenomenological Analysis (IPA)	This method was developed within psychology. It is concerned with individuals' perceptions of events and experiences (hence the term phenomenological) and acknowledges the researchers' role in making sense of those experiences (interpretative).	This study does not seek to offer an interpretation or perception of particular experiences, but rather an in depth analysis of stakeholders beliefs' across a general sphere.
Grounded Theory	This aims to generate, develop and verify theory from the data gathered. Grounded theory is an inductive thematic analysis where the data emerges from the analysis and is described as a cyclical process involving the continuous analysis of the raw data in light of the themes generated by constant comparison. Although it may, due to its inductive nature, be described as the 'purest' qualitative research method, it is time consuming and challenging to perform. It may also fail to take adequately into account existing knowledge in complex and/or already relatively well researched areas.	The primary aim of this study was to describe the views and opinions of stakeholders in the light of a wide range of pre-existing knowledge sources, as opposed to generating new specific theory.
Framework Analysis	Developed for the purposes of applied policy research. Although grounded in the original data it is best suited to addressing specific research questions via repeated systematic analyses that allow comparison between and within cases.	This method requires a priori ideas that can be used to form the thematic framework. The present study sought to takes a more grounded approach, while also drawing on a priori knowledge.
Thematic Analysis	This is a relatively weakly demarcated method, which is widely used in qualitative analytic work to identify, analyse and report patterns within data. Typically, themes that are judged important to broad research questions are pulled from the original data and then considered and re-considered in the light of both the immediate research observations and other relevant knowledge sources.	Although some commentators argue that this is not strictly an analytical method in its own right, it offers an accessible form of inquiry that was considered appropriate for use in the context of this study.

In the field of pharmacy practice research the three most commonly used approaches are thematic content analysis; grounded theory and framework methodology. They share a common initial stage of reading and re-reading interview based data to achieve familiarity

with it, which is often called immersal in the data. This allows for the identification of and assigning of codes to key and associate themes, using exerts from the data/transcripts. It is beyond that point that the differences between these approaches become apparent.

Thematic Analysis

Thematic analysis was chosen for this data set because it allows both inductive and deductive reasoning. Thematic analysis involves qualitative research data being categorised into themes by reviewing the transcripts and identifying, comparing and coding recurrent sets of linked concepts. By using the thematic content approach, interview records are distilled into a list of common themes that express the communality of views across the interviewees. The reported themes should be grouped in such a way as to reflect the text as a whole. Although interpretation is required to sort and name the themes, deep interpretation is reserved for the discussion of the data. This method is widely used. There is a lack of agreement across the academic community about precisely what it involves and how best it should be undertaken. Nevertheless, table 5.3 seeks to provide an outline of thematic analysis described in structured linear process terms.

Table 5.3 – Process of Thematic Analysis

Phase	Description of the process
1. Data Familiarisation	Transcribing data, reading and re-reading the data, noting down initial ideas.
2. Generating initial codes:	Coding interesting features of the data in a systematic fashion across the entire data set, collating data relevant to each code.
3. Searching for themes:	Collating codes into potential themes, gathering all data relevant to each potential theme.
4. Reviewing themes:	Checking in the themes work in relation to the coded extracts (Level 1) and the entire data set (Level 2), generating a thematic 'map' of the analysis.
5. Defining and naming themes:	Ongoing analysis to refine the specifics of each theme, and the overall story the analysis tells; generating clear definitions and names for each theme.
6. Producing the report:	The final opportunity for analysis. Selection of vivid, compelling extract examples, final analysis of selected extracts, relating back of the analysis to the research question and the available literature, and producing a scholarly and well reasoned report of the overall analysis.

Stage 1 – Data Familiarisation

During this study the initial familiarisation stage was achieved in the first instance via the interviewing process itself, followed by the transcription of some of the interviews and the verification of the accuracy of the audio file transcriptions. These were read and initial ideas and thoughts were noted.

Stage 2 – Generating Initial codes

All interviews were listened to again to allow full immersion in the data and an extended list of initial ideas was developed. All of the transcripts were then read through in a hard copy format and important quotes were highlighted in the text to allow a preliminary list of codes to be drawn up. This was an iterative process that involved a series of refinements based on intuition, logical conceptualisation, understanding and prioritisation.

The complete data set was then systematically analysed. Each of the interviews undertaken was organised into different codes. In some cases statements were given more than one code. The data extracts relating to each code were then mapped manually into different files using the cut and paste function in Microsoft Word. Where relevant a little of the surrounding data was copied in order to maintain the context of the data.

Stage 3 – Searching for themes

The long lists of codes were re-focused into broader level themes. It quickly became apparent that some of the codes naturally grouped themselves under similar overarching ideas. These were grouped together and placed under a preliminary thematic framework. During this process it became clear that several subthemes would need to be added to the framework. In some cases, several of the codes were combined. The full set of themes was drafted into a preliminary mind map that described all of the codes. While the representation here shows a clear linear structure, the reality of the process involved the movement of numerous post-it notes over a large table. During this process some aspects of the data gathered attracted increased attention. They tended to be linked to contrasts and conflicts of belief and attitude between different interviewees.

Stage 4 – Reviewing the themes

At this stage the current thematic structure and the coded data was discussed with this project's primary supervisor (DGT)⁵⁴. It became apparent during this phase that some candidate themes did not qualify as free standing categories (e.g. because there was not enough data to support them, or it was too disparate) and that in other cases two or more themes could be collapsed into one. The proposed final categories were then re-evaluated in relation to their coherence and meaningfulness.

Once again, problematic candidate themes were either reworked into already existing themes, made into new themes or discarded. This lengthy process went through several

⁵⁴ Professor David Taylor

iterations. The process of re-reading the whole data set and reshaping the thematic structure was only ended when satisfaction that the resultant integrated thematic framework accurately represented the data and communicated its overall 'story' was reached.

Phase 5 – Defining and renaming themes

The finally identified themes were then re-organised into a satisfactory thematic map and the essence of each of themes was defined. A detailed account of each theme was written, showing how it fits within the overall narrative of the data set. At this stage interactions between the themes were considered, as was the existence of valid subthemes (themes within themes). By the end of this phase the themes were clearly articulated and defined, and the titles of the themes had been changed to reflect their meaning.

Phase 6 – Reporting the Findings

The final stage of the process described above involved reporting the main themes accompanied by relevant detail from within the data, together with other evidence as and when relevant. For the purposes of this thesis only the most relevant quotations have been included, followed by their coding notations (table 5.1).

Ethical considerations

This study was granted ethical approval in 2010 by the then School of Pharmacy, University of London, ethics committee. All participants were sent electronically an explanation of the purpose and method of the study as well as their rights and requested contributions. Where interviews took place in a face-to-face basis survey participants were in addition provided with a hard copy of this information sheet, the contents of which was also re-iterated verbally at all relevant points. Informed consent was gained from all participants, and recorded either via signing or verbally for the digital recording of the interviews. Participants were assured that their anonymity would be protected and that no directly identifiable quotations would be used. Participants were not offered any honorarium and it was emphasised that they were all free to leave the study at any time. All the interviews were conducted at a mutually agreed location and time, often out of normal working hours to fit in with schedules of those involved.

Validity and Reliability

Validity and reliability in qualitative research is a suitable topic for a thesis in its own right. Some social science researchers reject the concept of validity in qualitative research. However, a perhaps more realist approach would be to accept that there are measures that can be taken to reduce the risk and enhance the quality and credibility of the findings.

Mays and Pope (1995) discuss how poor qualitative research is anecdotal, unreflective, descriptive and does not follow a coherent line of inquiry. To overcome this criticism this work has used several methods to help ensure the integrity of the data and to manage the inductive leaps made from the data collected.

Methodological considerations were explored from a variety of angles to ensure that the interviews were valid and reliable for information gathering purposes. Questions were first piloted with a number of politically active pharmacy students to ensure that they were clear and appropriately understood. Their open nature was intended to allow respondents to raise issues that they personally believed are important. Digital recording of interviews enabled them to be reviewed and verified. Consistency was assessed by a third party (Professor David Taylor) who acted as an auditor for the coding for the first few transcripts, which, as described above, were re-coded several times and between the cycles.

Demonstrating validity is a challenge, not least because it is not normally possible to apply statistical testing methods directly to qualitative research findings. However, other methods can be used. For example, third party audit can counteract interpretational bias, and help ensure consistency in coding and conclusions. Reliability was also improved through triangulation of the results with published literature and time points. Analytic process transparency should enable readers to trace explanations and conclusions through the way the data is recorded, referenced and charted. The inclusion of quotations within the results helps to demonstrate where induction was made from the interviewees' responses. The combination of these processes provides a governance structure that helps to limit unsubstantiated inductive leaps from the data collected, albeit that in the final analysis all qualitative research findings may be thought to require quantitative validation before being translated into actions that might affect human wellbeing.

Results

Organisation of the data

The data below is organised into four central themes (Table 5.4). They suggest that respondents believed that community pharmacy will need to move in the direction indicated in recent policy (see chapter 1). That is towards providing more cognitive services that utilise pharmacist's skills in order to contribute actively to improved health outcomes, while maintaining a safe and cost containing medicines supply. Although some respondents appeared to believe that promoting development in this direction will prove relatively straightforward, there was amongst others significant evidence of ambiguity and uncertainty about how such progress will be achieved in practice.

Table 5.4 – Central Themes

Theme	Summary Statement
Professional Identity	Pharmacists have a conflicted professional identity. They currently tend to operate as a risk averse, rule based, professional group, in contrast to expectations of their perceived future roles as clinicians who may be required to accept higher levels of risk and ambiguity.
Status and value	The contribution that pharmacists make to healthcare was felt by themselves and others to be under-recognised. This was perceived to act as a barrier to pharmacists changing and developing new contributions. At the same time their skills are commonly seen as under-utilised, even though they may also be constantly busy. This may be taken to imply that the supply role they play is not valued, and may not be thought to justify the status to which they aspire.
Business Imperative	The business imperative of community pharmacy is a vital aspect of its identity. It is reflected in the fact that pharmacists are overtly involved in cash transactions with service users. The recorded responses suggested that the 'business' image of pharmacy is something that pharmacists seek to preserve despite fears that it undermines their perceived standing as altruistically motivated health care/clinical professionals.
Technology development	Developments in information, dispensing and other technologies are seen as inevitably driving forward changes in the organisation of the community pharmacy business and as threatening to current pharmacy practice in the supply context. But they may also open the way to new clinical care provision opportunities.

The past, present and future identity of community pharmacists

One of the most striking themes derived from the interviews was the ambiguity of community pharmacists' identity in healthcare. The core contribution of the pharmacist as described by the majority of interviewees relates to safe medicine supply, which some respondents implicitly linked back to the profession's past medicines making role. The centrality of the safe supply of medicines to community pharmacy was regarded as valuable, although it is not without negative connotations.

I think as far as patients are concerned, the primary thing they expect from pharmacy is an efficient dispensing service, so it's a supply function. [PH1]

In a way, I'm saying if supply is the future, there is no future. [PH2]

Medicines supply is at the core of the pharmacist's traditional role. In his seminal study entitled 'Reprofessionalization in Pharmacy' Birenbaum (1982) argued that compounding was pharmacy's specialist area of knowledge and skill, and that it was lost as a result of the development of the modern pharmaceutical industry. Respondents to this study did not spontaneously mention this early nineteenth loss of core function (they talked rather of pharmacy taking on an extended set of functions in the modern setting) although an awareness of it may in part underlie comments made to the effect that pharmacists are 'under-utilised'.

I have long believed that community pharmacy is an under-utilised source of patient care David Colin Thome (Department of Health, 2008a: p21).

The latter can be taken to be indicative of an acceptance that greater contributions could and should be expected, and/or that the current role of pharmacists as suppliers of medicines is not in itself enough to justify the costs of the pharmacy system. Reflecting such observations, Waterfield (2010) also argued that pharmacy is an 'under-utilised' knowledge based profession. Yet he also maintained that community pharmacists have a potential ability to make a '*massive impact on society*'. The responses of some interviewees endorsed this perspective. But others said that the future of NHS community pharmacy is threatened by the activities of other groups, such as nurses, that are encroaching upon its perceived professional boundaries, as well as by developments in dispensing and other technologies (Edmunds and Calnan, 2001a). This can be regarded as indicative of high levels of role insecurity, and perhaps also of role conflict.

In this last context the medicines at the heart of the profession's expertise were also described in both positive and negative terms. On the one hand they were said to be a source of improved health and longevity. Seen from this standpoint their consumption is inherently desirable. On the other hand their perceived effectiveness was also associated with unwanted hazards: medicines are in this respect often regarded as a source of risk that needs to be minimised. Pharmacist interviewees tended to see risk management in terms of restricting medicines supply and to argue that they (pharmacists) are the only people who have a sufficient knowledge and motivation to balance the risk/burden of harm associated with medicines use against its possible benefits.

We have got something, something about our roles that the managers of medicines recognise, whether that is the procurement of them, the supply of them, the sourcing of them, making sure they are safe. Making sure that somebody who has been prescribed five to 10 medicines takes them, or that they are not being wasted,

or that when they are being administered in environments where there isn't a expert, that they are supported in doing so. [PH6]

Such responses imply a conflict with the simple goal of optimising convenient access to medicines. A more complicated concept of facilitating the appropriate use of medicines was suggested, through a focus on safety, process control, risk avoidance, prescription checking and cost control. This research suggests a picture of pharmacists as (public health related) rule enforcers rather than rule makers or flexible (clinician) rule interpreters. To the extent that this is a valid observation, the primary role of pharmacists may encourage them to become, and be regarded by others as, inherently risk averse (Rosenthal and Tsuyuki, 2010). Respondents' comments to the effect that pharmacists are 'ideally placed' to reduce waste, increase adherence and improve prescribing may be also linked to the social positioning of modern pharmacists as a group that seeks to police the risks taken by medical prescribers and the behaviour of medicines users.

Pharmacists' professional socialisation plays a part in inculcating such views. Pharmacy students are taught to be 'scientists' in the sense of being careful observers and actors who behave in an orderly and verifiably systematic manner. The 2008 pharmacy White Paper talked of the 'science of pharmacy' (Department of Health, 2008a). There is research indicating that the public tend to believe pharmacists have high academic ability but relatively limited social skills (Hean et al., 2006). At the extreme this can be linked to the stereotype of 'a scientist' as a socially inept workaholic (Losh, 2010). Rosenthal and Tsuyuki (2010) characterised the personality traits of pharmacists, at least as they are reflected in their approach to patient care, as encompassing a lack of confidence; fear of new responsibility; paralysis in the face of ambiguity; a need for approval; and risk aversion.

While the 'feminisation' of the profession may have served to counteract part of the science stereotype (Seston and Hassell, 2009b), some sources still appear to promulgate this view of the profession. Indeed, it can be argued that the pharmacists' main knowledge base rests on precise and systematic scientific observations made in areas such as pharmaceutical chemistry, rather than hypothesis generation or broad interpretational skills. At the same time activities such as dispensing require caution and a focus on avoiding mistakes (Harding, 2007), which may in turn promote or favour mindsets that are relatively rigid and oriented towards imposing an order based on set rules and procedures (Rosenthal and Tsuyuki, 2010).

As respondents in all groups suggested, this 'safety net' has a utility for prescribers and medicine takers alike. However, it appears that many pharmacists are consequently reluctant to depart from or extend their oversight role in the supply of medicines in the direction of becoming autonomous clinical practitioners who are supported by rules as opposed to being bound by them. This is in part reflected in attitudes towards the management of the dispensing process:

I think that pharmacist involvement is still essential for clinical checking, to make sure a prescription is safe and appropriate. [PH5]

Although Birenbaum (1982) assumed the traditional compounder role was no longer valuable, other pharmacy commentators and entrepreneurs have suggested the benefits of pharmacists formulating bespoke medicines to meet an individual's request. This idea is receiving a renaissance in Australia, USA and elsewhere, where increasing numbers of pharmacies are offering patients opportunities to purchase medicines compounded to their individual requirements. The desirability or otherwise of such developments is not explored here. But it is of note that some respondents suggested that patients will in future require a greater level of personalisation of their drug therapy as pharmacogenetics evolves and that 'only pharmacists' are/will be skilled enough to provide such a service.

If you think about medicines optimisation, as was spelt out loud and clear in the coalition government's White Paper, then pharmacy is well positioned to optimise medicines and that I would have thought would be in accordance to someone's genetic make-up as much as anything else [DH2].

Such comments indicate that NHS and/or other policy makers may in future seek to encourage pharmacists to play a greater role in diagnostic and allied processes. There is a logical case in favour of this. But the observations provided here raise questions as to the capacity of existing role based pharmacy identities to accept such an adaptation. That is, there are substantive barriers to change located within the roles played within pharmacy itself.

The research reported here has highlighted potential conflicts between the supplier of medicines role (which might naturally focused on volume maximisation) and the controller role (focused on risk and cost minimisation). Such tensions resonated throughout many of the views expressed. The situation of other health care professionals differs significantly. Doctors' responses, for example, implied their own uni-dimensional and un-conflicted role that relates to the maximisation of the health of their patients and the populations they

serve. Put at its simplest, it is always appropriate to 'sell more health', whereas it is not always right to 'sell more medicines.' This links to the conflict between business and professional identity issues discussed below.

Moving on from this, community pharmacies and pharmacists have always been directly involved in the support of self care and advising on, as well as supplying, treatments for common illnesses, defined in terms of minor and self limiting acute conditions (Dingwall and Wilson, 1995). By contrast, taking responsibility for making 'serious' diagnoses and disease treatment decisions (a category which has traditionally included the routine management of long term conditions and/or risk states) has been, and still normally is, perceived to involve levels of risk taking that lie outside the pharmacist's role boundaries. Therefore responsibility must be transferred to general or even specialist medical practice.

Limited though the current minor illness role may be in autonomy terms and current practice, it is of considerable importance to many pharmacists:

If you're looking at minor ailments then, I think minor ailments are so bread-and-butter for community pharmacy that they are in a very natural position.[PH1]

You're talking about just dispensing and supply, then you've got enough trained people to be able to dispense. But if you're talking about actually counter sales and actually prescribing over the counter, then you need a pharmacist. That's what our skill is.[PH4]

Interviewees raised a number of issues relating to the extent to which in future community pharmacists could play an extended 'public health' role, which will involve them accepting increased responsibilities relating to the provision of long term drug therapies as forms of primary, secondary and tertiary prevention. Depending on the therapeutic and service user support approach taken, one possible interpretation of such a 'pharmaceutical public health' role is that it represents an extension of 'healthy living' and 'compliant medicines use' rule enforcement, rather than a significant change in occupation outlook. As such, progress in this direction will not necessarily conflict with a 'risk minimisation' oriented pharmacist mindset.

Advocates of an extended community pharmacy role suggest that the profession should become more centrally involved in caring for and advising people with both acute and part stable chronic conditions. Others believe that pharmacists do not have the necessary diagnostic and clinical skills to manage such conditions appropriately (Richardson and Pollock, 2010), albeit that to date the development of minor ailment treatment schemes

suggests that pharmaceutical care can be cost effective and may in appropriate circumstances be preferred by patients (Baqir et al., 2010a; Baqir et al., 2011; Baqir et al., 2010b).

Some respondents to this survey were relatively cautious as to the extent to which community pharmacists' clinical role extensions will prove possible and desirable:

If you're expecting people to come along and say 'I've got this rash what do you recommend', the more clinical side of things, then you would need somebody with more clinical training. [DH4]

Embracing wider pharmaceutical care roles implies a greater level of uncertainty in practice. The qualitative observations offered here indicate that policies that encourage pharmacists to accept increased levels of clinical risk may often be interpreted as threatening to their fundamental identity and professional domain, as it is currently understood. This implies that if change is judged desirable it is likely to take time, and will require new approaches to pharmacy education. With regard to the latter, respondents implied that it presently succeeds in establishing a core set of knowledge but does not provide the over-arching competencies required for future role development, either individually or collectively.

The bottom line conclusion drawn here is that although most community pharmacists may feel comfortable treating patients within the limited constraints of the traditional 'symptomatic relief of minor acute illness' model, they are not commonly seen by themselves or other stakeholders as being ready to embrace clinical situations that involve higher levels of risk and uncertainty. Effectively presented role change proposals will need to build on this present reality, rather than ignoring it or attempting to bypass it.

The future status and perceived value of pharmacy as a profession

Pharmacists have historically enjoyed the privilege of professional status (Anderson, 2007). Those interviewed articulated being loyal and proud of their profession and of their personal status as regulated professionals. The pharmacist contributors to this research appeared to believe that only registered professionals can safely carry out or manage the medicines supply function. They expressed a sense of possessing a 'special knowledge' of medicines at the fundamental level that they believe is of value and that no other actor in health care possesses.

Over a decade ago Harding and Taylor found that extemporaneous dispensing represents ‘a potent symbol of the pharmacist’s status and value to the community’ (Harding and Taylor, 1999). Although in practical reality terms little extemporaneous dispensing takes place in countries such as the UK, the profession’s sense of its unique value seems to live on in relation to its members’ shared belief in their special knowledge of medicines. Arguably knowledge asymmetries between service providers and users lie at the heart of traditional professionalism. Through the latter the practitioners of certain trades gain financial and other privileges, including a degree of protection from competition, in return for a collective commitment to consumer protection and ‘altruistic’ standards of behaviour (see chapter 1).

However, respondents’ of all types also acknowledged that evidence indicative of the practically relevant, cost effective, use of community pharmacists’ pharmaceutical knowledge to improve health outcomes is at best limited. This lack of role verification, and the incursion of other professions into the ‘drug’ knowledge domain, is potentially threatening to community pharmacists’ and their perceptions of their role defined identity. Pharmacist respondents argued and appeared to sincerely believe that they have an essential role in the supply function that is important for protecting the public’s health. Yet other interviewees believed the supply process normally involves little more than ‘handing out packets’ of medicines. This represents a significant vulnerability:

If it were simply a matter of dispensing and handing out routine advice that was available from the packet, even for the prescription medicines, then you probably don’t [need a pharmacist in a pharmacy. [DH4]

Some argue that the ‘mystery’ that once surrounded the compounding of medicines and mixing of potions has merely been replaced by the de-mystified functionality of pill counting and bottle labelling (Hornosty, 1990). Yet at the same time pharmacist interviewees clearly thought that the profession and its members are often treated unfairly by other health care practitioners and misunderstood by policy makers. This is consistent with other research derived reports. There is robust evidence that pharmacists widely perceive that they are not treated as full professionals and are viewed by some as ‘non-professionals’ (Hassell et al., 1999; Hassell et al., 1998).

Pharmacists taking part in this research said that their professional role and value is not respected as much as it should be, with several describing themselves as an ‘underused’ resource:

I would argue community pharmacy has already been incredibly efficient and gained efficiency savings for the last 15-20 years. We haven't got a lot left to squeeze. I think that's not a point that is well understood by the policy makers. [PH1]

This sense of injustice is likely to be the result of a variety of factors. In addition to questions relating to the possible under- or over- estimation of the safety related and allied value of community pharmacists in dispensing process management (in contexts such as, say, preventing low probability catastrophic consequence events as well as every day moderate consequence errors) their sense of unfairness may to a degree be an artefact of community pharmacists not having access to clinical records. This last helps to ensure that 'important' medicines use decisions are, or are at least seen as being, under medical control. Hence some respondents argued that community pharmacist access to electronic patient records would help raise the perceived status of community pharmacy as a whole, as well as objectively opening the way to playing a more pro-active clinical care provider role.

A scientific knowledge of medicines composition and actions can be seen as providing pharmacists with the credentials needed for professional status (Brint, 2006). Some interviewees described themselves as being 'the expert in medicines'. This knowledge can be translated into providing valued information to others, whether they are patients or other health care professionals. Issues of cost effectiveness aside, it is this knowledge of drugs that Harding and Taylor – along with a number of those interviewed here – suggested that pharmacists should capitalise upon (Harding and Taylor, 1997).

Yet general practitioner respondents argued that an understanding drugs alone is not enough to justify pharmacists intervening in patient care over and above the basic supply process. As some interviewees' responses indicated, this poses fundamental questions as to the utility of the pharmacist's traditional knowledge base and skill set in the context of modern health care. This is not least because of the growing availability of increasingly efficient and effective computer based knowledge delivery systems (see below). One GP said:

I think pharmacy is probably less well placed to do long-term conditions management. Because it's an order of complexity and infrastructure, which is probably not as well suited to a pharmacy environment. [GP4]

Nevertheless, despite such questions and the role conflict related concerns discussed above, many of the pharmacists advocated the development of pharmaceutical services in the community.

I think the pharmacist's role in those services could expand, and should expand, really, because it's a resource that is underutilized right now, in the community where people need it. [PH5]

The findings offered here suggest that for many GPs (and probably other doctors) an extension of pharmacists' roles in areas such as supporting self care and managing the drug treatment of long term conditions would, despite their relative security, be seen as threatening to their roles. Other studies have reported that pharmacists appear threatening to general practice 'if they suggest too many (treatment) changes' (Ortiz et al., 1989).

During this investigation a number of views were expressed about pharmacists' subordinate positions to general practitioners in the health care hierarchy, not least by pharmacists themselves.

One interpretation of the available data is that community pharmacists share a hierarchical view of the world with the medical profession but fear they lack the standing they believe they deserve relative to doctors. They may therefore tend to express relatively high levels of role related status anxiety, while also being on occasions judgementally critical of the abilities of others, including doctors, nurses, patients and the public (see, for instance, York Health Economics Consortium and School of Pharmacy University of London, 2010). Pharmacist respondents said their advice was not respected by patients 'as much as it should be'. At the same time some interviewees with a general practice background also projected a hierarchical view, but with a greater tendency to suggest that pharmacists' contributions could be optimised within general medical practitioner led environments:

If you were being a bit more radical, you could say that if we truly want to integrate pharmacists into the GP team, you should make all practices dispensing. Pharmacists actually should become as part of that team. [GP2]

There's a control issue for GPs. So, in a perfect world, the GP would have a practice pharmacist and a practice nurse, and both would be working for him or her. [PH3]

GPs expressed concerns about work place location issues, notwithstanding the possibility that modern approaches to sharing computer based knowledge might be used to facilitate easier working across physical site boundaries:

Perhaps I don't think it (pharmacy support for improved medicines prescribing and use) should take place in the pharmacy, I think it should take place in the GP surgery, indeed in my last GP surgery we employed a pharmacist who did exactly that. She sat down with the patients and the medical record and went through their drugs. Because I think that advising on drugs without any knowledge of why there were prescribed is a strange thing to do. [GP2]

The tendency of pharmacists to believe that they are the only people capable of satisfactorily minimising the risks of medicines taking was also reflected in the view of support staff projected in some responses. Although it was suggested that future community supply models would 'use' support staff more along NHS hospital or say Scandinavian pharmacy model lines, there was a degree of reticence with regard to pharmacy technicians sharing 'their' (the pharmacists') knowledge domain. This is indicative of a perceived role challenge, although there was also a desire to form more effective working relationships:

(we) need to make sure that the team that is left back in the pharmacy is the right team, and not just some hotchpotch of employees brought in just to manage that day. [PH6]

It was of note that non-pharmacist respondents tended to describe the value of community pharmacists in terms of their potential activities, rather than that of their current practices. It appeared that to a degree the easy access afforded by pharmacy 'shops' and the consequently reduced 'social distance' between 'the pharmacist as shop keeper and the patient as customer' may have undermined the standing of pharmacy in some respondents' eyes. The desirability or otherwise of such a bias is of course questionable, but this does not negate such observations.

It is open to debate as to whether or not community pharmacists are unfairly under-utilised for what they presently do. However, the qualitative evidence presented here suggests that the current role of community pharmacists is perceived to be of relatively low utility by many GPs and other actors, and that this is a cause of concern to community pharmacists themselves. It may add to their sense of having 'guilty secrets' about their businesses (see below). Some policy makers seem optimistic about the opportunities for improved future collaboration between doctors and pharmacists working in primary care. However, there are significant barriers to change, and even positive medical expectations of community pharmacy often appear limited to a development of the 'rule enforcing' aspects of pharmaceutical care:

I can see pharmacists adding a lot of value around concordance and compliance. I tried unsuccessfully to get this working between my practice and my local pharmacy for a number of years.[GP4]

On the 'pharmacy side' the majority of those interviewed talked of better collaboration with general practice. However, in conclusion to this section of this qualitative analysis it may be observed that even pharmacists themselves often appeared to be limited in their clinical role aspirations and reluctant to move beyond their established identities as risk managers, safe supply facilitators and improved compliance advocates. A key implication for the future is that community pharmacists appear to need to consider much more deeply questions about how in practice they can effectively enhance medicines prescribing and use through either working more closely with GPs and practice nurses, or offering new services in competition with other primary care providers. They also need to ask to what extent substantive progress on either front is achievable within the confines of the existing pharmacy practice business model.

The Business Imperative

Perceived or actual conflicts between business and health imperatives can present another challenge for community pharmacists. As noted earlier, GP and other critics of the profession may see its members as little more than 'shop keepers with degrees' (Hughes and McCann, 2003). As private (or indeed public sector) contractors to the NHS, pharmacy owners need to make an adequate income and return on investment. The same is of course true for medical partnerships and organisations like NHS Foundation Trusts (Foy et al., 1998). However, several interviewees appeared to believe that reconciling commercial and professional incentives and priorities is especially challenging for community pharmacists.

Some respondents suggested that pharmacists supply items in the interests of profit rather than patient care. This view has also been reported in other countries (Cavaco et al., 2005), although its expression may on occasions be used as a rhetorical device by interests concerned to limit pharmacy role extensions rather than as an evidence based statement of fact/belief.

"Are they [pharmacy contractors] looking at it because they are really trying to make their pharmacies and pharmacists medicines experts or is it just a profit making scheme in the old supply model?"[PT2]

Respondents suggested that one reason for the fact perceived conflict between commercial imperatives in community pharmacy and health gain priorities is more acute than in the case of, say, medical partnerships is that people see pharmacies like those located in supermarkets as ‘business interest’ rather than professionally controlled. Another is that cash transactions between pharmacists and pharmacy service users are commonplace. Such factors were often assumed to have a negative effect:

I have a very high regard for pharmacists who I think are underutilized. I'd come to this conclusion a while ago, this is why I am prejudiced in a way, that actually, the public - the NHS, the taxpayer - generally would get a better service from pharmacists if more were liberated from being in community pharmacy.[DH4]

However, pharmacists themselves were typically more positive about the mixing of health care and other functions :

It may prompt people to ask – even if they are in there for something very trivial, picking up some hair spray or a corn plaster, they ask something else because they feel that there is a healthcare environment there. That could spark an interaction that could then lead to an intervention. [PH6]

Respondents discussed the extent to which respect for consumer sovereignty in the commercial setting means that ‘customers’ are not actively challenged about their behaviours or needs. Some seemed to believe that ‘consumerism’ would undermine the professional status and judgements of pharmacists. Others suggested that the dynamics of pharmacy business based relationships would encourage more equal discussions and (desirably) inhibit the development of paternalistic models of healthcare found in other parts of the health service.

It was commented that employee pharmacists may be rewarded with promotion for increasing dispensing volumes, rather than improving health outcomes. It was also argued that corporate management approaches may serve to disrupt the development of long term trust based relationships between local health professionals:

Our biggest issue, I think, for the multiples and their workforce, is that good pharmacists get moved to ever busier pharmacies, and that's the career progression within the multiple sector.....that results in an inability for the good pharmacist to really leverage the opportunities of a good working relationship with their patients and with the local GP's and other local healthcare professionals.[PH3]

The apparently strained relationship between health and business imperatives at times made it appear that pharmacists might be at risk of developing a ‘guilty secret’ mentality. Their responses suggested that this normally stops them talking openly about tensions

between the financial incentives driving their business activities and the health interests of individuals and communities. However, in the interview setting individuals with a policy background appeared rather more hesitant to accept the validity of 'business' priorities than pharmacist respondents, who seemed more secure in articulating the future in terms of a viable business model capable of delivering health related benefits.

We've always had, in pharmacy, this sort of conflict between the businessman who wants just purely to pile it high, sell it cheap, make a profit, and if there's a bit of professional acknowledgement around that it's a bit of a cache, really, that brings them on the pharmacist that only I can provide these medicines so there's a protectionist almost attitude, alongside those who want to provide a clinical role. [DH3]

General practice based participants in this research were, despite seeming to recognise the benefits that pharmacists can deliver in improving the public's use of medicines, on occasions overtly critical of the retail activities that take place in community pharmacy, and seem to lack understanding of pharmacy premises.

To me, it's been damaged bythe fact that pharmacists almost always end up selling something. Whereas, quite often the right answer to 'I've got a sore throat' is.....have some hot drinks, hot Ribena. [GP3]

It's [clinical care in the pharmacy setting] messed up by practical issues around the design of pharmacies to have consulting space and confidentiality and so on. [GP3]

The whole model of seeking that advice is a curious one. On the whole in most places, it's a shop-counter. It's not 'can I have a word' and then you go and sit down with the pharmacist. Are there many pharmacies that have a consulting room? [GP3]

Underlying tensions between GPs and community pharmacists have been reported elsewhere (Edmunds and Calnan, 2001a). They may yet prove a significant barrier to the implementation of community pharmacy policies in areas such as the management of repeat dispensing. The existence of corporate pharmacy chains has long been associated with such concerns (Shaw, 1972) and problems such as the lack of close personal relationships between GPs and pharmacists who may be expected regularly to move between localities.

Sidhu (2003) has also described how being located within a corporate business environment may influence pharmacists' professional roles. More recently some supermarket pharmacies have reportedly been reluctant to offer supervised administration of medicines and needle-exchange schemes to service users with drug abuse related care

needs (Bush et al., 2009). Such illustrations evidence the fact that business linked factors can impact upon the professional identities and role fulfilment of employed community pharmacists.

Some GP respondents seemed to believe that the community pharmacy setting does not offer an appropriate location for the provision of clinical services, but that pharmacists might usefully be able to deliver them in a primary care practice environment. This may be a deeply held position. But it is also possible that GPs may tend to respond defensively to the possibility that other independent professionals might become able to review patients' treatments more proactively than is presently possible. The idea that corporate bodies like those pioneered in community pharmacy could in future markedly change the balance of primary care practice ownership might also seem challenging and influence expressed attitudes.

Interviewees from all groups described the current pharmacy business structure and the dominance of dispensing activities as one of the main barriers to the development of cognitive service based pharmacy roles. Community pharmacy evolution was described as being constrained by the current funding system:

[Pharmacy] delivers what it's supposed to deliver. Delivers what they get paid for. [PH2]

If you choose to, you can invest in future patient services. But the current climate is such with Category M, that you'd be a brave man - and by brave, I mean stupid - to invest what profit you have, what cash reserves you have, in services when it might get clawed back in a few months time to leave you sort of minus equity. [PH5]

There is evidence that pharmacists are today facing increasing financial pressures (see Chapters 3 and 6). Yet one possible interpretation of such remarks is that economic challenges may be being used as a 'scapegoat' for practitioner failures to embrace new services opportunities in a more proactive way. This research suggests that the most profound barriers to the latter lie deep in the community based profession's role defined identity. However, the most important point to stress at this juncture is that community pharmacists are often (by themselves and others) seen as being caught between the altruistic values of professional practice and the realities of operating businesses in a competitive market.

Such a view may in fact be too simplistic. But even so, the continuing existence of perceived serious conflicts between the commercial imperatives driving pharmacy owners and the requirements of high quality professional healthcare provision may significantly

damage community pharmacy's development opportunities. Resolving related presentational and, to the extent they in fact exist, substantive business issues may prove essential for community pharmacists to extend significantly their clinical roles in the NHS primary care environment of the future.

Technological developments

All the interviewees taking part in the survey reported here said that technological progress will be central to future health care interactions, and play a vital role in defining the future of community pharmacy.

...I think in all areas in which the citizens transact with professionals, there's a dynamic at play as a result of modern technology and ways of living, which is a trend toward self-service, automation and not having to go to the physical embodiment of the service. Doing it online or by phone or whatever. [PT1]

Pharmacist respondents talked positively about technological changes allowing supply processes to be completed more efficiently. Yet as it currently exists community pharmacy is threatened by computer and robotic developments.

Technological advance in any walk of life, profession or just public life is hugely threatening.....I understand that for a workforce that feels very pressured, they almost feel that a robot or whatever that maybe will take over my job.... is very threatening. [PH6]

Improvements in supply chain technology, such as the electronic transfer of prescriptions and the automation of the dispensing process, were viewed as having a capacity to confer harm as well as benefit. In line with various policy statements, it was believed that automated dispensing will result in pharmacists spending less time fulfilling their supply role and so allow the development of more cognitive services.

However, respondents also expressed concerns that increasingly sophisticated dispensing technologies could facilitate medicines supply being physically separated from community pharmacy. This may affect funding arrangements and ultimately undermine the pharmacist's identity in the high street.

The more you get supply not through a pharmacy, the more it will disassociate in the public's eye the expertise and input of a pharmacist. If they get their stuff through the post, they probably won't even know the pharmacist's been involved in it. It will alter their perception of (a) pharmacist as someone embedded in the function of supply. [PH1]

In particular, access to patient records was (as already observed) seen as an important driver of future practice. However, pharmacist respondents, in line with their risk minimiser/manager role, said that such access should be governed by strict controls, with an emphasis on protecting patient confidentiality through rules and procedures. They also expressed concerns about the prospect of taking on greater risk and responsibility without additional funding:

I think to enable us to have an extended role, more records should be accessible, but it's got to be balanced. There's got to be perspective put on that, so that it's not extra responsibility for the sake of it, without remuneration for that responsibility.
[PH5]

Despite this evident caution, some interviewees with medical backgrounds challenged pharmacists' abilities to use patient data responsibly and effectively. Whether the expression of such views was due to genuine concerns about pharmacists' abilities and behaviours or to a protectionist desire to restrict access to what has previously been a medical domain is uncertain. It could be argued that medical assumptions about the commercial imperatives of pharmacists were partly validated by the response of the pharmacist who was unsure about the desirability of gaining access to records without additional payments. But there is evidence that GP behaviours are also driven by financial incentives (Foy et al., 1998).

The main finding of this work is that while technological developments are universally seen as important drivers of future practice change, they are also perceived as being inherently threatening. It was through technological progress that the traditional 'medicines maker' role that represented 'a potent symbol of the pharmacist's status and value to the community' (Harding and Taylor, 1999) was in the past replaced by that of being a 'medicines supplier'. This is in turn under threat from technical change (Varnish, 1998). The automatic dispensing of medicines has the potential to remove the existing human input into the technical supply process. The extent to which this will allow community pharmacists to adopt roles that serve to augment or parallel those of clinicians such as doctors is uncertain. But this research highlights the fact that to make best future use from a public (health) interest perspective of technological developments relevant to medicines supply and use optimisation the sectional sensitivities and interests of professional stakeholders such as GPs and pharmacists themselves will need to be fully understood, and effectively addressed.

Discussion – Tiers of Conflict within the Community Pharmacy Role

The approach adopted here helps to reveal how the members of different groups ‘socially construct’ the role of the community pharmacist. The thematic analysis of the interviews revealed the role(s) of community pharmacists as ‘business men’ and shopkeepers, medicines suppliers and risk managers, medicines makers and scientists, and clinicians/health professionals. It also identified tensions and conflicts that individuals may experience in seeking to fulfil the demands of such differing parts.

Medicines supply is what today’s public predominately expects from community pharmacists, who continue to have legal responsibility for medicines provision. Even though up until the Second World War their role was much wider, medicines supply is arguably central to the modern community pharmacist’s ‘functional’ identity. As shown in chapter two it consumes a major proportion of their time.

Community pharmacists now appear to be involved in a partially voluntary process of transition towards their playing a greater role in ‘managing’ the overall risk and benefits associated with the supply and use of medicines and/or providing care related services. Current policy statements suggest that their future roles are likely to revolve to a large extent around developing further their professional identities as pharmaco-therapeutic risk managers and medicines use optimisers through changed relationships with both medical prescribers and patients. Their current credentials for playing such a part rest to a significant degree on their training as ‘pharmaceutical scientists’. But there are important questions relating to whether or not this historic positioning is going to prove adequate. Their public acceptance as clinicians is at best limited, and it is of note that until the gradual evolution of NHS hospital clinical pharmacy between the 1960s and the 1980s pharmacists were nowhere in the world seen as prescribing advisers to doctors such as GPs.

Harding and Taylor (1997) recognised that technology based advances had impacted on pharmacists work. They argued that the social objective of pharmacists is to transform drugs into medicines, and consequently that role developments that stopped medicines being at the profession’s focal point could well prove damaging to its status. They suggested that there would be a de-professionalising effect if ‘*drugs lose their centrality to pharmacists’ activities*’ and that pharmacists should therefore further consolidate and focus their knowledge and skills on areas related to medicines’ (in part socially defined) actions and interactions.

The 'clinical' role that pharmacists are evolving into from a policy perspective (see chapter 1) may stand in contrast to this in as much as it involves pharmacists widening their therapeutic and allied competencies into areas outside medicines use *per se* and the traditional pharmaceutical sciences. While there are several definitions and interpretations of 'clinical pharmacy' in the community setting, it is generally understood to be services provided at the individual level, using the 'skills of the practitioner' (Department of Health, 2008a) – knowledge and 'professional judgement' – to facilitate better personal care and outcomes.

The commercial imperatives of community pharmacy were described as an important barrier to its further development and integration with the rest of the health service. This echoes findings reported elsewhere (Bush et al., 2009; Hughes and McCann, 2003). By comparison general practice are less overtly commercial than pharmacy, not least in as much as they do not normally sell goods or services directly to the public (Foy et al., 1998). Structural and economic challenges, such as the growth of large chains and recent debates about issues such as parallel trading in pharmaceuticals and associated supply shortages, may also have fuelled perceptions of pharmacies as commercial entities rather than health care providers (Davis et al., 2009).

Tensions and disparities between the four community roles described above ('business men' and shopkeepers; medicines suppliers and risk managers/minimisers; medicines makers and scientists; and clinicians/health professionals) arguably place community pharmacists in a deeply conflicted position. The resulting internal contradictions (which to a degree reflect additional ambiguities about medicines as both treatments and poisons) are often recognised by observers external to the profession.

In terms of 'clinical' role development such findings help to explain why pharmacists may in practice have failed to receive the positive support that political policy statements appear to suggest and why they have been relatively slow to take up relevant opportunities. There is additional evidence that community pharmacists' conflicted images as shopkeepers 'versus' health care providers have further impaired progress towards role extension (Hughes and McCann, 2003), despite pharmacy users' beliefs that such concerns are exaggerated (Varnish, 1998).

The health professions in England may to date be seen as having developed along relatively isolated or 'separatist' as opposed to integrated lines. Notwithstanding policies aimed at

promoting better co-ordinated working and enhanced inter-disciplinary collaboration, this still appears to characterise community pharmacy. Alongside this, concerns have also been expressed about 'role boundary' encroachments (Edmunds and Calnan, 2001a; Eaton and Webb, 1979; Ritchey and Raney, 1981; Tully et al., 2000; Harding and Taylor, 1997; Weiss and Sutton, 2009), into the general practice domain. In this context GPs are reportedly most likely to be antagonistic towards activities that require independent judgement or autonomous action related to patient care on the part of the pharmacist (Adamcik et al., 1986).

Before the establishment of the NHS and the creation of regulatory arrangements that made most effective medicines 'prescription only' the *de facto* situation was that community pharmacists and general medical practitioners offered alternative gateways to care. Today this is not so much the case, but there remain areas of competition. The recent opening by GP practices of integrated community pharmacies can to a degree be compared to pharmacists' expansion into the clinical activities – such as, for instance, giving immunisation – that were once carried out exclusively in doctors' surgeries or other medically controlled environments. An underlying desire to prevent such competition (and through it greater consumer choice) may in part explain the apparent preference within general practice for employing pharmacists in practice settings rather than developing alternative collaborative models.

Such observations lead on to questions about whether or not the desired social functions of pharmacy are primarily delivered by pharmacies or by pharmacists independently of their settings. In this context it is of note that there is evidence that many pharmacy users cannot tell the difference between pharmacists and their support staff (Cavaco et al., 2005; Oparah and Iwuagwu, 2001). This may be especially so when pharmacists are out of sight in the back of the pharmacy.

Such observations raise a variety of issues. But for the purposes of this analysis the most important are taken to relate to the future capacity of community pharmacy to adapt to its changing environment on ways that will permit it a continuing role, whether or not this involves concentrating on medicines use and outcomes optimisation or becoming a broader health care delivery oriented profession. In this context Tuner (1990) suggested that the successful implementation of new roles relies upon the extent to which current role incumbents are unified in their desire for role change and can be mobilised to achieve

it. He also, perhaps unsurprisingly, identified client demand for change as a critical success factor.

The findings of this research indicate that at present community pharmacy is relatively poorly aligned in terms of its collective thinking on role change, and that different external stakeholder groups also have contrasting views on what future progress might or might not be desirable. The interpretation offered here is consequently that, despite the apparently clear policy prescription offered by documents such as 'Pharmacy in England: building on strengths - delivering the future' community pharmacy is in reality facing a crisis of identity. This suggests that if the profession is to survive and prosper in the medium to long term then it will be required to more effectively address these issues than currently appears to be the case. At the centre of the dilemma being faced are questions like:

- 'should pharmacists seeking a more clinical role be located more frequently in general medical practices, or does the future of community pharmacy as a contributor to improved and more cost effective primary health care lie more in offering treatments for an extended range common acute and chronic conditions in independently located pharmacy settings?' and
- 'should medicines supply also be more frequently located in integrated primary care settings, or will it continue to be more safely and efficiently provided via physically separate community pharmacies that also offer self care support and allied preventive services, supplemented as appropriate by home delivery and other medicines supply services?'

Possible answers to such queries are considered later in this thesis. But at this point it is most relevant to emphasise that the evidence presented here indicates that from a public interest perspective the problems, challenges and conflicts underlying them will not be easily resolved by the community pharmacists and general medical practitioners most directly involved. It seems unlikely, for instance, in the light of the current NHS reform process that locally oriented Clinical Commissioning Groups will be able to look beyond short priorities and sectional medical concerns objectively to consider long term strategies for overall primary care development. It is more probable that leadership offered at the level of the NHS Commissioning Board could help provide an appropriate resolution, although this will in large part depend on the NHS CB's interpretation of its role and the

development of a wider, more comprehensive, primary care development linked pharmacy policy vision than has in the past existed.

Limitations

This qualitative study was purposively conducted with a specific sample of policy leaders from across primary care. Care was taken in their selection. But it is possible that their views and opinions do not adequately reflect those of practitioners 'at the coal face'. However, given that most of the interviewees continue to practice, and that some of the findings reported here are echoed by larger practitioner based studies, this is unlikely to be the case.

Given the position of interviewees close to the centre of policy discussions it is also possible that they may during interviews have put forward positions for political or associated reasons, rather than to reflect their most deeply held personal views. Such possible distortions cannot be entirely avoided. But in the main the strength and consistency of the themes running across the interviews in relation to concepts such as the 'under-utilisation' of community pharmacy suggests that this was not a major problem.

As with any qualitative method, the structure of the guide used and questioning style of the interviewer (who was identifiably a pharmacist) can also influence the nature of the responses (Pope et al., 2000). While every effort was made to maintain a neutral position it is again possible that respondents were to a degree influenced by such factors, and could as a result have been (for example) more positive about some aspects of community pharmacy than if the interviewer had been a doctor or a non-health professional. But it is observable that statements critical of pharmacy were made.

Chapter Conclusions

The roles that community pharmacists in England are in today's conditions expected to play are in a number of respects conflicted. The evidence available indicates that many pharmacists and GPs wish to perpetuate their 'traditional' role as the suppliers of medicines, employing new technologies in relatively conservative ways to enable them to act as guardians of their safe and appropriate use. However, policy leaders within pharmacy and the NHS are more likely to want them to play an extended part in clinical/health care. This can be seen as an encroachment on the doctors' professional domain which threatens medical practitioners and may expose established pharmacy businesses to retaliatory action.

Risk management involving risk elimination/minimisation wherever possible appears central to the role defined identities of many community pharmacists. But this may impair their ability to manage complex uncertainty and engage more fully than at present in clinical decision making. Further perceived and experienced conflicts around issues such as the 'shopkeepers with a degree' as opposed to 'ethically motivated health professionals' or clinicians add further tensions, and may contribute to community pharmacists feeling they have a 'guilty secret' about the reality of their work and its value to others.

While such ambiguities remain unresolved they are likely to act as a substantive barrier to change. Directive leadership from outside general medical practice and community pharmacy itself may be required to open the way to more productive approaches to primary care development that will allow pharmacists to contribute as cost effectively as possible to the supply and use of medicines in the community, and so optimise health outcomes.

Chapter 6. Strategies for the Pharmacy Business

Chapter Introduction

Community pharmacy operates at the boundary between the retail and healthcare environment. To implement and support future roles, the attributes of the business and the market within which it operates must be considered.

Developing a business model that supports a future 'clinical' role for pharmacists is challenging. A key part of future healthcare policy will relate to cost containment and management of patient expectations, pharmacies will be required to do more for less. Healthcare costs will continue to rise faster than taxation and insurance can meet them. In 2004 the UK Treasury projected that if the proportion of healthy life remains constant then spending for health and long term care will need to increase from 7.9% of GDP to 11% by 2053-54 (House of Lords, 2004). The Wanless report (2004) suggested only with a public who were 'fully engaged' in their own health could the NHS hope to meet the expectations of the aging population. Pharmacy businesses owners will be only too aware that as expectations and costs increase their margins of return on capital invested will be squeezed. Indeed, pharmacies, like many other sectors of the healthcare system will be required to deliver more for less.

Defining the industry boundaries allows for analysis of the external factors and competitive forces that help to define future threats and opportunities. Like any business, community pharmacy will need to react to the market pressures that it is likely to face, and make its services, outputs and outcomes as profitable, sustainable and efficient as possible. At present the evidence suggests that the community pharmacy industry, taken as a whole, is profitable (Keynote Report, 2011b), but the future sustainability of these profit levels is being brought into question.

There are some unique features of the community pharmacy market which change the market dynamics. A particular attribute is the above average degree of political intervention which seeks to regulate the market. This above-normal regulatory intervention alters the way the market operates and needs to be considered closely in this analysis.

Other internal aspects of the pharmacy market are exceptional. Due to the fact that prices for prescription medicines are fixed or non-existent for many consumers, there is no incentive to search for 'low cost' providers. Therefore internal rivalry for prescription medication supply is instead based on location, business hours and other factors that affect consumer access costs, the availability of additional pharmacy services, the breadth and depth of consumer goods, brand image, advertising, store attractiveness and other dimensions of quality, such as prescription dispensing time. All of these factors must be considered in the future alignment of the business and the profession.

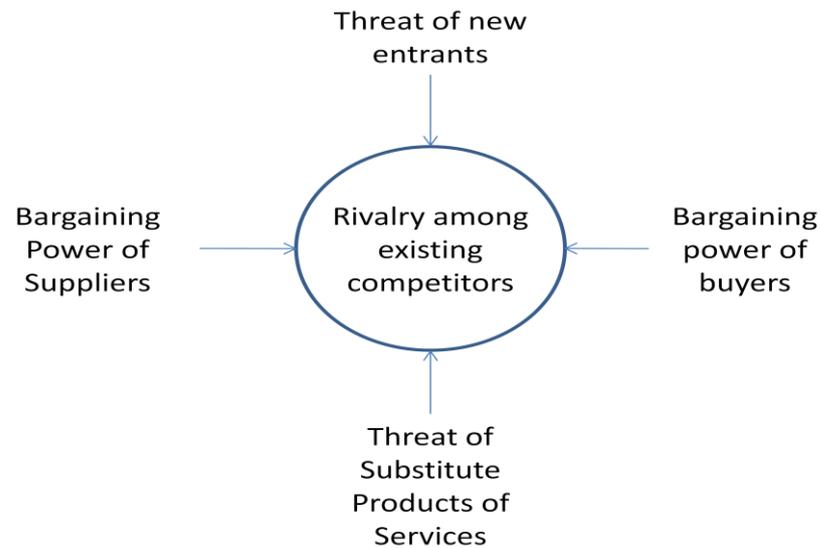
This chapter considers approaches to business strategy in the community pharmacy market in order to address the main research question of future models of business and professional practice in England. This is achieved by defining and quantifying the market within which community pharmacy operates using the Porters five forces framework. There is little evidence that the community pharmacy market has ever been publically explored in this way, with such depth.

Using the evidence from the qualitative interviews in chapter 5, publications in the trade press and original thought, this chapter begins to address the different strategies that the community pharmacy market as a whole can take in the short term to maintain the business.

Theoretical Framework

This chapter uses a theoretical base of business strategy, known as the five forces framework defined by Michael Porter (Porter, 1980; Porter, 2008). This framework focuses on the risk of entry of potential competitors, the intensity of rivalry among established companies within the industry, the bargaining power of the buyers, the bargaining power of the suppliers, as well as the closeness of substitutes to an industry's products (figure 6.1).

Figure 6-1– The Five Forces that shape industry competition (adapted from Porter, 2008)



The strongest competitive force (or forces) determines the profitability of an industry and become the most important to strategy formulation. However, the most salient force is not always obvious. Understanding the competitive forces, and their underlying causes, reveals the roots of an industry's current profitability while providing a framework for anticipating and influencing competition. Therefore understanding an industry structure is also essential to effective strategic positioning.

Porters Five Forces

Risk of Entry (Weak)

A competitive market is characterised by free entry of firms into the marketplace. In such a market, firms enjoying above normal profits will soon find these profits being reduced by new entrants. The community pharmacy market in England differs from this free market approach through restrictions on NHS dispensing contracts.

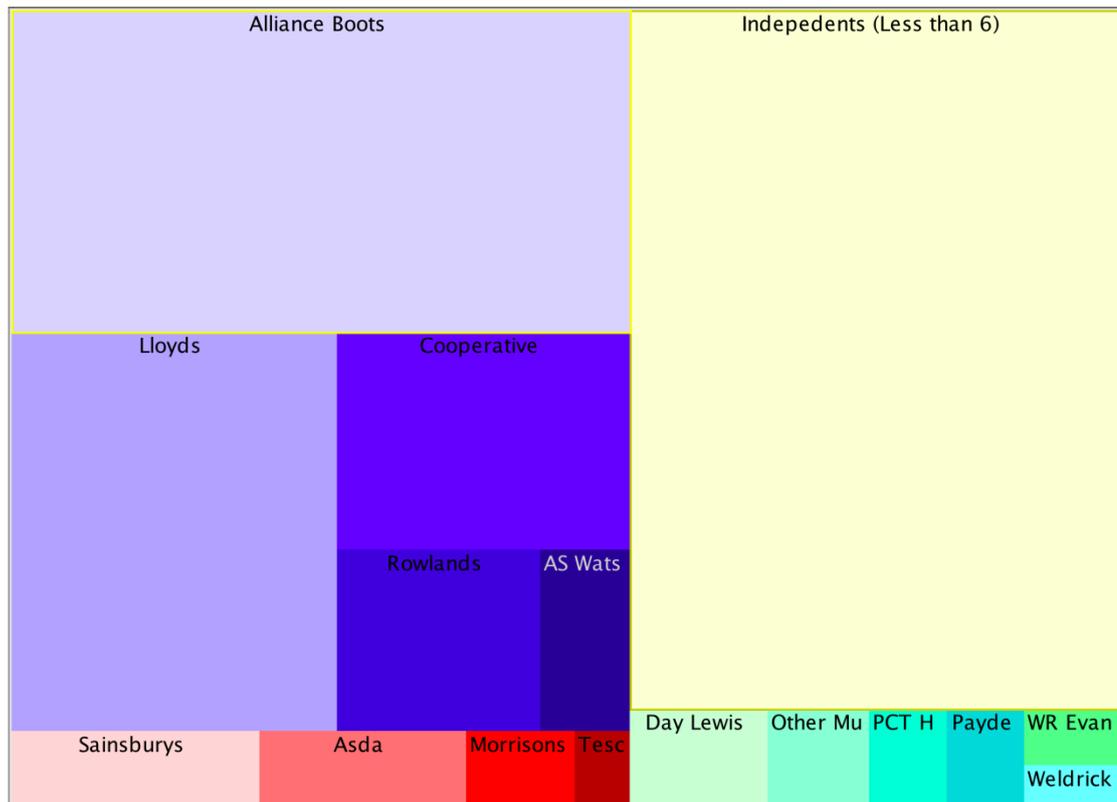
The Pharmacy Market

On the 31st March 2011, there were 10,961 community pharmacies registered with an NHS contract. Across the sector about 1% of pharmacies operate without an NHS contract. These pharmacies tend to be located in airport terminals supplying P medicines, or in areas where the supply of private prescriptions supports their operation, such as private hospitals or locations close to Harley Street. Although the focus here is on England, it is worth noting that there were 707 pharmacies in Wales (Welsh Assembly Government,

2011), 1215 in Scotland (ISD Scotland, 2010) and 529 in Northern Ireland (Department of Health and Social Services and Public Safety, 2012) in 2010. Therefore including private contractors and hospitals increases this to 13,930 registered pharmacies operating in Great Britain (General Pharmaceutical Council, 2011).

Each of these pharmacies will operate in different ways and to a large extent this is driven by their ownership, geographic location, and business philosophy. The sector within which pharmacy operates is dominated by several large multiple providers. Boots is the clear market leader with approximately 2,000 stores in England (Boots UK, 2012). The closest competitor is Lloyds pharmacy which operates approximately 1,400 pharmacies in England (Office of Fair Trading, 2010).

Figure 6-2– Community Pharmacy Market Composition in England by Ownership 2011



Blue: Large Multiples; Red: Supermarkets; Green: Small Multiples; Yellow: Independents. Left: CCA Members. Right: Non CCA Members. Source: Company Reports & Websites; Mintel Reports; NHS Information Centre; Trade Press; OFT Calculation in 2009 and author estimations.

The Company Chemists Association is a trade association that represents the large multiple providers, and therefore exerts significant influence on the delivery and structure of the

community pharmacy market. Together its members own in the region of half of all pharmacy contractors in England (left hand side of figure 6.2).

The community pharmacy sector operates across several markets, and therefore on the fringes of the sector are other specialist health and beauty retailers. While across the specialist health and beauty market, Boots remains the market leader, other entities such as Wilkinson's, Superdrug, Space.NK, Savers and Body Shop all compete for market share of health and beauty product sales.

Patterns of Pharmacy Ownership

One of the significant developments affecting the community pharmacy sector in England is the changing pattern of ownership. Historically, self-employed community pharmacists owned the majority of pharmacies in England and Wales. As predicted in the late nineties (Ottewill and Magirr, 1999), the last decade experienced a steady increase in the proportion of pharmacies in chains of five or more, increasing from about a third to over two-thirds (The NHS Information Centre, 2011). For the last four years, the proportion of pharmacies in a chain has remained at around 61.5%. This varies within geographical areas, with Milton Keynes PCT recording 88% of their pharmacies in multiples, compared to just 16% in Islington PCT.

Control of Entry

The ability to gain an NHS dispensing contract is the biggest obstacle to community pharmacy market entry. Until 1989 pharmacy contractors were reimbursed on a cost-plus basis for drug ingredient costs. This system was introduced in the 1960s and 1970s to remedy the declining number of pharmacies. The resulting increase in pharmacy contracts led to increased costs and an inappropriate expansion of community pharmacies in some areas. The Department of Health sought to address the uncontrolled increase in numbers with control of entry regulations, introduced in 1987. These stated that any pharmacy wishing to obtain an NHS contract had to satisfy the relevant authority that it was either "necessary or desirable". Effectively this created a closed market for pharmacy, resulting in fairly static numbers of community pharmacies throughout the UK network, until 2005.

In 2001 the Office of Fair Trading (OFT) began a market investigation, under section 2 of the Fair Trading Act 1973, to examine if the community pharmacy market was working well for consumers. Two years later in January 2003 the OFT published a report into the control of entry of retail pharmacy services in the UK and had one key recommendation.

"We recommend that the control of entry regulations for community pharmacies in the UK should be ended. This would mean that all registered pharmacies with qualified staff may dispense NHS prescriptions." [Para 1.25](Office of Fair Trading, 2003).

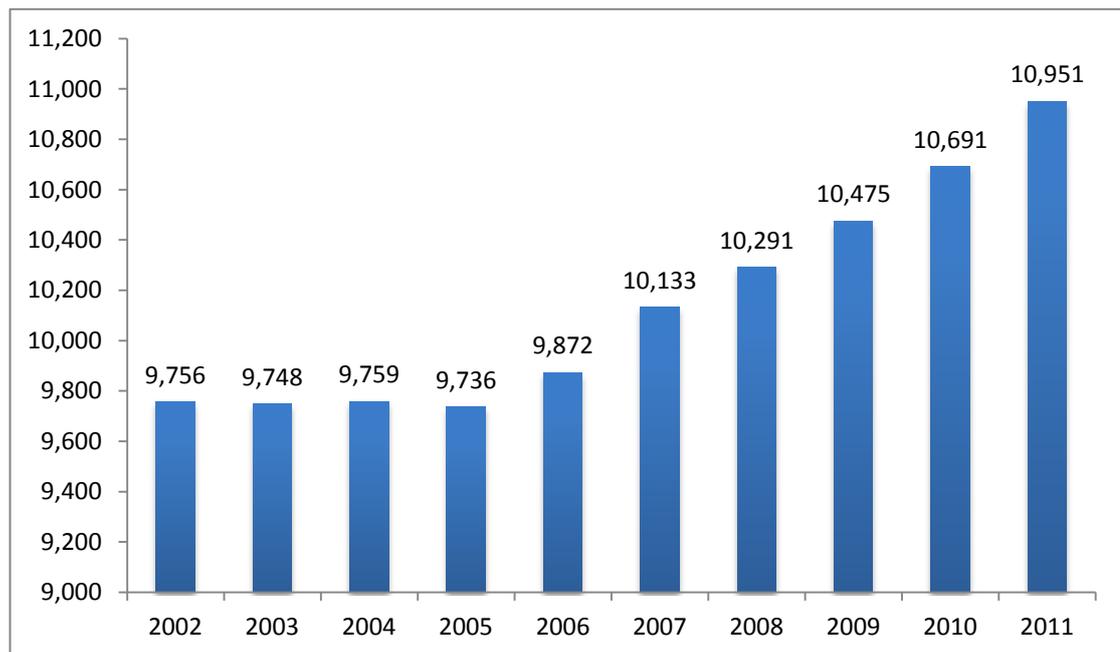
The OFT believed that control of market entry increased costs, limited efficiency and reduced innovation in the pharmacy market. The threat of market de-regulation presented a significant risk to existing contractors, who could potentially lose their geographical monopolies. Within policy circles, the civil servants with a responsibility for pharmacy recognised that full deregulation of market entry would have detrimental consequences for local healthcare provision, and limit future investment in pharmaceutical services (Office of Fair Trading, 2003).

Therefore the government response rejected complete de-regulation, instead putting forward proposals for a “balanced package of measures” to allow further market entry. After consultation, the government offered several exceptions to the control of entry of pharmacies, these being:

- Pharmacies located in shopping centres over 15,000 square meters but only in out-of-town developments and not in town centres;
- Pharmacies that intend to open more than 100 hours per week;
- Pharmacies set up by consortia as part of new one-stop primary care centres. The centres must offer more than usual GP services serve a substantial population of around 18,000–20,000 patients and be part of the local PCT’s strategic service development plan; and
- Pharmacies that are wholly mail order or internet-based. These pharmacies will be required to provide a fully professional service within the provisions of the new contract.

It took until April 2005 for the majority of these reforms to be introduced by revising NHS regulations. The result was an increase in pharmacy numbers, with the majority of pharmacies opening under the 100 hours exemption (figure 6.3).

Figure 6-3- Number of Community Pharmacies in England by Year

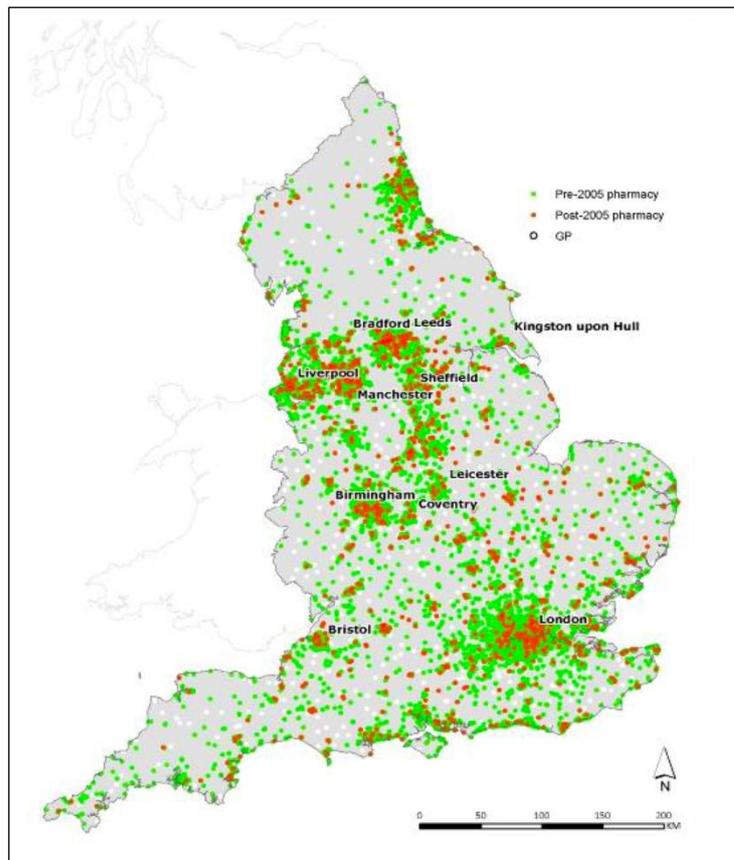


*Data collected on the 31st March of each year. Source: NHS Information Centre

From an existing contractor perspective this increased market competition. The PSNC highlighted how the global sum for pharmacy has not increased to meet this demand. The result has meant that funding is now shared between a greater number of pharmacies, reducing the income that each individual pharmacy receives (PJ News, 2008) (Also see chapter 3).

Due to the relaxation of opening restrictions in 2005, over 1200 new pharmacies opened, However, these new openings tended to be located in urban areas, as shown in figure 6.4.

Figure 6-4 – Map of Pharmacies in England, July 2009



Source: OFT, NHS BSA, DotEcon analysis Annex VII.

The increase in pharmacy numbers seen following the reforms has created little tangible increase in accessibility to the average consumer as the mean distance to a pharmacy from either home or a GP surgery has only decreased by 40 meters (Office of Fair Trading, 2010). Pharmacies continue to locate close to GP surgeries, with almost a third (32.5 per cent) of prescriptions written at a surgery where a pharmacy is co-located, and 93.1 per cent are written within 500m of a pharmacy (Office of Fair Trading, 2010).

The main benefactors of these legislative changes have been the multiples and the supermarkets. The majority of the 100 hour and out-of-town applications for pharmacies have come from the retail driven multiples and the supermarkets, which are keen to increase their market share within the sector.

Pharmaceutical Needs Assessments

While the introduction of full market restrictions could be considered a major shift in community pharmacy policy, the tendency to revert to the status quo has prevailed. The government and the policy subsystem resisted the wholesale relaxation of the rules and

instead opted for a more considered and conservative set of adjustments to the market entry system.

In the 2008 pharmacy White Paper, it was proposed that the current entry tests for community pharmacy should be replaced by ones based on the Pharmaceutical Needs Assessments prepared locally by Primary Care Trusts. The health act regulations governing this received royal assent in November 2009. This legislation requires primary care trusts to develop and publish pharmaceutical needs assessments (PNAs) and then use PNAs as the basis for determining market entry to NHS pharmaceutical services provision. There is uncertainty as to how these will be implemented due to the current flux in primary healthcare. This is complicated by the introduction of further revision of control of entry regulation later in 2012⁵⁵.

The new regulations propose introducing additional quality requirements for contractors. This is another way of bringing pharmacy contractors within the governance framework of the NHS. It will allow the local primary care organisation to dictate entry to the market and to a large extent market exit.

This development is incredibly important for community pharmacy as it will give the primary care organisations the power to withhold funds and close those pharmacies that are not reaching the required quality standards. Currently it is extremely difficult for primary care organisations to close pharmacies over quality concerns. Only with intervention from the regulator can this be made possible. In theory this new regulation should increase quality and drive up consumer experiences. However, it will also add to the bureaucracy that pharmacies will face.

Pharmacies use their geographical location in order to maintain a local monopoly on prescription medication supply. Changes in market entry legislation therefore have a significant effect on the ability of pharmacies to maintain a local monopoly. In some, particularly urban areas the saturation of pharmacies has led to intense local competition.

Distribution of pharmacies geographically

The accessibility of community pharmacies is recognised as one of their key strengths. In 2010 it was calculated that over 43% of the population lived within 500m of a community pharmacy (Office of Fair Trading, 2010). Research conducted by the Department of Health

⁵⁵ In July 2012 the pharmacy minister Earl Howe announced that the 100hr exemption category would be scrapped.

(Continental Research and Solutions Research, 2008) suggests that 99% of the population are within 20 minutes of a community pharmacy by car, and 96% by walking or using public transport, when there were about 200 pharmacies per million population (Department of Health, 2008a). This figure has increased to over 210 pharmacies per million since the changes to market entry were introduced in 2005 (table 6.1).

Table 6.1 - Distribution of Prescription Items and Pharmacies in contract with PCTs, by SHA at 31 March 2011

	Community Pharmacies	Multiple Contractors (percentage)	Independent Contractors (percentage)	Prescription items dispensed per month (000)s 2010-11	Population (000)s Mid 2009	Pharmacies per 100,000 population 2010-11
England	10,951	6,730 (61)	4,221 (39)	70,889	51,810	21
North East	581	1,114 (65)	214 (37)	4,669	2,584	22
North West	1,701	367 (63)	587 (35)	11,635	6,898	25
Yorkshire and the Humber	1,139	785 (69)	354 (31)	7,975	5,258	22
East Midlands	873	566 (65)	307 (35)	6,009	4,451	20
West Midlands	1,203	737 (61)	466 (39)	7,692	5,431	22
East Of England	1,083	618 (57)	465 (43)	6,997	5,767	19
London	1,810	683 (38)	1,127 (62)	8,985	7,754	23
South East Coast	835	572 (69)	263 (31)	5,404	4,340	19
South Central	722	530 (73)	192 (27)	4,629	4,095	18
South West	1,004	758 (75)	246 (25)	6,893	5,231	19

Source: General Pharmaceutical Service, NHS Information Centre.

Around England, pharmacies tend to coalesce in urban areas close to GP surgeries. Across the different parts of the country there are between 18 and 23 pharmacies per 100,000 of population, with London having the highest density of pharmacies.

In the future there is a strong possibility that other healthcare providers will seek to enter the pharmacy market, particularly general practitioners or private healthcare firms to complement their current enterprises. It is highly likely that private companies will be established to deliver pharmaceutical care services at the bequest of local commissioning groups in direct competition with community pharmacies. Health clubs, particularly

Nuffield Health and Virgin Health are seeking to offer screening services in competition with community pharmacy providers. Synergistic alliances between private healthcare suppliers and community pharmacies are currently being explored, as are contract agreements with hospitals and secure facilities.

Recently there has been an increase in the number of applications to open pharmacies from general practitioners. This has been driven by changes in their governance resulting from the new NHS framework and the perceived benefits of operating with community pharmacists. Close integration between a pharmacy and a GP surgery can limit the income to those operating further away from the surgery. This is likely to increase the competition within the prescription sector and lead to questions about the impartiality of GPs.

Consumers report that they have a usual pharmacy and may therefore be unwilling to utilise new market entrants, especially as several established companies, such as Boots, have significant 'brand loyalty'. However, the switching costs for the consumer are relatively low. In some localities new 100 hour pharmacies have managed to obtain a significant amount of dispensed prescriptions from the incumbents.

For OTC medicines and health and beauty products the risk of new traditional high street entrants is limited as the market is currently saturated. Nevertheless, novel channels of supply, particularly Internet shopping could pose a future risk.

Internal Rivalry (Strong)

Rivalry is intense within the community pharmacy market. The limit in profitability available from the contract has only sought to intensify the competitive struggle between companies. In rural areas, pharmacies also compete with dispensing doctors to secure prescription income.

Within certain geographical localities internal rivalry between pharmacies is mounting. Local pharmacies are being squeezed by the large grocers seeking to increase their market share in prescription supply, but also their health and beauty sales. In response independent pharmacies now open for longer hours, offer prescription collection services, dispense medicines in medication aide devices and contract with care homes to secure trade.

Until 2001 there was little rivalry in OTC medicines due to re-sale price maintenance, however since this has ended, there has been intense competition. Pharmacies must now

compete on price for over the counter medicines as well as health and beauty products. The supermarkets, owned by some of the largest companies in the world, have significant buying power that allows them to be extremely competitive on price. In times of economic recession consumers are drawn towards these savings. This has led to a decrease in the average cost of OTC medicines and has drawn custom away from traditional pharmacy suppliers to cheaper outlets.

One of the consequences of the reconfiguration of primary care has been an increase in private providers operating in traditionally public service roles. The efficiency of private sector operations in secondary care settings has provided patients with faster dispensing and shorter waiting times. The involvement of the community sector into secondary care is likely to increase because of further pressure to reduce costs through VAT savings⁵⁶.

Pharmacy services are negotiated at a local level by discussions between the local pharmaceutical committee and commissioners. In most cases contractors accept the negotiated LPC price for services. However, as competition increases some contractors have been undercutting the LPC price to gain market share for services in a locality, undermining the whole sectors negotiating platform.

Externally there is rivalry between pharmacy contractors and general practitioners who are effectively negotiating over the same primary care budget to provide pharmaceutical services. Management of this interface will be key to future income because under the current proposals general practitioners will be responsible for an even greater proportion of the primary care budget.

The development of electronic prescribing systems is likely to further increase internal rivalry. Consumers will need to nominate their chosen pharmacy, which will effectively lock the patient into this pharmacy and may increase the effort required for consumers to change pharmacy. This is one of several technology developments that are likely to affect future practice.

Technology development and Electronic Prescription Service

Several drivers within the market are pushing pharmacies towards more technology focused delivery mechanisms. The electronic prescription service is currently being

⁵⁶ In simple terms primary care medications are VAT free, while secondary care prescriptions include VAT.

implemented across England. This allows prescriptions to be sent directly from a GP surgery to a community pharmacy in a near paperless way.

The widespread implementation of this system encourages pharmacies to adopt more technology into the dispensary and change their work patterns to accommodate computer systems. On a market level, this also removes the geographical monopoly operated by some pharmacies. The electronic message can be sent instantly to any pharmacy in the country, opening the market to greater internal competition. This will devalue the location aspects of the community pharmacy that support its income. The 'winners' in this situation are likely to be the large multiples who can exploit their networks to embrace the electronic system.

EU legislation designed to prevent counterfeiting will also increase the amount of technology in the dispensary. The Falsified Medicines Directive suggests that each product will require an authentication device, necessitating pharmacies to scan and process individual packs of medicines. The market will have to bear the costs and additional burden to the supply chain. However, this innovation in pack design will help to drive original pack dispensing. This in turn will help to facilitate the large scale automation of supply processes.

In conjunction with electronic prescribing, original pack dispensing and automated scanning of products represents a drive towards a more technologically focused supply chain. Inevitably moves will be made to use technology to drive efficiency in the market. The winners in this case will be those who have large supply centres, especially the vertically integrated multiples, or the supermarkets who have efficient supply networks already in place.

The changing nature of the geographic monopoly would suggest that there is a market for internet based supply of prescriptions. These still represent a marginal minority of pharmacies but the trend of opening has increased. Technology advances and growing need for consumer convenience may drive an increase in their existence (as seen in other countries including Germany, Sweden and the Netherlands). The UK has embraced internet shopping. It represents the largest online retail market in Europe. The competition between these pharmacies in cyberspace will increase. Yet at present this still only represents a fraction of the market. The PAGB estimate that only 4% of OTC consumers in the UK use mail order and the internet to acquire self medication.

The extent to which internet pharmacies will develop should not be overstated. Internet sales in health and beauty products have been limited. This is chiefly because consumers need to smell toiletries and perfumes in order to make an informed decision. In addition, many of these discretionary product categories are impulse driven, which is difficult to recreate in an online environment. Secondly, pharmaceuticals are controlled substances. In the P medicines category, certain regulatory obligations concerning safe supply limit the ease at which these products can be sold. Some prescription medications require cooling and have specific regulations about their transport via postal services (e.g. Controlled Drugs). These represent a major barrier to entry for online retailers. Therefore the online market will undoubtedly continue to grow, but without regulatory change it is unlikely to have a significant impact on the rest of the sector in the short term.

Strategic unrest within the Market

For a relatively small professional group, over 100 different organisations represent the interests of those in the profession. This leads to internal conflict about the future development of the market. As a result politicians and policy leaders are challenged in every decision. Without strong leadership the sector is likely to remain weak in primary healthcare as it seeks to manage the stronghold of general practice. The internal priorities of the different parties need to be resolved if the conflict and challenges within the market are to be addressed. Yet, as rivalry continues achieving such consensus may prove extremely difficult.

Buyers (Strong)

Consumers are one of the key factors driving any market. In the case of pharmacy there are three main consumers, the Department of Health, the local commissioners (currently PCTs) and the general public. Each of these consumers in the pharmacy market has their own needs and desires.

The Department of Health

The Department of Health is one of the main generators of revenue in the community pharmacy market through NHS prescriptions. The national contractual framework represents the primary source of income for many pharmacy contractors. Effectively the Department of Health is a monopoly buyer of pharmaceutical services. Therefore in negotiations they wield significant power, demanding fast and efficient prescription medication supply at a viable cost.

The financial crisis of 2008 followed by the bailout of banks placed a severe strain on government finances. A series of budget cuts were outlined in the 2010 comprehensive spending review to address the structural deficit. While the NHS budget was spared significant cuts, pressure to increase productivity in all areas resulted in the need for the NHS to deliver efficiency savings worth £20bn by 2014. Therefore it is unlikely that new investment will enter into the contractual framework. At present the savings have been implemented through a concerted effort to reduce spend on drugs. For example the October 2011 negotiations led to a reduction of £39million in category M to March 2012. Although the Department used these drug budget savings to support the New Medicine Service, there is no guarantee that future savings will be invested back into the pharmacy sector.

Against this economic backdrop healthcare outcomes need to improve, efficiency needs to increase, but without additional investment. Pharmacy has been described as key in achieving this by helping shift care from expensive secondary care settings to comparatively cheaper primary care settings in the community (Department of Health, 2010).

The role of community pharmacy in delivering this ambition has been described in several policy documents, most recently by the NHS Future Forum. An attempt at enacting this policy has been through the development of Healthy Living Pharmacies⁵⁷.

The fragmented nature of the retail pharmacy industry does not aid the contractors' position within these negotiations. The Department of Health and the NHS are deeply political organizations, with all major decisions requiring ministerial sign off. Larger firms can afford to lobby at the parliamentary level, while smaller contractors need to rely on the PSNC. Therefore the PSNC has to manage the interests of a wide range of businesses which can undermine negotiations, further adding to the power of the Department of Health.

As a consumer, the Department of Health will continue to seek efficiency improvements at the expense of community pharmacy contractors. The year-on-year growth in contract funding has failed to keep pace with the growth in prescription items (see chapter 3). It is unlikely that this will change, in fact, the Department of Health is likely to require even greater improvements in productivity.

⁵⁷ As described in the appendix

Beyond supply, the Department of Health also demands a return on the investment made in nationally commissioned advanced services. In particular MURs have been criticised for not achieving sufficient improvements in healthcare (Cook, 2012). Reference costs for inpatient admission are £1,400 per patient (Payment by Results team, 2011). Therefore if 1 in 50 MURs prevents a medication related admission then the service is cost neutral. However, as a consumer of this service the Department of Health requires evidence for its continued investment. For this reason a national evaluation of the most recent advanced service -the New Medicines Service- has been commissioned (see chapter 4).

Primary Care Commissioners

In 2010 the government White Paper “Liberating the NHS” represented the biggest fundamental restructure of primary healthcare services since the inception of the NHS. This set out a vision for placing power in the hands of local clinicians in GP led clinical commissioning groups. These groups will be responsible for the provision of health services and healthcare budget within a locality. Although the extent to which they will commission services from community pharmacy is currently unknown it is unlikely that pharmacy services will be a priority. In the short term local services will be GP commissioned, but without the links and support between general practice and pharmacy, this is unlikely to produce positive results. Indeed, community pharmacy will need to develop better relationships with the rest of the NHS if it is to capitalise on these developments.

Under the new configuration, Public Health England (PHE) and Local Authorities (LAs) will use NHS pharmaceutical services for the delivery of public health services, which are subsequently recharged to the national commissioning board. However the national commissioning board and the local authorities will inevitably seek to limit their exposure to the costs of general pharmaceutical services.

Beyond services, these primary care commissioning groups will also govern the nature of prescriptions dispensed. In doing so they can exert significant influence over the remuneration that pharmacy contractors receive by adjusting what and how much is prescribed. For example, if doctors are encouraged to prescribe three monthly prescriptions, then community pharmacy income from prescriptions will decrease.

Creating the mind-set within the Department of Health, GPs and patients that pharmacy is a credible player within the primary care arena will require significant investment in building relationships outside of the current market. The profession needs to embrace

these services as part of their practice and drive them forward if success in these areas is to be achieved.

The General Public

The final 'buyers' are the patients who purchase healthcare products and present their prescriptions for dispensing. Patients can decide where to take their prescriptions and are free to move from one pharmacy to another. According to an OFT survey of 1,000 households, 94% claimed to have a 'usual chemist' for their prescriptions (FDS international, 2003). These pharmacies offer social stability and support, especially for the more vulnerable in society (Continental Research and Solutions Research, 2008). In the same market research patients described locality, convenience and waiting time as the most important factors when deciding which pharmacy to patronate.

The choice of pharmacy for a P medicine is driven mainly by convenience and locality (62 per cent) but also by the availability of staff who can offer advice (23 per cent) (FDS international, 2003).

Consumer behaviour in OTC medicines and health and beauty products reflects typical retail dimensions of cost, convenience and service quality. For some, convenience is important, for others, dimensions of product range or price take priority (table 6.2). There has been a strong growth in own label OTC products in categories previously dominated by well-known brands (Wood, 2009). This is because consumers are "feeling the pinch" and therefore willing to trade down from branded products. As such consumers are gravitating towards supermarkets, which offer convenience and lower prices, taking market share from pharmacies (Keynote, 2011).

Compared to supermarkets, retail driven multiples are recognised as being more expensive for health and beauty products. They are attempting to maintain market share through customer loyalty, reward card schemes, depth of product selection and higher customer service standards. However the trend shows a shift in consumers from pharmacies to supermarkets.

The older population are more empowered and demanding than their predecessors. They are less likely to be duped by promotion led tactics. Therefore the emphasis within the sector is likely to switch from promotional led tactics that drive impulse buying towards more everyday low pricing that supports large volume sales. Such strategies support those companies with sufficient buying power.

Despite the loss of market share, the overall sector is growing. Health and beauty sales remain resilient as these represent the main non-discretionary spending of consumers. Given the arguments presented above, the overall growth for traditional pharmacies will most likely be minimal as a result of market saturation and the increasing competition from supermarkets.

Euromonitor data suggests that in 2011 health and beauty specialist retailers increased by 4% in current value terms with a stable 1% growth in the number of outlets and sales area (Euromonitor, 2012). The sector is underpinned by the affluent female middle classes. But growth has been attributed to the expanding interest in personal health and well being and the aging population, that demand specialist health and beauty products (Euromonitor, 2012).

As shown in table 6.2, for pharmaceutical services consumers prefer expertise and quality and are willing to travel further to receive them. The attributes associated with services, such as obtaining a diagnosis, expert knowledge on medical conditions, ability to have an examination, and a professional who is able to access medical records all influence where patients go for advice (Hughes et al., 2008). Yet the challenge for pharmacists and pharmacy contractors is that these attributes typically sit in the general practice domain. Discrete choice experiments suggest that consumers currently have a strong preference for GP advice over pharmacy advice for both minor and more complicated medical problems (Porteous et al., 2006). If pharmacy contractors are seeking to provide more services then they will need to adopt qualities traditionally associated with general practice.

Table 6.2– Dimensions of consumer choice for pharmacy goods and services (adapted from Office of Fair Trading, 2010)

	Prescription medicines	Pharmacy Medicines	General Sales list medicines	Clinical Services
Proximity	😊😊😊	😊😊	😊😊	×
Opening Hours	😊😊	😊😊	×	×
Waiting Times	😊😊😊	×	×	×
Convenience/ one stop shop	😊😊	😊😊😊	😊😊😊	×
Range	×	😊😊	😊😊😊	×
Price	×	😊😊	😊😊😊	×
Advice/Expertise	😊😊	😊😊😊	😊😊	😊😊😊
Quality of Service	😊😊	😊😊	×	😊😊😊

Key: 😊😊😊 important to many consumers; 😊😊 important to some consumers; 😊 important to few or not relevant.

Consumers are uncertain about pharmacists’ training and knowledge (Department of Health, 2009a). Research suggests that there is a correlation between understanding of pharmacists’ expertise and patient willingness to ask for advice. However it is not solely consumer education that is required to change behaviour, but also adequate resources. For example consumers consider that poor privacy prevents pharmacies from providing blood pressure testing or diabetes services (Department of Health, 2009a). Further examples are listed in table 6.3. Consequently consumers believe that more serious tests would be less appropriate in a pharmacy. Although they are willing to accept the role that pharmacists play in common minor more manageable illnesses (Department of Health, 2009a).

Table 6.3– Negative Consumer Views of Community Pharmacy

Dimension	Consumer Views
Environment	Perception of cluttered and busy environment, particularly independents
Privacy	Lack of appropriate environment in which to perform services
Records	Lack of access to a shared medication or healthcare record
Training	Lack of qualified staff to perform services and a basic lack of knowledge of pharmacists training
Joined up Working	Fears over the two-way communication between general practice and community pharmacy
Feminisation	Viewed as a very feminine environment, which is not ideal for most male consumers.

Source: adapted and updated from Pharmacy Consumer Market Research, OFT, 2010, DH,2008.

Across the different buyers, pharmacy contractors sit in a relatively weak position. The reliance on the Department of Health for the majority of income coupled to the challenging retail environment suggests that the market will face a tough time ahead. The strategy put forward by government policy is to invest in clinical service delivery. But to meet these demands pharmacies will need to increase service awareness, invest in the pharmacy environment to improve privacy, develop integrated records and educate patients. The ease of implementing such changes when income streams are being squeezed should not be underestimated.

Suppliers (Strong)

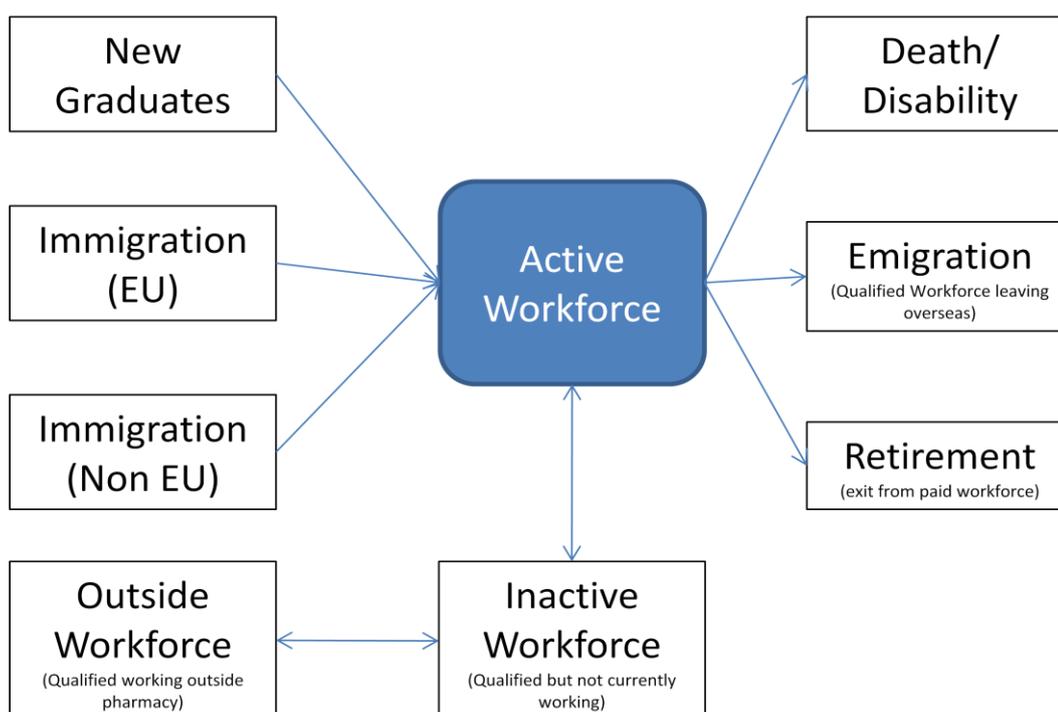
There are several suppliers into this market. This is not only those suppliers associated with products such as the pharmaceutical industry and medicines wholesalers, but also those associated with the supply of labour. Indeed, the universities and government represent the main controllers of the adequate supply of trained labour.

Community Pharmacy Labour Market

Pharmacists

Pharmacies require a pharmacist who has undertaken five years of graduate training at an accredited university to be present in order to trade. There are currently over 45,4580 registered pharmacists in the Great Britain⁵⁸. Of these 71% of pharmacist are employed in the community sector, with just over a fifth in hospital practice (21.4%), and 7.2% working in primary care (Seston and Hassell, 2009a). With the exception of 2005⁵⁹, the number of pharmacists joining the register has grown steadily at about 2% each year since 1997. However, the number joining the register recently has increased dramatically, driven by both supply and demand. Figure 6.5 represents the different factors to be considered in the pharmacy labour market.

Figure 6-5– Workforce Flow Model



Source: Adapted and updated from Guest et al (2008).

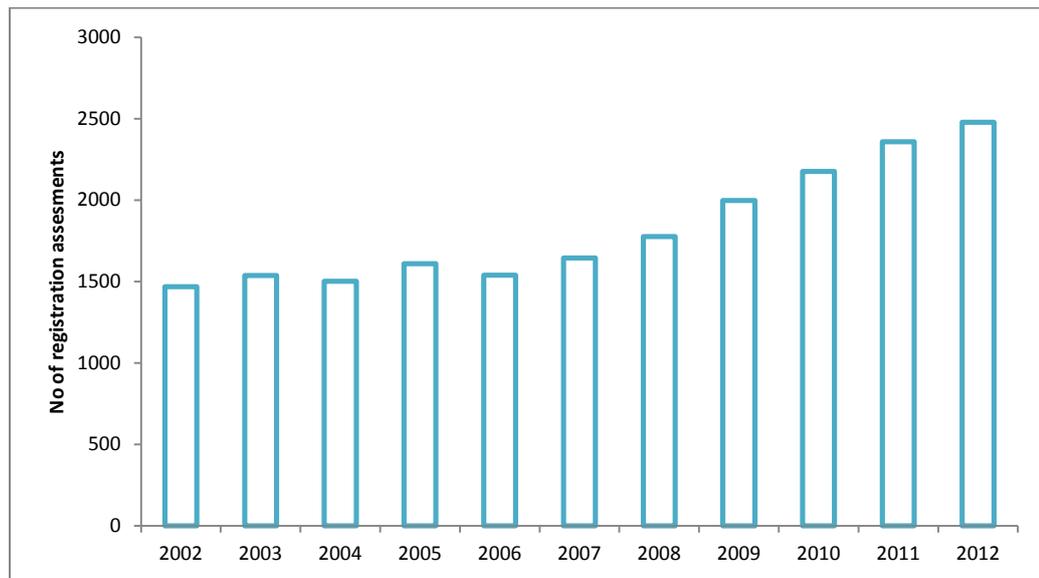
In 2010, 2,505 new trainees entered pharmacist pre-registration training, bring the total number of trainees that year to 3,071 (General Pharmaceutical Council, 2011). This is compared to a figure of around 1,000 a decade ago. This surge in numbers has been created by a swell in undergraduates studying pharmacy. New schools of pharmacy at the

⁵⁸ Personal Communication with General Pharmaceutical Council 28th May 2012.

⁵⁹ In 2005 a new payment structure resulted in more pharmacists leaving the register.

University of East Anglia in 2003, Reading, Kingston and Medway in 2004, Hertfordshire in 2005, Wolverhampton, Huddersfield and Keele Universities in 2006 and the University of Central Lancashire in 2007 have all contributed to the increase in the number of students studying pharmacy, and subsequently applying for the registration assessment (figure 6.6) and entering the pharmacy labour market. This has happened at a time where existing schools of pharmacy, under pressure from changes in higher education funding, have also sought to increase their numbers⁶⁰. Further new pharmacy schools are planned.

Figure 6-6– Number of Registration Assessments

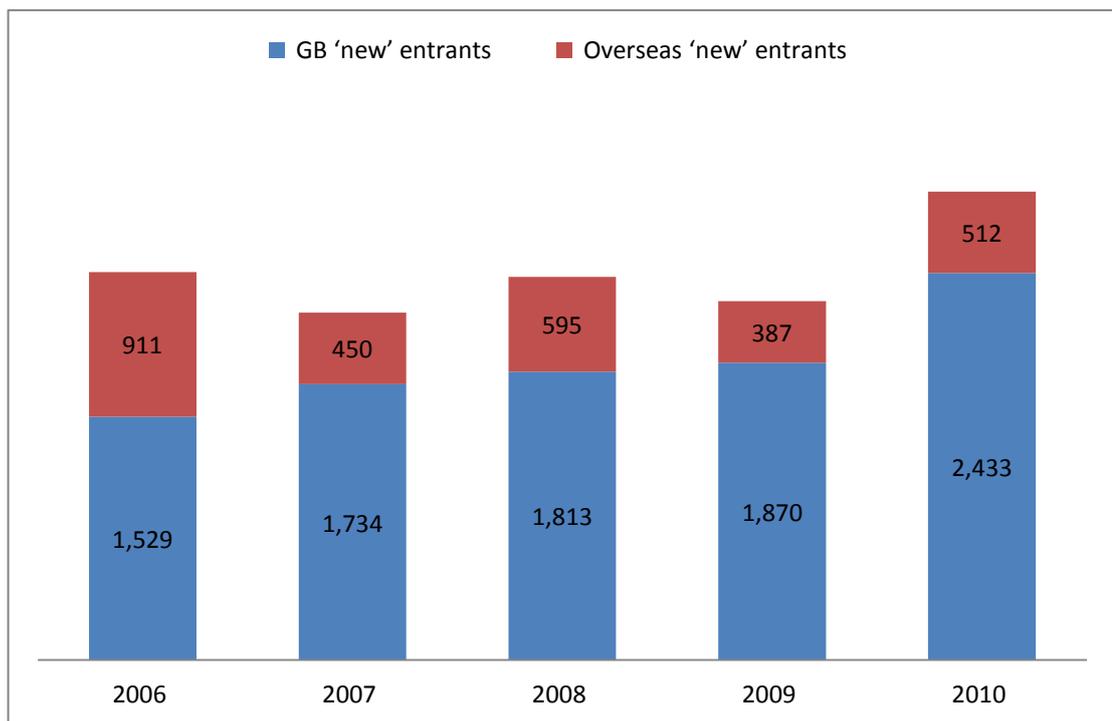


Historically there has been a slight undersupply of pharmacists for workforce requirements. This had led to pharmacists being classified as shortage occupations by the UK border agency Migration Advisory Committee. However it was recommended in November 2011 that pharmacists be removed from the list⁶¹, reflecting the changing balance in pharmacy numbers driven by new entrants. Since 2006, the proportion of pharmacists who come from overseas has remained fairly static (figure 6.7), representing about 12% of the register (Seston and Hassell, 2011). The most popular route of entry for these pharmacists was via the European Route (44.6%) (Seston and Hassell, 2011).

⁶⁰ Further details of this have been published by this author on behalf of the British Pharmaceutical Students Association. http://www.bpsa.co.uk/pressreleases/BPSA_Student_Numbers_Discussion_Paper_-_17th_July_2012.pdf

⁶¹ <http://www.ukba.homeoffice.gov.uk/sitecontent/newsarticles/2011/november/18-short-occup>

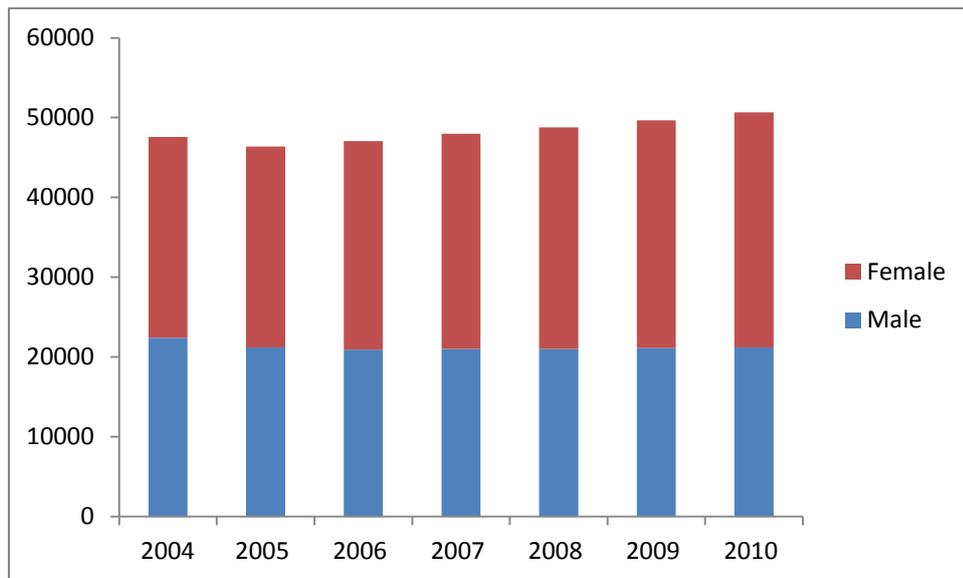
Figure 6-7– Entrants to the Register 2006-2010



Source: (Seston and Hassell, 2011)

Those leaving the register have also remained fairly constant. However, the inactive workforce has grown slightly due to the increasing feminisation of the profession. New female entrants to the profession outnumber men by two to one (Seston and Hassell, 2009b) a pattern being mirrored around the world (International Pharmaceutical Federation (FIP), 2009). The pharmacy workforce census found an increased prevalence in portfolio working, part time working (Seston and Hassell, 2009a), which is driven by feminisation (figure 6.8). The tendency of the female workforce to work part time or to have career breaks can be attributed to the demands of child care.

Figure 6-8– Feminisation of the pharmacy profession



Source: (Seston and Hassell, 2011)

The full effect of the increase in numbers is yet to be felt. However the effect of more graduates entering the register will inevitably lead to greater competition for jobs. The new graduates may be considered to be a threat to those already employed as their training is more clinically orientated than their experienced colleagues. This may lead to a shift in the demographic profile of the profession and in turn result in a loss of experienced staff.

The pharmacy workforce census suggests that more than a third of pharmacists in the community sector work as locums (Seston and Hassell, 2009a). The availability of locum positions is likely to decrease because of the swell in graduate numbers. As a result securing work will be harder and therefore those working as locums are likely to opt for the security of permanent contracts. Therefore the work-life balance and flexibility that locum work once offered (Shann and Hassell, 2006) may decrease, forcing these workers out of the profession.

It is likely that the position developing in England is likely to follow that of countries like Sudan, unless policies relating to recruitment of trainees in the higher education sector are reviewed. In Sudan, the number of pharmacists increased by 130% over twenty years as a result of government policies to expand higher education. The result was an oversupply of pharmacists, particularly in urban areas (International Pharmaceutical Federation (FIP), 2009). There is anecdotal evidence of this beginning to happen in urban areas of England.

Unless more jobs can be created to meet the current supply of pharmacists, it is likely that the overall effect will be a decrease in the average salary of pharmacists. On one hand it is argued that increased competition in the labour market will improve quality. On the other, the knowledge that a pharmacist can be easily replaced may prevent them from exercising professional autonomy that is in contradicts their employers wishes, even if it is in the interest of the patient. Therefore pharmacists are likely to have less autonomy and more likely to obey the demands of their employer. However, the recent creation of a pharmacist's union may mitigate the extent of this in practice.

Registration of Pharmacy Technicians

Support staff are often the first point of contact for many customers and are integral to the running of a pharmacy. It is imperative that the values of this interest group are not underestimated. Measures introduced by the Government in response to the current economic climate include a commitment to making efficiency savings in the health service. In this context the development of pharmacy technicians is important strategically as this group are increasingly being considered as a group for intra-professional role-substitution (Willis et al., 2011).

In July 2009 statutory regulation of pharmacy technicians began on a two year voluntary basis, becoming mandatory in July 2011. Currently there are 21,000⁶² registered pharmacy technicians in England. As with the pharmacist workforce, most technicians work in community settings. As many as 40% of community pharmacies operate without a technician, compared to the hospital setting where most pharmacists work with one (Schafheutle et al., 2008).

Substituting labour to technicians is not a new proposition. It was first recommend in the Nuffield report that pharmacists should delegate activities to suitably trained staff (The Nuffield Foundation, 1986). In the hospital sector pharmacy technicians have successfully extended their roles in response to the long-standing shortage of pharmacists since the early 1980s (see chapter 1). In secondary care settings pharmacy technicians have successfully extended their roles to release pharmacists into more clinically orientated tasks. Yet this reconfiguration of roles has not been achieved in the community sector (Hassell et al., 2002), primarily due to liability issues associated with personal control and supervision.

⁶² 20,998 registered pharmacy technicians 28th May 2012.

Current evidence of the effectiveness of labour substitution is positive, but based on small-scale, descriptive studies where the research design prevents generalisation to other settings (Willis et al., 2011). There is little evidence that labour substitution in community pharmacy is cost effective. For example, Savage (1995) found that when comparing two pharmacies with and without a technician, an hour of pharmacist's time could be released each day. However, this time was sporadic and not predictable in the working day, thus preventing the time being used for improving patient care (Savage, 1995).

While the UK evidence remains weak, European experience suggests that this sector of the workforce could grow. Pharmaconomists in Denmark, prescriptionists in Sweden and pharmacist's assistants in Holland are able to undertake pharmaceutical tasks with a greater level of responsibility when compared to their UK counterparts. However, compared to the UK, these 'technicians' have longer periods of training. Prescriptionists are trained to Bachelor degree level, similar to a UK BPharm, and are therefore able to complete technical tasks without supervision. As are Dutch pharmacist's assistants, who are able to dispense prescriptions, counsel patients and undertake medication reviews without the direct supervision of pharmacist. However the current regulatory environment in community pharmacy practice and the training of UK technicians limits the further development of technicians' roles.

Pharmacies have medicines counter assistants and pharmacy (dispensing) assistants in addition to pharmacists and pharmacy technicians (Schafheutle et al., 2008). The consistency of support staff across the industry is hugely variable. There is little national data on this workforce, although NHS staffing survey reports that there are 3,569 FTE pharmacy assistant posts in NHS trusts in England (NHS Pharmacy Education and Development Committee, 2011). The average number of employees in the pharmacy any time varies across pharmacy type between 1.7 employees (for supermarkets) and 3.9 employees (for smaller multiples) per hour that the pharmacy is open (PricewaterhouseCoopers LLP, 2011). This suggests that nationally there are in the region of 30,000 non-pharmacist full time equivalents employed in this sector.

Workforce capabilities and education

The reengineering of the pharmacy education in schools of pharmacy is creating practitioners who are more competent in clinical care roles and proactive care delivery. Those joining the profession should be able to embrace extended pharmaceutical roles with greater ease. However, if those opportunities to practice clinical skills do not exist,

then it is likely that they will be disillusioned and leave the labour market. Therefore creating a synergy between the activities of the sector and the education of pharmacists is important to keep the workforce motivated.

Pharmacists already in practice will need to consolidate their knowledge and develop their skills to become 'clinical practitioners' if the profession is to embrace the 'utilisation' demanded by policy. This requires a payment structure and culture that supports the development of education in the workplace. However such a requirement is unlikely to be achieved in the short term future because incomes into community pharmacies are strained.

Wholesalers

The pharmaceutical industry is the main originator of prescribed pharmaceuticals in England. Their profits are governed by the pharmaceutical price regulatory scheme (PPRS). As a result of the 2009 negotiations the industry reduced prices by 3.9% in February 2009 and 1.9% in January 2010. As pharmaceutical companies reduce prices they have sought to limit their exposure by introducing reduced wholesale or Direct to Pharmacy schemes. These schemes remove the discounts applied in the supply chain to help maintain the manufacturers' margins. These distribution arrangements are significantly less lucrative for wholesalers, although for the time being do not financially impact pharmacies beyond the additional complexities of the supply arrangements (Office of Fair Trading, 2007). The justification for these arrangements is to prevent counterfeiting and to maintain the integrity of the supply chain, and currently the manufacturers have to demonstrate that pharmacy profitability is not impacted⁶³.

The UK wholesale market is separated between a handful of large full line wholesalers and numerous smaller short line ones. These groups can significantly influence the ability of a pharmacy to obtain a 'purchase profit' through the pricing structures and discounts that they offer. They are being squeezed by their suppliers in the pharmaceutical industry and are therefore passing this onto community pharmacies further down the supply chain. This reduces the margins for all of the actors involved.

By contrast OTC products are traded like most other retail commodities. Consumers expect branded pharmaceuticals, such as Nurofen and Benadryl to be stocked in pharmacies. In negotiations the grocers and large retail led multiples are able to obtain larger discounts

⁶³ Further discussion of DTP schemes is described in chapter 3.

due to their buying power. As consumers trade towards own label products, those contractors with strong product ranges and internal suppliers are able to entice more custom. This leaves smaller pharmacies in a weaker position, and has led to the increase in the number of buying groups in an attempt to sustain margins.

Virtual Chains

In order to address the imbalance between the buying power of the large multiples, many independent contractors have opted to join buying groups. In the UK about a third of pharmacies are members of voluntary groups. The largest of these groups is Numark, with over 2,640 pharmacies as members, owned by the wholesale distribution company Phoenix who took charge in 2005. The group grew in 2008 following a merger with NuCare. In similarity with other major wholesalers, Numark offers a joint ownership scheme to enable pharmacists to open new premises. The debt equity scheme allows pharmacists to have a 49% share and Numark a 51% share of the business. After five years the pharmacist can purchase Numark's share

Alliance Healthcare introduced Alphega, the leading network of pharmacies in Europe to the UK in 2009 and currently has 700 members in the UK. Other buying groups include Avicenna, CamRx, PharmaPlus and Cambrian Alliance.

Avicenna is primarily a buying group with over a thousand members. Pharmaplus (formed after the merger of Pact group and Wisebuys) has a membership of over 200, and acts as an advocate for independent pharmacies. CamRx brand themselves as a pharmacy development group, and like Cambrian Alliance, work to represent independent pharmacy interests.

Changing structure of Medicines supply

The nature of the products supplied on prescription by community pharmacies is changing. The 'blockbuster' innovations of the previous decades have reached the end of their patent lives. The market, by volume, is therefore predominately generic products, with little sight of significant innovation in solid dosage forms (Light and Lexchin, 2012). New pharmaceutical products tend to be focused on secondary care, and represent complex technologies that require increased monitoring and support for administration.

The result of this in the medium to long term is that through whatever mechanism the discount and margins available to pharmacy contractors will decrease. As the genericisation

of medicines continues, the relative value of the products that pharmacies supply will decrease. At this point questions will be asked about the cost of the supply chain that in some cases is ten times the cost of the product being supplied.

Substitute products (Weak)

The above average degree of political and regulatory intervention in the pharmacy market makes substitutes a minimal threat. Firstly, the government has conferred in doctors, dentists and other suitably qualified healthcare providers the exclusive rights to prescribe medication for NHS patients. Pharmacists (and in some cases doctors) have been provided the exclusive rights to supply these prescribed medication to consumers. Secondly, the government pays for the cost of the medication supplied as well as additional fees associated with the supply process, such as the pharmacists' professional dispensing fee. As the eventual payer of medications, the government seeks to use methods to control and balance the costs of drugs supplied in the NHS. Thirdly, the government limits who can supply those medications and in what locations, by adding controls upon the market.

Therefore the only alternatives for medication supply are dispensing doctors or secondary care facilities, such as A&E. However, internally within the market substitute supply through internet pharmacies could create competition for traditional community pharmacies on the high street, as could the potential expansion of GP businesses into dispensing. For pharmaceuticals services general practices but also health and fitness centres are potential threats⁶⁴.

⁶⁴ These are both considered in the section that relates to market rivalry.

Summary

The combination of the forces identified using the Porter’s framework represent eight market attributes that those within the sector need to be cognisant of in the future. These attributes, shown in table 6.4, represent variables that require consideration in any future models of practice.

Table 6.4 – Main drivers of Community pharmacy

	Summary Statement
Economy	Future investment in public services and health will remain limited for the foreseeable future. Government investment in pharmacy and other healthcare services will continue to be restricted.
Consumerism	The aging population will demand more a higher standard of care and be more demanding of future healthcare services.
Technological Advancements	Technology has the potential to dramatically change the supply model and alter the nature of rivalry between pharmacies.
NHS Reconfigurations	The buyers with the market are changing, which could shift the ability of pharmacy contractors to be commissioned. There are potential threats and opportunities for services to be commissioned from pharmacies.
Market Entry and Consolidation	The current framework of market entry is unsustainable and is therefore continues to intensify internal rivalry.
Structure of Medicines Supply	Prescription volumes are increasing and medication prices are lowering. The changing nature of medicines supply places increasing power in the hand of manufacturers and limits the power of pharmacy contractors in negotiations.
Workforce Capabilities and Education	The capabilities of the profession to deliver an altered model of practice is an essential component of change beyond the status quo.
Organisational Unrest	The business rivalry internally has led to organisational distrust, which has negated a united strategic view for the profession. This is echoed by the lack of strong leadership within the professional body.

Chapter Conclusion

Porter's framework provides a suitable strategic basis on which to view the pharmacy market. There are several important conclusions to draw from this analysis. First is the unpredictable effect of macro-economic forces on community pharmacy businesses. The downturn of global markets has meant that significant 'new' investment into community pharmacy is unlikely. The NHS reorganisations may possibly present a window of opportunity for investment, but given the rivalry between GP and pharmacy in primary care this would, in the short term, appear unlikely.

The buyers in the market are also affected by the wider economic downturn. Consumers, operating under restricted budgets, are more price conscious and demanding more for less. This squeezes the margins across the pharmacy business. The main buyers in pharmacy, the Department of Health, are also experiencing budgetary constraints. They are seeking to find ways of reducing spend on medicines, a trend that began before the economic crisis and one that looks set to continue. Community pharmacy businesses are finding that their revenues from the NHS are being reduced; a trend that is unlikely to reverse in its direction.

The suppliers and other actors in the medicines supply chain are equally seeking to maintain their profit margins. In doing so the environment for pharmacy is becoming more competitive as a result of reduced 'purchase profits'. The margin may be offset by a reduction in the largest cost to the business; labour. The increase in pharmacy graduates, unless controlled, will drive salaries for community pharmacists down across the sector. The workforce, uncertain about the security of their jobs, and suffering from the effects of increasing workloads are disillusioned about the future.

Taken together these forces for change and threats in the current community pharmacy market are placing pressure on current profit levels. Strategically the pharmacy market will need to represent itself in such a way that allows it to continue to receive premium incomes and develop strategies that allow the business to be sustainable. If the trends observed within each of these domains continue to full effect, then the current viability of community pharmacy businesses will be brought into question.

The purpose of the business in societal terms remains uncertain. To many people, particularly consumers and general practitioners, the purpose of the business is to supply prescription medicines together with health and beauty products. Yet, those in policy

circles continue to describe the purpose of the community pharmacy as being one of public health delivery that addresses inequalities in health.

The payment for medicines does not purely represent the product supplied. It also understood to include a recompense that supports the 'value' of the community pharmacy business to health and social care (appendix C). Yet several disruptive technological developments have the potential to fundamentally change the nature of medicines supply and undermine the value currently added by the business.

More recent investments in the sector have been based on a transparent fee per service model which remunerated pharmacy businesses for advice. Yet such models require evidence of outputs and healthcare gains if they are to continue to receive investment. As such businesses across the sector are likely to change their model from relying on supply towards reliance on advice and proving the 'value added' by the business.

There are many different strategies that can be taken in the short term to develop the community pharmacy business. However, these rely to a large extent of the level of future funding provided by the government to support the development of community pharmacy. The range of service begins at a position of limited investment where the purpose of the service is purely to maintain the supply of prescription medicines at the lowest possible cost. The alternative end of the spectrum is a pharmacy service that has increased levels of investment and moves towards becoming a central part of the healthcare service, acting alongside and in conjunction with general practitioners. It is the development of these strategies and the alignment of the strategies with the professional models that forms the basis of the discussion in the final chapter.

Chapter 7. De-professionalising pharmacy and re-professionalising pharmacists? – Discussion

Chapter Introduction

This thesis has presented qualitative and quantitative research findings generated via a series of separate, although logically linked, studies. This final chapter provides a narrative synthesis of the total body of research and original thought offered. It addresses the fundamental research question at the heart of this body of work, namely *How are business and professional practice models for community pharmacy in England likely to be structured in ten to twenty years time?*

Even within the relatively narrow parameters of the UK pharmaceutical sector there are many aspects of the future which cannot be accurately predicted. But for those seeking to safeguard and support the ongoing development of community pharmacy in a complex, evolving, world it would be wrong to ignore the potential value of rational forethought about major trends, and the ways in which demand for medicines and their effective use will alter as the next two decades unfold. Without open minded, critical, inquiry it will be impossible to determine what established aspects of the profession are most worth defending, and what new capabilities are most worth pursuing.

This chapter begins by briefly reiterating the background to the development of modern community pharmacy practice. It re-examines material from the literature review contained in chapter 1 in the light of the additional findings presented in subsequent chapters. It then seeks to explore the perceived 'problem' that underlies the research question posited above before discussing the possible 'solutions' identified. This relates to changing expectations of, and needs for, pharmacists' services and their capacity to adapt to meet existing and new needs at least as cost effectively as other potential service providers. Alternative future scenarios are considered, along with the views of different stakeholder groups with direct or indirect interests in pharmacy related business and/or professional activities (see chapter 5). Aspects of the power and dependency relationships within pharmacy and between pharmacists and other groupings, such as the medical profession and its members, are investigated.

The concluding sections of this chapter then return to the Freidsonian perspective on (health) professionalism as it applies to modern community pharmacy, before discussing some of the limitations of the research methods used and highlighting opportunities for future work. Freidson's work on the sociology of professionalism was outlined at the beginning of this thesis. It is argued here that community pharmacy as a profession is only likely to enjoy a 'strong' future if its members understand the need to balance his 'three logics' of bureaucratic (typically politically led), market incentive driven and professional directed control in the work place, and follow a 're-professionalisation' strategy that genuinely seeks to make substantive value-adding contributions to the public good, rather than pursuing sectional or merely rhetorical goals.

Background

In national settings like that of England a significant attrition of the 'traditional' pharmacist's role took place in the first half of the twentieth century. This occurred as a result of the transfer of medicines manufacturing from the profession to the pharmaceutical industry. In the wake of that historic shift, the impact of the Second World War on British society led to the development of publically funded health and (at least to a degree) social care. The birth of the NHS in 1948 further eroded the compounding function of community pharmacists and coincided with the introduction of many more 'prescription only' medicines. Together, these developments led to a sustained increase in prescription numbers coupled with a shift away of many consultations about illness from pharmacy to the general practice setting.

This was desirable in as much as it was a reflection of improved access for most of the population to primary healthcare services. Yet the impact on pharmacy was mixed. Increased dispensing volumes served financially to support community pharmacy businesses. But community pharmacists were to a degree marginalised as health care providers, not least because they in the main felt obliged to retreat to the 'back of the shop' to conduct and/or supervise dispensing and allied activities.

Prior to the formation of the NHS pharmacists were recognised as practicing with a high level of autonomy. Their standing in the community and their knowledge of medicines allowed them to advise and treat people as they felt fit, even if the lotions and potions supplied were of questionable efficacy (Anderson, 2008). Community pharmacists often provided semi-formal health care to the less prosperous, whilst doctors tended to focus

their attention on the wealthier classes. The asymmetry of knowledge underlying exchanges between professionals like pharmacists and the public tended to promote 'paternalistic' practices and facilitated the development of a 'social contract' that allowed pharmacists to charge premium prices for the products they sold, balanced by the 'free' advice accompanying them. Knowledge asymmetries between consumers and service providers lie at centre of the social processes leading to 'professional' status (Freidson, 1970).

However, as suggested above, community pharmacists' discretion to treat conditions was reduced by the creation of the NHS and allied mid 20th century developments. They were in effect forced to spend most of their time dispensing general medical practitioner written prescriptions for treatments. This benefited the standing of GPs as against community pharmacists, whose position was further challenged by growing public awareness that increasingly powerful medicines were being supplied in 'patient ready' dosage forms by the emergent pharmaceutical industry.

In addition, the growth of prescription volumes aided the expansion of commercial pharmacy chains, which benefited from savings to scale and linked supply chain economies. This made pharmacists more likely to be employees than owners. In association with this trend, both the NHS and corporate management began to push for greater standardisation of behaviours and practices to promote efficiency and service quality as defined in their process and task oriented terms. This further impacted on the perceived standing of pharmacists as autonomous health professionals.

Notwithstanding educational and allied reforms designed to offset such effects, the available evidence indicates that community pharmacists gradually became regarded as an 'under-utilised resource' (chapter 1). Despite being busy, the content of their role has increasingly been seen as discordant with the substance and ambitions of their professional training. It can be argued that this in time helped to promote changes in the functions of the Royal Pharmaceutical Society. Yet since the 1990s reforms across the entire UK healthcare sector have gravitated towards a rebalancing of both internal and external professional power and dependency relationships.

For pharmacy this led to the establishment of the General Pharmaceutical Council, which ultimately answers to the public for its governance of the profession. Managerialism and extended regulation have acted to control the work environment for pharmacy in a way

which serves to limit not only individual but also collective 'autonomy', and arguably to weaken further the 'traditionally' defined professional status of community (and other) pharmacists. Loss of ownership opportunities and falling incomes relative to both medicines supply work load and the medical profession's earnings have further influenced the situation of pharmacists. So too may have the emergence of relatively assertive forms of 'consumerism' in the health arena.

The 'normalisation' of some forms of medicines supply and use through increased access in non-pharmacy outlets such as supermarkets and petrol station forecourts, coupled with the greater 'lay' access to knowledge about pharmaceuticals and their appropriate employment, have to an extent 'de-mystified' pharmacists' – and to an apparently lesser degree doctors' – roles. The basic mechanism implied here is that exclusivity over access to and the ability to interpret the knowledge at the centre of the pharmacists' professional 'territory' has been undermined by technical and social progress. Hence the 'power' enjoyed by pharmacists by virtue of their 'agency role' has declined.

The Problem

NHS community pharmacy businesses rely heavily on NHS prescription dispensing and allied payments for their income. These typically account for over 80 per cent of revenues in independent pharmacies. But it is becoming increasingly possible to automate such 'semi-cognitive' work. Just as in the past many factory and agricultural tasks have been mechanised, this challenge is now confronting pharmacists. The genericisation of much medicines use, which is in many instances making it transparent that the current cost of dispensing is as much as (or more than) that of purchasing medicines from their manufacturers, is further destabilising the financial base of pharmacy businesses. Such trends are leaving the established community pharmacy business and its professional model increasingly exposed to fundamental questioning.

The Department of Health and other sources have already suggested that further cost savings could be achieved via the 'commoditisation' of medicines supply, in contexts ranging from product purchasing to prescription assembly (Agwunobi and London, 2009). This will, all other things remaining constant, over time push down dispensing fees to the lowest possible level consistent with public interests in safety and sustainability. Such a trend could render the typical community pharmacy business of today commercially unviable, and in reducing the returns available to normal profitability remove the economic foundation that has (whether or not it has been cost effective from a public interest

standpoint) in the past underpinned the provision of professional services other than dispensing in community pharmacies.

In line with this picture, service funders outside the DH have also questioned whether or not the premiums paid for the expertise of pharmacists in the supply of prescription medicines deliver value for money. It is increasingly being argued that (with the exception perhaps of the clinical screen, although computerisation could eventually impact this area as well) dispensing can today – given the development of pharmacy technicians' roles, as well as that of automated dispensing machines – be safely performed without the direct oversight of the pharmacist (Department of Health, 2008a).

Outside the profession it is often recognised that pharmacists are relatively well educated, and have a set of skills and knowledge that could be used to fulfil a direct health care/improvement role beyond that of simple medicines management. Yet their knowledge is not presently seen as being used to full effect. As noted above, it is this situation which has led to the conclusion that pharmacists are 'underutilised' (as distinct from under-occupied) and are 'wasting' their time on activities which they need not directly undertake.

Pharmacy policy documents in the UK and similar nations like The Netherlands have, with varying degrees of clarity, expressed such thinking since the early 1980s. Community pharmacists in England are currently processing, checking and supplying nearly a billion prescription items a year. While income streams remain closely associated with prescription volumes, it is understandable that these factors have driven pharmacists to the checking bench (chapter 2). Yet the commentary provided by the policy and practice research literature of the last three to four decades suggests that a more efficient, less wasteful, approach would almost certainly place pharmacists in a more direct health improvement role.

The pharmacy policy cadre, defined here as an amorphous leadership group disseminated across a variety of settings, has attempted to respond to the challenge to their core professional base by developing a strategy that shifts from a 'supply based product focus' to a 'patient based clinical therapeutics focus', while at the same time seeking to minimise both current business risks and the dangers associated with overt conflict with the medical profession. Terms such as 'medicines management', 'role extension', 'pharmaceutical care', 'medicines optimisation' and 'public health pharmacy' have filtered into policy documents. Their use implies that pharmacists should step beyond the logistical supply function and

embrace roles that support both patients and other health workers in their efforts to use medicines to best (or at least better) effect, in order to enhance health outcomes (chapter 1).

The new contractual framework introduced in 2005 represented an important step along this change pathway, by creating a tiered nationwide commissioning structure for pharmaceutical services. Yet barriers to increasing the supply of extended services (such as perceived inadequacies in funding, and in some instances a lack of individual expertise and/or confidence combined with a risk averse group culture) have persisted (chapter 4).

The research reported here indicates that the single most important impediment on the business model 'side' of the community pharmacy equation has been the current system's incapacity to incentivise incrementally sustained change. Evidence is emerging that pharmacists are able to perform wider health improvement roles in 'public health' areas such as smoking cessation (Blenkinsopp et al., 2003) and alcohol use moderation (Dhital et al., 2010), as well as in 'medicines optimisation' areas such as promoting greater adherence in medicines taking (Clifford et al., 2006). Yet pharmacists working in a business led environment presently tend to revert to the dispensing bench because it is not economically viable to re-allocate their skills to activities of this type.

One implication of this is that pharmacy businesses will require substantive investments to be made in non-pharmacy staff and dispensing automation, if a permanent re-allocation of pharmacy labour use is to be achieved. At present there do not appear to be enough opportunities to allow an economically viable rebalancing to take place (chapter 6).

Although the present contractual framework was intended to facilitate re-allocations of pharmacists' activity, it has failed to do so (chapter 2). Unless new agencies such as the NHSCB decide pro-actively to promote such progress it may in future become even more difficult for community pharmacy owners to re-engineer their NHS and/or wider primary care role.

Comparisons between the research findings presented here with those of previous UK based studies and the wider international literature underline the entrenched nature of early 21st century pharmacists' supply roles. The situation has been further complicated by regulation and governance arrangements which have reportedly kept community pharmacists in fear of prosecution for making dispensing errors (chapter 3 and appendix A) and (as noted above) further limited their 'professional autonomy'. The analysis presented

in this thesis suggests that many (especially younger) community pharmacists are eager to use their skills for health improvement but that in practice they are often prevented in having opportunities to do so (chapter 4). The resultant sense of frustration has added to the tensions associated with factors such as the commoditisation of dispensing services discussed in chapters 3 and 6.

In looking forward it may be argued that there is presently still a potential for both 'strong' and 'weak' community pharmacy futures. The latter would be one where the profession continues to be pre-occupied by the medicines supply and a narrow management role, with other groups – such as medicine and nursing – incorporating the clinical aspects of pharmaceutical care and optimal medicines use support into their roles. At the extreme, pharmacists could become replaced by less expensive technicians who would take on the main elements of supplying medicines to the public. The overall cost and profitability of the process would be minimised. The pharmacists displaced may (in competition with the increasing number of new graduates entering the market) be able to find employment in GP practices or other medically led community settings. But their individual earnings may over time fall to the levels paid to other practice employees, like nurse practitioners.

By contrast a 'strong' future scenario may be seen as one where pharmacists have a robust and well defined health improvement role, gained through the application of their current and as required extended future abilities in areas such as risk management, improved safety and health promotion (chapter 5). Such a future, based on demonstrably cost-effective value-adding contributions to enhanced public health and wellbeing, could represent an effective 're-professionalisation' strategy capable of bringing benefits to both service users and pharmacists themselves. It may be the case that any successful 're-professionalisation' strategy would at least in the short term need to be consistent with the commercial contexts within which pharmacists and pharmacies currently operate (chapter 6). However, incremental evolution may in time lead to radical change. At the individual level it may also, at least in some circumstances, be possible for those willing to accept risk for the chance of future gain (and/or who presently have relatively little to lose) to 'step out' of existing pharmacy structures into new environments.

Secure professional groups normally require clear boundaries that define their functionally relevant practices and identities (chapter 1). Yet within community pharmacy there is disagreement as to the best way to progress. The objectives and interests of, for instance, younger pharmacist employees as opposed to pharmacy contractors may often overlap,

but are not necessarily identical. Such realities can cause confusion, if not overt conflict, and lead different stakeholders to perceive the 'problem' that needs to be resolved in differing ways (chapter 5). Further, powerful external influences like that those linked to political expectations and expediencies may on occasions require pharmacy to go down paths that are not necessarily the most rational or beneficial from a health gain standpoint. Such realities cannot be ignored. However, neither should they be permitted to obscure public interests or conceal important long term opportunities.

Possible Solutions

There are several broad conclusions that can be drawn from the research evidence presented in this thesis, which offer insights relevant to developing solutions to the problem identified above. They include, first, the understanding that **pharmacists must genuinely be willing to adapt and change, to use their existing and as necessary new skills to meet the evolving needs of societies they serve** if they are to embrace a successful 're-professionalisation' strategy (chapter 4). The latter will need to incorporate the concept of cost effectiveness as central to the meaningful optimisation of medicines supply and use, if a continuing role for pharmacy is to be found acceptable by the community as a whole.

Second, following on from the above, **there is a need to re-specify the twenty first century role requirements of pharmaceutically qualified professionals working in the community setting**. Current ambiguities relate to the balance between drug supply and clinical care delivery, and the extent to which community pharmacy based services could and should compete with and be able to substitute for, as opposed to complementing and enhancing, GP and allied services (chapter 3). Seeking radical primary care re-design as opposed to current system improvement may well involve higher risks and uncertainties for all the professions involved than would incremental modification of the status quo. But from a public interest viewpoint it may also offer greater potential advantages.

Third, on the basis of the evidence gathered during the work undertaken for this thesis and presented in previous chapters, **perceived and actual conflicts between the commercial imperatives underlying pharmacy as a business and the values that community pharmacists aspire to have as professionals represent a significant barrier to overall service improvement**. They therefore need to be understood clearly so that effective action can be taken either to reconcile them, or dispel needless fears. One important issue

to consider in this context relates to the extent to which corporate cultures can internalise professional values.

When seeking to identify ways forward in relation to the above it is of note that Freidson (1970, 1994) argued that professionals need both an ideology and a practical commitment that expresses a greater devotion to 'doing good' than to obtaining financial rewards. On this basis pharmacists and pharmacy related companies need to distance themselves from commercial imperatives that are perceived as being excessively dominant, and redefine their core mission in more altruistic and health gain focused terms. As with other professions, this is required to justify the market shelter under which they operate.

It is argued here that if pharmacists remain in the community location and simply seek to hold onto their core supply role as it currently stands, then robotics and technology will in time very probably push them towards being relatively low paid technicians. To paraphrase Bill Scott, the Chief Pharmaceutical Officer for Scotland: *"if supply is pharmacy's sacred cow, then it is on its way to the abattoir"*.

If this view is accepted it follows that pharmacists would be well advised to focus on areas where they can demonstrably contribute the greatest possible health gains and net financial savings. These can broadly be divided into three main categories:

- **Advising and treating patients/customers with common (minor/uncomplicated) ailments, and reducing individual and community-wide disease risks.** There is evidence that the largest area in which errors occur is medicines taking (Garfield et al., 2009). But looking initially beyond this, pharmacists and their community pharmacy teams already diagnose common 'minor' ailments and assist patients in the treatment of chronic diseases. Part of this role is reassurance (Harding and Taylor, 1997). But role extensions have in this context recently been supported by a strategy aimed at making effective medicines (ranging from chloramphenicol for conjunctivitis to tamsulosin for prostatic hyperplasia) more easily available to patients via pharmacies (Aronson, 2004). Historically, both self purchased and NHS funded pharmacy and GSL medicines have been supplied for acute self limiting 'minor' conditions such as 'athlete's foot', and for the relief of symptoms such as pain or nasal congestion. But they are also of potential relevance in common chronic disease or related risk management contexts, such as the prevention and control of vascular diseases via blood pressure reduction.

Problems such as smoking, obesity and excessive alcohol use will also continue to require interventions designed to influence behaviour, supported as and when possible by the supply of pharmaceutical products. Although there has been a degree of (medically led) controversy surrounding steps such as the licensing of chloramphenicol for sale as a Pharmacy medicine, the available evidence suggests that (even if sustained monitoring is required) public health has benefited as a result of improved community pharmacy facilitated access (Walker and Hinchcliffe, 2010).

- **Supporting the prescribing and effective use of therapeutics by clinicians.** As average life expectancy increases beyond eight decades, further (healthy) survival improvement is likely to demand the informed, early, use of effective medicines and an increasing use of targeted interventions based on genetically mediated health risks. The use of relevant technologies is likely to expand out from hospitals into primary care settings, and to create in the community setting more need for clinical pharmacy and allied services similar to those pioneered in UK hospitals (Aronson, 2006). Arguably, clinical pharmacologists could provide this service. Yet the capacity available in this speciality is limited.

By contrast, community pharmacists appear to be relatively well placed to build on their existing roles in areas such as identifying drug contra-indications and potential interactions, and in future pro-actively supporting the development of more 'personalised' patterns of pharmaceutical therapy. But questions remain as to the extent to which the co-location of pharmacy, medical and nursing labour will be required to facilitate optimal progress.

- **The oversight/'quality management' of broadly defined medicines supply, to ensure that patients have safe and reliable access to the treatments they need.** This became regarded as the central role of pharmacy in 'developed countries' during the era after medicines manufacturing shifted to industry, and many medicines became 'prescription only'. It is still central to pharmacy practice in countries like the UK. The findings reported in this thesis show that this is the role that currently dominates the time of community pharmacists (chapter 2). Through the use of automation, communications technology and dedicated staff, pharmacists may in future be able use their knowledge and skills to not only

provide better 'oversight' of drug supply and further minimise dispensing errors and unwanted events of all sorts, but to extend their role beyond medicines management into optimising patient support and therapeutic choices. It is reasonable to conclude that further (cost effective) improvements at this level of pharmaceutical care should be possible. However, against this it might be asked why significant problems in relation to medicines use appear to remain, and whether or not there is evidence that merely increasing 'the treatment as previously administered' (i.e. investing more rather than less in community pharmacy) will in fact enhance outcomes.

To achieve desired progress, a variety of changes in current community pharmacy working practices and financial structures will be needed. The research presented here has identified the following possible 'solutions', the implementation of which will – as has been argued in previous chapters – depend on both external 'political will' and internal pharmacy commitment and willingness to both invest and accept risk. Potential measures include:

- **Reducing the prescription dispensing workload.** Original research undertaken as part of the work reported earlier in this thesis indicates that reducing the volume of dispensing could open the way to the redistribution of pharmacists' time towards other patient care activities. One way of achieving this would be to increase prescription durations, and give patients' greater responsibility for storing their own medicines. Arguably, a significant number of 'chronic disease' prescriptions may in future only need to be dispensed every three months, rather than every month. This may entail a rise in the value of individual prescriptions, and risk increasing waste. Yet against this it should help to consolidate dispensing and allied workloads, not only in pharmacies but also in general practices.
- **Supervision regulations** can at present be said to be 'keeping pharmacists bound to the dispensing bench'. There is some evidence that productivity gains could be achieved by **changing responsibility requirements, de-criminalising dispensing errors and making a clearer distinction between the separate issues of personal liability and the liability of the pharmacy business.**

- **Making better overall use of the pharmacy team.** The changes to regulations outlined above could allow pharmacies to utilise more effectively the skills of their staff teams. This has been a key theme in the recent Healthy Living Pharmacy (HLP) proposals. A re-definition of supervision should permit community pharmacists to embrace more effectively the role of leader of their pharmacy healthcare teams. Such an approach need not prevent pharmacists from continuing to provide dispensing oversight and patient care, but should allow them to play an extended part in facilitating and as appropriate managing enhanced pharmacy staff contributions to health improvement.
- **A managed community pharmacy market,** that balances fairly the access and service quality demands of consumers against the level of business and allied risk to which pharmacy owners and their employees are exposed, is vital for maintaining the sustainability of community pharmacy. Deregulating the community pharmacy environment to permit free(r) competition is favoured by some authorities. But this could result in more pharmacies pursuing a limited quantum of public funding, and result in reduced access to pharmaceutical services amongst some community groups.

Current data suggest that increased competition from providers such as supermarket pharmacies is undermining the levels of investment made by other types of contractor (Bush et al., 2009). Well directed market management interventions might check such trends. They could also enable action to ensure that pharmacy premises of poorer quality close. This may allow NHS funds to be re-allocated between remaining (and any required new) pharmacies to improve services. Although the enhanced regulation of (NHS) pharmacy premises might be robustly opposed by some stakeholders, a planned market consolidation may in future represent the most viable way forward. This is especially likely to be so if in the longer term 'austerity conditions' prevail in the macro-economy.
- **Electronic record exchanges.** Future healthcare systems will almost inevitably enjoy a greater degree of electronic connectivity. Trends in this direction ought to present many opportunities for community pharmacists to engage in aspects of healthcare provision previously possible only in the general medical practice domain. Yet to date progress in this direction has been slow, partly because of the

concerns of doctors as represented by stakeholder bodies such as the BMA. One possible way forward might be for community pharmacists to seek systematically to improve their relationships with local general practices. Closer integration may not only support better care across the interface, but will also help to create trust between the two professional groups.

It might be argued that, in theory at least, an extended and better 'linked in' primary care role for community pharmacy in England could permit pharmacy businesses to access sums in excess of the current circa £2bn NHS budget for pharmacy services. However, in practice GP business interests are strongly placed to resist changes that they may regard as threatening. It is unlikely that 'organised medicine' could in future block the development of large scale, low cost, dispensing facilities capable of further reducing medicines supply outlays. Yet the medical profession and its representatives may have more power to promote the development of clinical pharmacy within medically controlled settings, rather than permitting its further development in community pharmacies.

- **Redesigned remuneration structures.** The need to promote better integrated working between community pharmacy and other parts of primary health and social care, together with a closer alignment of pharmacy business and professional incentives, will almost certainly result in a re-engineered payment system for contractors. Until recently the NHS rewarded pharmacy businesses for the advice and knowledge provided by their staff through permitting income (in part derived via discounts and allied mechanisms) acquired from supplying products to underpin such activities. There was no clear distinction between the price paid for the product and the price paid for the service.

The new pharmacy contractual framework introduced in 2005 began to create a more discernable demarcation line, by establishing a more transparent payment matrix for pharmacy services. But as the returns from narrowly defined medicines supply are reduced it may well prove difficult for community pharmacists to obtain compensatory revenues from the provision of cognitive services, unless more positive evidence of their value can be generated (appendix C).

This is challenging, because the 'advice' provided by pharmacists is not a tangible 'good' that can be evaluated in the same way as can supplying a priced box of medicine. One of the possible reasons why pharmacists have to date been limited

in their ability to capture data relating to the value of their 'extra-supply' service offers is because of their being primarily concerned with dispensing. But looking beyond that there are also substantive questions about what is in fact being achieved, and how best contributions to health such as, say, giving the relatives of sick children or vulnerable adults the confidence not to go to their GP or local hospital A&E can be assessed.

Future scenarios

There are a variety of ways that new funding systems could be structured and the delivery of innovative forms of pharmaceutical care in the community achieved. In such a complex field it is not possible to identify a single most probable way forward. However, building on the above discussion of potential solutions to the problems community pharmacists as both 'businessmen' and health professionals are now facing, the scenarios suggested below outline a range of alternative possibilities as to how progress may be realised.

1. The list based system

In this scenario, the current distinction between community pharmacy and general practice is maintained. However, pharmacies are remunerated in a similar way to general practice. Better functional integration of NHS services helps to ensure that patients are free to 'nominate' their chosen pharmacy. Supply costs are covered in the list prices of medicines in ways which incentivise pharmacists to advise prescribers on the most cost effective therapies. Patients purchase advice, medicines and other goods and services in the pharmacy. But NHS pharmacists also have responsibilities and financial incentives to manage patients with long term conditions on their lists. Each community pharmacy acts as a coordinating centre for 'their' patients for hospital admissions and discharge and specialist outreach services. Pharmacists are mainly concerned with assuring optimum therapy for individual patients and are rewarded by 'quality outcome' payments. A significant part of their role in this scenario – the origins of which stem from reforms in Scotland and the establishment there of the Chronic Medication Scheme (Community Pharmacy Scotland, 2010) – is concerned with the delegated management of diseases diagnosed by doctors. This requires close collaboration with local surgeries, which have overlapping patient lists. However, a proportion of GPs have expressed concerns that pharmacists are undermining medical authority. Examples of substandard therapeutic management are on occasions used to try to prevent pharmacists from contributing further to 'medical' domains of work.

2. The healthcare hub

In this model pharmacies serve as 'walk-in' health centres for NHS and private users. Funding is in large part based on item of service fees. Pharmacists are encouraged to provide support and care to patients on an *ad hoc* basis, most often in the context of treatments for acute 'minor' ailments. However, there are also case finding and risk management services. Such activities involve the whole pharmacy team. Pharmacists remain to a large extent focussed on supply but also use their skills and expertise in training staff and supporting them to carry out the majority of interventions. Through strengthened links with local authorities pharmacies run 'disease/health' awareness campaigns and are able to reach a significant proportion of the population due to the high footfall through their premises drawn in by their supply and retail services. The development of larger GP practices has reduced their accessibility, and helped pharmacies to become healthcare hubs within the community. In addition to item of service fees, pharmacies receive overhead and allied fixed cost contributions, alongside reduced dispensing incomes. The origins of this model can be seen in the 'healthy living pharmacy' concept. It is regarded as a limited success, although the more retail driven pharmacies struggle to balance a healthcare focus with that demanded by the sale of their commercial product lines. Further, many members of the public still consider pharmacists to be 'lower tier' or 'partial' professionals.

3. Traditional model, reduced cost

In this illustration the funding model for pharmacy businesses remains broadly unchanged, and pharmacists' roles also remain fairly static. Each year the Department of Health squeezes the margins permitted to community pharmacies. This leads to an increased concentration on the supply side of the market, which is dominated by a few large 'vertically integrated' multiple pharmacies. (This results in a decrease in pharmacists' salaries as they compete for declining employment opportunities.) These large providers have adopted a central warehouse based supply model. A relaxation of supervision requirements has also allowed them to reduce costs via the creative use of registered pharmacy technicians. Small and medium size chains are being driven out of the market, although some 'independents' survive despite declines in NHS funding for pharmacy services. Pharmacies are seen by the public as places to collect medicines and to purchase other goods, and are often relatively hard to differentiate from other retail based entities. Patients are able to buy and access a wider range of pharmaceutical and diagnostic

products and services than was in the past available. But pharmacies are not in the main seen as having a 'serious' health care role.

4. The separation of dispensing and primary pharmaceutical care

In this framework many primary care pharmacists work directly for or with general practitioners, or in clinical commissioning groups and allied bodies, to advise on prescribing and care for GP referred cases. Dispensing, by contrast, remains located outside GP/primary care practices. It is in large part located in 'very high volume' community pharmacies or centralised dispensing units run mainly by technicians, which deliver fully assembled prescriptions either directly to service users' homes or intermediate locations. This transition has been aided by the electronic transfer of prescriptions and automated processes which allow prescriptions to be dispatched within a matter of minutes. A new tier of the workforce, similar to Scandinavian 'prescriptionists', has evolved to carry out the majority of medicines supply and oversee the sale of GSL medicines. They provide protocol based advice on minor ailments. Surviving pharmacy businesses remain profitable due to high volumes and low overheads. However, (as in the scenario above) many smaller chains and independent pharmacies have been driven out of the market.

The pharmacist workforce in primary care as a whole has therefore decreased. The great majority of those that remain employed have, following in the footsteps of their hospital colleagues, adopted an almost entirely 'clinical' role. 'High flying' established and newly qualified pharmacists welcome opportunities to develop their therapeutic and patient protection roles, although a number of pharmacy schools have closed and graduates of the remainder have had increasingly to seek work outside the health sector. Many patients recognise that pharmacists are professionals who are equipped with a knowledge of medicine based therapeutics similar or superior to that of many doctors. Yet working in relatively large general practices has made them less available to the public than staff working in traditional community pharmacies. They normally operate on an appointment only or clinic basis. Some more enterprising pharmacists have formed their own 'primary care groups', and are commissioned to provide pharmaceutical care as a result of innovative agreements with local commissioners.

It is envisaged that in all instances pharmacy role developments outlined above will be supported by technological developments, albeit that vested interests in primary care may

on occasions seek to inhibit their uptake. It is of note, for instance, that the ability of hospital pharmacists to innovate and expand their clinical role may paradoxically have been related to past shortages of hospital pharmacy manpower and resourcing. This led to the expansion of technician numbers that in turn opened the way to pharmacy labour reallocations.

Embracing apparently 'risky' innovations might well be key to developing 'stronger' future practice models. Defining and adopting the latter, should they emerge, will require not only educational reform at the undergraduate level, but also educational support for those in practice. In this context relevant developments are being proposed by the Modernising Pharmacy Careers Programme Board, which aims to support and develop a workforce ready to apply its skills and knowledge in the pursuit of public and patient interests. Yet any recommendations that this group makes will inevitably take time to have practical effect. They are likely (given the duration of the MPharm course) to take at least six years to start to impact practice, and a further decade or so to have widespread effects (Smith and Darracott, 2011). Even then (failing sufficient political will and public demand to ensure that beneficial reforms are effectively implemented) stakeholders active in the pharmacy arena seek to moderate the systemic effects of changes in pharmacy education and service provision.

Choosing the Future - Stakeholder Interests

Many events lie outside the direct control of the populations and institutions that they affect. Environment disasters such as earthquakes and floods normally fall into this category. Similarly, non-catastrophic but nevertheless mould-breaking events such as new scientific discoveries or the introduction of innovative technologies ranging from novel medicines to high performance computers can act as exogenous forces, strong enough to alter economic and social orders. Hence the discovery and subsequent treatment of *Helicobacter pylori* as a causative agent in peptic ulcer disease markedly decreased the demand for gastric surgery, and the need for gastric surgeons. Events outside their control limited the need for this professional group.

In the same way, pharmacists could not even if they had wished to turn back the tides that led to the introduction of the industrial pharmaceutical manufacturing processes that undermined their historic compounding function. In that sense the pharmacy profession is part of a complex social system that is driven by economic, social and technical forces that it cannot hope to control. Developments in the pharmaceutical and biomedical sciences, in

the diagnosis, prevention and treatment of illness, and in understanding the genetic and allied mechanisms pathways underpinning the aetiology of the complex diseases of later life, will all influence the future of health care delivery.

For instance, near-patient monitoring, 'personalisation' and more specific targeting of medication might in time serve to revolutionise pharmacists' therapeutic roles in both the community and hospital settings. Another example of an exogenous technical factor that is important in this context is the rapid and continued advancement in the power of automated computerised dispensing systems. These are leading to new ways of mechanising the supply of medications.

However, having acknowledged the above realities, the potential for individual or group human agency to influence the course of events should not be ignored. The overall direction of travel for community pharmacy (from compounding and unregulated medicines supply through to regulated, higher volume, finished product supply in the first half century of the NHS' existence and now towards commodity or near commodity price supply balanced by an extended clinical function) is almost certainly set. Yet those working in pharmaceutical sector should still be able to influence many specific facets of this transition.

In this context some of the most difficult aspects of seeking to predict how in practice the future will unfold relate to balancing the different viewpoints and perspectives of those involved in the ongoing change process. This in a large part involves, as the analysis offered in chapter 5 indicates, understanding the capacity and willingness of pharmacists themselves, individually and collectively, to adapt to their evolving environment in a timely way. The summary overview of stakeholders' perspectives provided below reflects this fact.

Pharmacy Business Owners

The community pharmacy business model has provided the financial framework within which community pharmacy as a profession has developed. As indicated above, it has throughout the lifetime of the NHS had medicines supply at its heart. Indeed, even in the days of manufacturing in chemist shops this was the case. The difference was that in the period up to World War II pharmacists were still relatively free to supply any medicine to any customer as they judged appropriate. Today, the current multi-billion pound contractual framework is built upon the supply of industrially manufactured medicines. Pharmacy business owners have consequently had an interest in keeping the margins to be

made via medicines supply as high as possible. On the service purchasing side negotiators have had a corresponding interest in reducing dispensing costs, although given the political sensitivities surrounding health care they too may be described as ‘inherently risk averse’.

The research undertaken for this thesis has found that, unsurprisingly, the pharmacy business community has been reluctant to move away from its medicines supply centred financial base without guarantees that a more ‘health service’ oriented approach would provide a similarly profitable and sustainable income stream. Pharmacy contractors, who have tended to dominate the profession’s representative bodies, have invested in the current community pharmacy infrastructure. Unless faced with the prospect of imminent losses, there will be little reason (whatever their size or structure) for them to accept greater perceived risk of any sort without a counter-balancing guarantee of a satisfactory return on capital invested.

Given the need to maintain medicines supply continuity, the purchaser side response to this is likely to involve a gradual reduction of dispensing and allied fees. That is, a situation akin to scenario 3 (*traditional model, reduced cost*) above will develop, should the logic of traditional business interests prevail. This could mean that employee and ‘small owner’ community pharmacists who remain ‘in business’ will become trapped in a supply role close to that of a bureaucratically directed technician, rather than that of an autonomous health care professional.

However, ‘enlightened’ pharmacy owners may also see long term advantages in moving towards scenarios 1 (*the list based system*) and 2 (*healthcare hub*), or relevant hybrids thereof. At the same time if actors outside pharmacy respond negatively to attempts to (even at reduced cost) preserve the traditional business model, this could result in an accelerated precipitation of scenario 4 (*the separation of dispensing and primary pharmaceutical care*).

‘Pharmacist practitioners’

Many practicing community pharmacists currently report feeling burdened with the volume of dispensing they undertake (appendix C). Locum and other staff pharmacists value their employment. Yet both qualitative and quantitative analyses indicate that they typically believe that their profession has failed to achieve that status that it (and they) deserves, and that they do not have the opportunities required to use their professional skills to the full. They therefore accept the ‘under-utilised’ label.

There is also evidence that the 'new breed' of pharmacist whose mindsets are presently being formed in higher education institutions is more clinically orientated than their predecessors. Yet the academics responsible for their education tend to disagree between themselves as to whether or not pharmacy students are destined to become scientists, clinicians or both (Jesson et al., 2006). This is perhaps in part because many have too little insight into current health care demands and priorities of the wider NHS. Students recognise this contradiction, the deficient contextualisation of their knowledge, and the questions surrounding their future contributions (Jesson et al., 2006). This 'inconsistent socialisation' within schools of pharmacy has led to 'disillusionment and disenchantment', associated with a sense of role ambiguity (Chalmers et al., 1995).

The conclusion drawn here is that many existing and potential new pharmacy practitioners desire a more fulfilling role, and are willing to accept a greater degree of collective risk than pharmacy business owners would find acceptable in order to achieve it. All other things remaining constant, their preferred direction of travel will be towards scenarios 1, 2 or 4.

Doctors and other GP practice or health centre based primary health care providers

In the community setting, pharmacists are in a sense reliant on the medical profession to prescribe. In power and dependency terms medical dominance has put pharmacy in a subordinate position, a situation which is at times positively reinforced by members of the profession themselves (Edmunds and Calnan, 2001b). Even with limited pharmacist involvement in CCGs, the NHS reforms due to be formally introduced in April 2013 appear unlikely to reduce the disparities in status between pharmacists and GPs, failing intervention by the NHS CB and/or the local authority based Health and Wellbeing Boards.

The findings offered in chapter five indicate that any significant renegotiation of pharmacists' roles within primary care will need support from other providers – most importantly GPs – in order to be successfully introduced. Yet in hospitals, the initial development of clinical pharmacist roles was not infrequently met with hostility by medical practitioners. The same appears often to be so in the community setting. Despite individual examples of constructive joint working pharmacists have historically had relatively weak relationships with the rest of the 'primary healthcare team' (Erwin et al., 1996; Eng, 1987; Ellis, 1992; March et al., 1999; Bond, 2000). Managing this interface will become even more important if pharmacists are to move towards a role such as that described above as scenario 1 (*the list based community pharmacy practice system option*), and there is a significant risk this will be seen as an encroachment on the economic interests and core

professional activities of the medical profession (Eaton and Webb, 1979; Freidson, 1970; Edmunds and Calnan, 2001b).

Members of the medical profession working in primary care and elsewhere hold significant managerial, social and political power. As such they are able to exert considerable pressure on community pharmacy, and are in a position to strongly influence its future development. The available data suggests that GP interests may cause them to tend to favour a scenario 4 type (*supply and clinical role separation*) future. However, even if this is not uniformly the case, pharmacists' abilities to constructively shape their relationships with the medical profession will without question be important in relation to the continuing development of their profession and the extent to which they are genuinely able to contribute to enhanced public health.

NHS planners and Department of Health officials

NHS bureaucrats with responsibilities for managing pharmacy services and influencing their roles are required to locate pharmacy within the context of the health service as a whole and its users' overall interests. However, the latter are not always easy to define. One conclusion offered here is that health sector officials' views often appear to be influenced by the extent to which they personally identify with pharmacy or with other stakeholder groups.

Attitudes may also be influenced by (as suggested above) the degree to which seeking change in any given area is (even if potentially beneficial (or damaging) in the long term) linked with immediate political costs and benefits. As such, the maintenance of a secure drug supply and the avoidance of conflict and/or embarrassment to Ministers may be particularly important to members of this community. Therefore they tend to favour a gradualist evolutionary approach across a range of alternative scenarios, until or unless they receive unequivocal political direction. That is, they will tend to be risk averse, which will increase the likelihood of 'pathway dependence' and existing trends towards scenario 4.

Politicians and the determinants of 'political will'

Politicians should act to protect public interests in an informed and fair manner, although in electoral terms they need to be mindful of the prejudices and preferences of 'their' voters. The selection and timing of policy interventions is often therefore a matter of judgement, which needs to be consistent with not only temporal considerations (for

example, introducing higher charges or service withdrawals just before elections could well be ill-advised) but other, sometimes 'softer', perceptions. For instance, in some communities investing new funds in private community pharmacy businesses may be regarded as inherently less desirable than placing resources in what may be seen as 'publicly owned' GP practices or NHS hospitals.

Politicians also need to balance competing legitimate interest issues, such as on the one hand supporting an innovative pharmaceutical industry and on the other minimising drug costs. In the case of community pharmacy it is unlikely that any political group would want to be seen as responsible for a sudden wave of closures of familiar community assets. Politicians might rather wish to be seen to be supporting self care and more convenient access to care, although at the same time few would want to risk being exposed to charges of undermining safety or confidentiality made by medical institutions.

Public and patient interests

The consumers of community pharmacy services are the public, including both healthy people and those prepared to accept the label of 'patient'. The research reported here did not include a quantitative investigation of current perceptions of how members of either group wish to receive pharmaceutical care, or the extent to which – for instance – they would be happy for community pharmacists to (with appropriate permissions) to have greater access to electronic health records. Experience in, for example, areas such as smoking cessation suggests that attitudes towards issues such as whether or not it is acceptable for community pharmacists to offer clinical services are relatively plastic, and can be changed by positive or negative experiences. But the key point to emphasise here is that consumer sovereignty is arguably as important a concept in any professional arena as it is for democratic market economies as a whole.

In normal contexts markets 'work' by permitting incremental change, and the step by step movement of funds in the direction of preferred options and away from those judged by customers to provide poorer value. Progress of this type is difficult to achieve in all professionally led, publicly funded, health care systems. But in looking to the future it may be suggested that wherever possible service users should be able to make choices between different types of primary care provider, as well as options to select alternative providers of the same type. Otherwise even if members of the public were potentially to desire developments such as those summarised as scenarios 1 or 2 above it may, despite modern

approaches to service commissioning, be very difficult for them to be dynamically involved in expressing their preference.

The Future – Towards a ‘professional business’ model?

The Kingdon model of the policy process (described in chapter 4), suggests that it is not simply the availability of a solution to a problem that results in political change. Political will and external support is required for any given policy intervention to succeed. Substantive change normally needs ‘policy entrepreneurs’ to couple the multiple streams of the model together. The view taken here is that the policy cadre in pharmacy would be well advised to seek to develop a stronger internal consensus as to which way forward is most desirable for the profession, while at the same time seeking to strengthen external support for pharmacy development. It is also important to remember that in any evolutionary process the changing environment will be the ultimate arbiter of what is fit for purpose, rather than the preferences of existing populations.

At present the fractured discourse between pharmacy owners and pharmacist employees appears to be creating a real obstruction to delivering professional progress. This has been exacerbated by internal pharmacy business rivalries (most notably between ‘multiples’ and ‘independents’, as well as pharmacist employers and pharmacist employees) that have further inhibited the creation of a united strategic view in ways that are quite different from the internal dynamics influencing the development of, for instance, the medical and nursing professions. For pharmacy itself to influence its future evolution more effectively than presently seems to be the case arguably necessitates a level of leadership and strategic thinking that at present seems lacking within the policy cadre of the profession.

Wider political support for relevant policy proposals is also needed at both the macro level, from key decision makers, and the micro levels. Those most influential in the latter context include local general practitioners and other primary healthcare providers, managers and commissioners. In practice, it seems inevitable that support from the medical profession will be key to influencing the direction that community pharmacy takes. Aside from competitive concerns this will only be forthcoming in situations where there is substantive evidence that community pharmacy providers offer a comparable or better quality service than the available alternatives. This will require the demonstration of ‘true’ systematic health gains beyond just the avoidance of low-probability high-risk events that the current supply function may or may not deliver. Without such evidence it seems almost certain that current NHS community pharmacy income streams will continue be squeezed in England. If

all other things remaining broadly constant then this will promote trends like those suggested in scenario 3.

Simplistic policies intended to promote financial savings might well, accidentally or otherwise, undermine the capacity of community pharmacy business to go on adapting to meet future health needs, and address the issues at the heart of what can be termed 'medicines optimisation'. If and where this proves to be the case it will not only damage the profession's interests. It is also likely over time to generate added costs and lost health related opportunity for the community as a whole by blocking desirable lines of evolution. Likewise if short term business pressures are permitted to cause stagnation and prevent change similar outcomes will result.

As already argued, there is in reality no certainty as to which one of the scenarios outlined above is most likely to dominate in 2020s and beyond. Yet having noted this there will almost certainly continue to be at the heart of the community pharmacy role a combination of assuring the availability of good quality (and good value) medicines and working with doctors, nurses and the public to apply knowledge about how to provide and use them to best effect. Against this broad understanding, a path dependency perspective (see chapter 1) suggests that the line of development indicated in scenario 4 can most reasonably be taken to represent the probable future model for community pharmacy at this point in time. This 'separation of dispensing (supply business) and primary pharmaceutical care (professional)' scenario has an increased chance of becoming a reality as a result of the external support for such an approach from those outside the profession (chapter 5) and the weight of disruptive technological advances that may already be taken to be catalysing change in this direction.

However, this likely endpoint may not in fact be the most desirable one to pursue, either from a professional or a public interest centred perspective. It is in this context worth noting that progress in all professional fields in part reflects the political and economic attempts of given groups of skilled individuals to attain and maintain control and autonomy in specific areas of activity, and to protect territory in the labour market in order to secure income and favourable working conditions. The future outcomes of such struggles have the potential to play a large part in defining the scale and nature of community pharmacy in the twenty first century, over and above past determinants.

It can be reasonably argued that the most desirable way forward would be for pharmacy and pharmacists to put (and be seen to put) the public's (health) concerns and best interests at the top of their agenda. For some observers this is in essence what medical doctors like GPs have done in countries such as the UK, in ways which could be said to locate commercial aspects of their roles within a robust outer professional coating. It seems probable that if (community) pharmacy could move more in this direction it would as a group become better positioned to gain greater public and political support for policies that would enable it to make a significantly extended contribution to healthcare, and secondarily assure the income streams needed to sustain appropriate 'business' models.

Freidson's (2001) work and related studies suggest that there are three logics relating to the organisation of complex functions in society – bureaucratic (politically led) managerialism, consumerism (and market led 'sectional managerialism'), and professionalism. The latter rests upon traditions of individual 'virtue' and autonomous decision making based upon the complex, scientifically supported knowledge. This is intended to deliver good quality services to clients in ways which put their needs first, in exchange for State granted protections.

That is to say, professionals are legally provided with forms of market shelter that modify competitive forces and are in return required to put each of their client's interests above their own financial and managerially directed concerns. However, in the modern world professionals are increasingly required to work in complex managerially controlled settings, driven by 'consumerism' and political decisions.

This has led to disputes and uncertainties in areas like health care that are difficult to resolve. But for the purposes of this thesis the ultimate judgment of Freidson's approach is arguably that professionals can legitimately operate businesses with a commercial interest so long as the values of such an enterprise put the client's interests over and above those of the business. This implies that 'ideal type' community pharmacies and pharmacists are right to be concerned with keeping the income streams and environmental business conditions required to maintain their viability provided that they in return deliver social 'good'. The challenge for all such businesses, whether corporately or individually owned, is to be able to show that they are governed in ways that ensure that professional values are not only respected but are genuinely central to their cultures and actions.

The current trends in community pharmacy practice seem to indicate a weakening of the 'professionalism logic'. To an extent the economic market shelter provided by professionalism and the existence of the NHS may have been abused for financial gain. Pharmacists themselves must accept responsibility for their own actions, albeit that such trends can also be linked to inadequate national policies that on occasions may have failed to acknowledge and support the role of professionalism in maintaining all aspects of health care quality, including the provision of pharmaceutical care, as services adapt to changing needs and circumstances. In this context sociologists have described the proletarianisation of the profession, as pharmacists move away from the autonomy of self employment towards salaried labour (Hassell, 2004); the de-professionalisation of pharmacists as a result of loss of professional characteristics, in particular autonomous decision making (Harding and Taylor, 1997); and increasing corporatisation that has turned the pharmacy market from a healthcare providers into a profit maximising corporation (Bush et al., 2009).

The conclusion drawn here is that rather than considering concepts such as the professional as opposed to the business aspects of community pharmacy as separate phenomena, as has in places been the case earlier in this thesis, the Freidsonian logics should instead be approached, understood and developed in an integrated manner in order to fundamentally understand the challenges facing community pharmacists, and the best way forward for community pharmacy as a whole.

The maintenance of a credible and sustainable market shelter (that is, conditions in which fees are not driven down to a basic commodity level which precludes anything but the provision of minimal services in the community pharmacy setting) is heavily dependent on being able to demonstrate and guarantee a level of quality that a market based approach could not support. At present the necessary evidence is lacking, and many of the findings contained in this thesis have disappointing implications. But if pharmacies and pharmacists could embrace a rigorously defined professional approach to their overall working practices and so become professional-value-driven businesses there remains reason to hope that the community pharmacy model of the future could reach more towards the 'scenario 1 and 2' end of the spectrum. This will entail going above and beyond basic legal frameworks, and creating corporate environments that expresses professionalism throughout all aspects of their activities.

This thesis does not seek to provide a reply to the question 'how can this be achieved in practice?'. But it does at least identify the fact that answering, successfully or otherwise, is

a task that will be central to the profession's future. Taking the long view, practitioners of pharmacy and their antecedents have, despite the prophecies of professional demise outlined at the beginning of this thesis, continually adapted and transformed over the last millennium to keep pace with demographic, epidemiological, technical and social developments. The history of pharmacy tells of a profession that has acted with resilience to threats and embraced opportunities. But it will need to continue in this vein in order to resist the paths that point towards a 'weak' pharmacy model. Perhaps paradoxically, the view offered here is that in the final analysis (community) pharmacy's continuing survival will ultimately depend on its practitioners' abilities to recognise and demonstrate to other stakeholders in health that what matters most to them is not their own profession, or even the medicines at its centre. It is rather preserving the lives and optimising the wellbeing of the people and populations that professional status grants them the privilege to serve.

Limitations of this thesis

In retrospect the biggest limitation of the thesis presented here is the broad and wide reaching nature of the core research question that this research has sought to address. In reality there is no single way in which the future can be accurately predicted. The advent of the supercomputer and endless databases has not made the dream of long term prediction any closer than that of our forbearers. However, this does not mean that one cannot think systematically about the future and try to make some sense of the trends, developing issues and emerging technologies.

Early preparatory work for this program of research explored the benefits and limitations of futurology and foresight studies. However the relative methodological weakness of these approaches precipitated an alternative methodological approach. The end result of which has been a series of distinct research studies that have followed a theme to uncover the trends underlying community pharmacy and allied primary healthcare practice, and created original knowledge upon which further practice research can be built.

The strength of the conclusion of any research is limited by the quality of the data that is analysed. In the case of policy analysis the target is constantly moving and evolving within the fluidity of social change and the dynamic relationships of the social world. For example much of the initial research presented here commenced during a period in which the coalition government were preparing unprecedented changes to the face of primary healthcare services in England. It could even be suggested that the role structure of community pharmacy in such turbulence represents a 'wicked problem', and therefore limits the applicability of the research beyond a particular point in time.

For this reason the economic and strategic analyses provided in chapters 3 and 6 are probably the weakest part of the work presented here. The lack of robust and transparent data on which to build economic models of community practice prevented hard conclusions from being drawn about the cost effectiveness of the different scenarios of future practice presented earlier in this chapter. Therefore it is difficult to economically ascertain the relative advantages (and disadvantages) of the models of practice proposed above. However the qualitative research which has reported overarching sociologically trends and beliefs about practice provides a value insight into the potential of future practice, which in many respects may be of more value than narrowly defined economic analyses.

Elsewhere in the thesis the methods of research have been documented transparently alongside reasons that justify their use and appropriateness. No scientific method, especially when used in the 'real world' can be free from methodological weakness at some level, but efforts have been taken to limit these confounding factors. The background of the author as a pharmacist is one such factor that requires acknowledgement. However, where weaknesses exist they have been documented and efforts to reduce them recorded.

The results presented here have focused on the English community pharmacy setting. While many of the challenges and trends observed and recorded here are likely to be experienced by pharmacies and pharmacists around the world, the generalisability of these findings beyond the English context should not be overstated. The findings of this thesis have helped contribute to a paper written for the International Pharmacy Federation (FIP) which sets out the global case for change in pharmacy practice (Thum-Bonanno et al., 2012) as other actors across the world are likely to relate to the underlying trends observed here.

Future Research

The wide reaching nature of the work presented in this thesis, which covers the disciplines of social science, political science, economics and pharmacy practice exposes many possible avenues for future research. In many ways, this section offers a critique of the areas where the whole of pharmacy practice discipline requires further development.

Economic Analysis of Pharmaceutical Care - In the literature review and its subsequent analysis it was evident that economically led data to support the development of the pharmacy profession is lacking. The policy process is increasingly driven by economic decisions and yet pharmacy lacks robust economic literature to support its services and outputs (see limitations section above). Therefore the creation of a credible economic basis for current community pharmacy activities would help decision makers to settle on future courses of action and will provide a counterfactual that can be used for the evaluation of any future interventions into primary care. For example, it is known anecdotally that pharmacies help to create social cohesion in a given locality, but the quantitative value of this cohesion to the local population is unknown (appendix C).

Pharmacy Workforce - Understanding and interpreting the needs and the basis of the pharmacy workforce are integral to any future developments as these practitioners will be tasked with implementing political decision at the coal face. The maintenance of a census

that seeks to understand the needs of the community pharmacy workforce, both pharmacists and pharmacy staff is essential. In particular there is a lack of even basic descriptive data on the numbers, needs and desires of community pharmacy counter assistants that at present plays a key role in the delivery of pharmaceutical care.

The management and processing of repeat prescribing systems - The repeat prescribing of medicines in system terms should theoretically be very simple. However in reality there are a vast number of processes that patients must follow in order to access their repeat medications. Understanding patients needs and reengineering this system to relieve general practice and pharmacy workloads, as well as improving patient experience is a key area in which future health service research should focus. The evidence presented in this thesis suggests that 28 day prescribing polices require review, but lacks enough data to form a solid conclusion. Embracing a system wide view of prescribing and repeat supply systems on all stakeholders across primary care is important if polices are to change.

System Wide Modelling - Models are by their nature a simplification of reality and therefore they are subject to the flaws that simplification provides. The models of community pharmacy used throughout this thesis can be further strengthened and improved by adding further layers of complication that were not possible given the economic and time constraints of this thesis. Such data will be a useful base for the development of future funding models of community pharmacy practice.

Chapter and Thesis Conclusion

“I claim not to have controlled events, but confess plainly that events have controlled me”

Abraham Lincoln

Most of the future lies outside the direct control of the populations and institutions they effect. Pharmacy as a business and as a profession is no different. Yet, the potential for groups to influence the course of history should not be ignored. This thesis has explored the question **‘how are business and professional practice models for community pharmacy in England in the ten to twenty years time likely to be structured?’** It has examined aspects of how community pharmacists and community pharmacy businesses might seek positively to influence their future direction of travel. The research presented above has scrutinized how members of the professional group, known as community pharmacists, might seek to influence the advancement of public interest orientated healthcare models of the future. This has been achieved through understanding the perspectives, beliefs and agency positions of the different stakeholders that are involved in the ongoing process of change. To a large extent this has involved understanding the capacity and willingness of community pharmacists and community pharmacy businesses to individually and collectively adapt to their evolving environment.

For community pharmacy, the transition from compounding and unregulated medicines supply at the beginning of the last century, through to the supply of regulated and automated high-volume finished product commodity supply, has destabilised their base and created a need for community pharmacy to adapt and change. Such transition has been accompanied by a changing societal relationship with professional groups, as the government and wider public begin to question the benefits of providing professions with State granted protections. These factors have undermined the pharmacy professions’ economic and social standing and created a need for further change.

Policy makers have suggested that pharmacists are ‘underutilised’ (as distinct from ‘underworked’) and should contribute more to health improvement than their role currently permits. Yet change has been slow. The fixed interval work sampling study carried out here established that community pharmacists’ continue to spend over half of their time on basic dispensing and supply activities.

One significant inhibitory factor has been the increase in prescription volumes seen since the 1950s, coupled with a payment structure that has incentivised pharmacy contractors to focus on dispensing. There are many factors that have led to the increase in prescription volume. But the research findings contained in this thesis indicates that shortening of prescription durations has been a contributing factor. The ostensible reason for this trend has been medicines waste reduction, but its overall cost may not always have been balanced by the benefits gained. Increasing prescription lengths may allow pharmacists to redistribute their time towards those patient care activities that are deemed to better 'utilise' their skills. Further regulatory changes such as the relaxation of supervision regulations and making a clearer distinction between the separate issues of personal liability and the liability of the pharmacy business may also provide a further avenue down which practice change can be advanced.

The path down which community pharmacy drives will be the result of a variety of political negotiations between different stakeholder groups. It is only when the problem, solution and political will of the policy system combine that politically expedient change can take place. The literature on the implementation of Medicine Use Reviews suggests that community pharmacist led service developments have been affected by seven factors, namely: the pharmacy environment; financial drivers; accreditation and training issues; patient recruitment problems; lack of external support; documentation/evidence deficiencies; and practitioner motivation. Using the Kingdon model of the policy process, qualitative interviews with 'policy leaders' provided insight into how these factors have influenced policy and its implementation in contexts like that of the New Medicines Service. The latter was, for instance, delayed by inconsistent external support and political will.

Re-specifying the twenty first century role requirements of pharmaceutically qualified professionals working in the community setting is the first step in establishing change within the community pharmacy sector. However, pharmacists must genuinely be willing to adapt and change away from their current risk averse medicines supply management role bounded by standard protocols and procedures, to instead use their existing (and as necessary new) skills to meet the evolving needs of the societies they serve. In embracing this change the profession needs to consider the use of other members of the pharmacy team as well as their wider relationships with other actors in primary care.

No profession or business can safely regard its long term survival as assured. Managing the interface between the professional priorities and the need for economic income is a challenge for all professional groups. The current remuneration structure in community pharmacy relies heavily on the supply of prescription medicines. Integrated working between community pharmacy and other parts of the healthcare (through for example the introduction of electronic record exchanges), together with closer alignment of pharmacy business and professional incentives, will almost certainly result in a re-engineered payment system for contractors. Yet any remuneration structure must be managed against the perceived and actual conflicts between the commercial imperatives underlying pharmacy as a business and the values that community pharmacists aspire to have as professionals. This latter represents a significant barrier to overall service improvement.

Only the future will reveal the 'true' answer to the question that overarches this thesis. However, history indicates that to continue being relevant in the future and to ensure their long term survival, community pharmacists in England must offer timely and economic ways of solving contemporary health problems and go on attracting public and political support. Future success will ultimately depend on the profession's ability to recognise and publicly communicate that what matters most to them is preserving the lives and optimising the wellbeing of the people and populations they serve.

If this professional grouping chooses to operate in the wider public interest then they have the potential to undergo a 're-professionalised' strategy. Such a strategy would require them to reengineer their offering in such a way that they are seen to represent a key tier of easily accessible, public interest focused, primary healthcare where pharmacists' role in society would be concerned with preserving the lives and optimising the well being of the population.

The transition towards an integrated business model driven by professional values requires both stronger internal leadership and robust external stakeholder support. A path dependency approach to the current situation suggests that without these medicines supply will probably split from the provision of clinical pharmacy in the community setting, leaving community pharmacy as a weak 'commodity cost' service provider.

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Appendix A - The Nature of Community Pharmacy Work

It was shown in chapter 2 that the majority of pharmacists' time was spent on 'traditional' dispensing activities, which have been described as an 'underutilisation' of pharmacists' time (chapter 1). Yet, while the proportion of time spent on activities has not markedly changed, the productivity within each of the work categories has increased, most notably the increase in number of prescription items dispensed.

In order to understand the changing nature of the community pharmacy workload, the processes within the community pharmacy require mapping against each of these work categories. Using the framework developed for the work sampling study, the work activities of pharmacies and pharmacists were narrowed down to discover the driving factors associated with workload (table 3.1) in each of these categories. This analysis provided workload groups in the community pharmacy setting, namely: safety workload; counselling workload; self care workload; services workload; administrative and regulatory workload; training workload; business workload; personal time; and prescription medicines supply workload

Table A.1 – Workload Factors

Activity	Workload Classification
1. Prescription monitoring and appropriateness	Safety Workload
2 Assembly and labelling of products	Prescription Medicines Supply Workload
3 Endorsing prescriptions and clerical health related work	Administrative & Regulatory Workload
4 Counselling patients on prescribed medicines	Counselling Workload
5 Non-prescription medicines counselling/responding to symptoms	Self Care Workload
6 Professional encounter with non-patients	Safety Workload
7 Health Related Communication	Safety Workload
8 Provision of Advanced Services	Services Workload
9 Provision of Enhanced or other NHS Services	Services Workload
10 Provision of Private Enhanced Services	Services Workload
11 Provision of services to homes	Services Workload
12 Inventory and Stock Control	Prescription Medicines Supply Workload
13 Staff training and Education	Training Workload
14 Housekeeping	Administrative & Regulatory Workload
15 Sales Transactions	Business Sales Workload
16 Money and Managerial Administration	Administrative Workload
17 Rest Waiting and Personal time	Personal Time

Each of these workload categories is considered in turn to reveal how the nature of pharmacists' workload has changed, and to reveal any anticipated trends in future workload.

Prescription Safety workload

Dispensing is a multistage process, where upon presentation of a prescription (which is effectively an invoice). Medicines are prepared and supplied to the patient. This includes checking the prescription for errors and assessing its suitability in terms of interactions, contraindications and possible adverse drug reactions; selecting the correct product; appropriately labelling and recording the prescription supply; checking the patients exemption status; providing appropriate advice on medication use to the patient; and when warranted discussing medication matters with prescribers. One of the key responsibilities of community pharmacists is to maintain safe supply of medicines by reducing medical errors. The development of computer printed prescriptions helped to reduce the number of typographical errors made by general practitioners, although others persist. Previous estimates suggest that around 7.5 per cent of prescriptions in general practice contain an error (Shah et al., 2001). However, more recently the PRACTICE study, which examined 6,048 unique prescription items for 1,777 patients, found that 1 in 20 prescription items contained either a prescribing or monitoring error, affecting 1 in 8 patients. Although the majority of errors were judged to be either of 'mild' or 'moderate' severity, 1 in 550 of all prescription items contained an error judged to be 'severe'. Therefore despite efforts to reduce the burden of prescribing errors, pharmacists are required to remain vigilant.

While prescribing errors remain a challenge, the onus on pharmacists to check and maintain the quality of medical products in the community pharmacy has reduced due to improved regulatory standards. Despite improvements in supply chain security, the MHRA continues to issue regular recalls of medicinal products. In the past five years there were at least three recalls due to suspected counterfeit medicines in the supply chain. The falsified medicines directive (2011/62/EU) introduces a mandatory pan European safety feature for medicines at risk of falsification to tackle this threat. While this legislation proposes a technology-based safety feature, which ideally will allow the pharmacist to automatically read the batch number, serial number and expiry date of a product, it will inevitably create

changes in the workload faced by pharmacists (Davies and Taylor, 2009). The requirement to capture a unique code within the pharmacy will create an incentive to automate pharmacy processes. But until this happens, pharmacy staff will be burdened with additional processing steps.

The personal regulatory responsibility for ensuring the safe supply of products by the pharmacist has also increased. In 2009, the pharmacist Elizabeth Lee was given a custodial sentence at the Old Bailey for a dispensing error under section 85.5 of the 1968 Medicines Act. Despite the court of appeal overturning the verdict, the media attention drove many pharmacists towards more defensive practice due to fears of imprisonment. Regulatory reform of the Medicines Act is anticipated to address pharmacist concerns. However, until this is enacted, pharmacists will be overly risk averse and therefore less willing to delegate tasks to other staff. Indeed, they will have additional tasks in checking the activities of others in the pharmacy for which they are liable.

Counselling workload

The increase in prescription volume correlates with an increase in the number of patients requiring counselling and support to use of their medicines. Theoretically, pharmacists should provide advice to support all patients, seeking to ensure that medical directions are understood (Puspitasari et al., 2009).

Since the nineties, a new paradigm of pharmacists' advice has been to support patient adherence to medicines. This has been embodied most recently in the New Medicines Service (chapter 4) which allows pharmacists to spend time advising patients on newly prescribed medicines. As poor adherence has become increasingly recognised as a problem, on the back of arguments associated with waste (see later discussion), pharmacists will find themselves increasingly pre-occupied with adherence interventions.

Yet, as shown in chapter 2, balancing the demands of supply and counselling can impose restrictions on pharmacists' abilities to support medicines taking. Policy is seeking to shift more consumers towards self care advice from community pharmacies. Meanwhile the need for advice with prescription medications will continue to increase as new medicinal technologies, particularly bio pharmaceuticals, are developed. Managing these conflicting demands is already proving difficult (chapter 2).

Self care workload

Defined by the WHO as 'what people do for themselves to establish and maintain health, prevent and deal with illness' (World Health Organisation (WHO), 1998), self care has become a cornerstone of recent health and social policy. The geographical accessibility of community pharmacies, coupled with convenient opening times, has resulted in pharmacies being championed as a provider of minor ailments advice (Paudyal et al., 2011; Cavaco et al., 2005; FIP Pfizer, 2010). Inevitably these policies will drive consumers into pharmacies. However, the availability of the pharmacist to address these consumer needs is limited by their other tasks (chapter 2).

Services workload

Additional workload was created by the 2005 contractual framework, which introduced new service-based income streams to community pharmacies by reallocation of funding from supply. Therefore pharmacy contractors needed to provide extended services in order to maintain the same level of income. As described later in chapter 4, the first of these advanced services, medicines use reviews (MUR) take about 55 minutes to complete, creating significant additional work for the pharmacists and their team. If the relative value of such services increases then workload will inevitably shift towards service delivery.

Administrative and Regulatory workload

On 1st October 2009 the Department of Health introduced the 'responsible pharmacist' regulations creating a legal duty for pharmacists to ensure the safe and effective running of the pharmacy at all times, even when absent. The intention of the legislation was to clarify the roles and responsibilities of pharmacists, as distinct from owners, as well as creating provisions in which pharmacists could be absent from the pharmacy in order to develop extended clinical roles. Yet recent research carried out by the RPSGB and PSNI found that many pharmacists felt disempowered to influence the running of the pharmacy and struggled to implement the regulations in practice (TNS UK Limited, 2011). By contrast, many complained that the additional record keeping burden and had concerns about personal liability, which prevented them delivering clinical services. Indeed, some believed that the legislation has driven behaviours which undermine patient safety and add to professional stress and tension in the workplace (TNS UK Limited, 2011).

Governance regulations for community pharmacies have further added to the administrative burden, to such an extent that additional funding was made available in

contract negotiations. For example in 2008 increased payments were made in recognition of the extra time required to sort prescriptions and declare expenses, as well as the additional paperwork required due to controlled drug (CD) regulation changes. Further administrative tasks have followed as a result of NPSA alerts and changes in primary care information governance arrangements. These have been further compounded by the structured series of reforms that have been implemented by the General Pharmaceutical Council, which have acted in the short term to distract pharmacists from direct patient care.

Training workload

A further regulatory encumbrance has been the mandatory requirement for pharmacists to complete at least nine continuing professional development 'cycles' per year to maintain their place on the general pharmaceutical register. While many pharmacists were already working in such a way as to improve their personal development, the addition of recording these cycles puts further strain on their time.

Business workload

The changing landscape of the retail sector in England has placed increasing pressure on small businesses, particularly those in high street locations (see next section). The economic recession, the development of out-of-town shopping malls, the expansion of supermarkets coupled with their changing consumer offer (over one third of supermarket floor space is dedicated to non-grocery items), have all acted to create a difficult economic environment for community pharmacy businesses. As a result of the reductions in profitability caused by changes to the NHS contractual framework – for example Day Lewis, a chain of over 160 pharmacies, reported that despite a growth in prescription items of 6.2%, this only represented a 4.7% increase in value (Day Lewis, 2011) - have meant that businesses are being forced to make difficult staffing choices to maintain operating margins.

When staffing (as discussed later in chapter 6) represents the largest single outlay, it is understandable that under a difficult economic outlook working hours are reduced, further increasing the workload for those who remain in employment. These challenging business conditions not only increase the workload of individual pharmacists but also have repercussions on the safety and profitability of the pharmacy.

Personal time

The increase in workload is having potentially negative effects on personal health and patient safety. In a survey by the Pharmacists' Defence Association (the pharmacist union), many pharmacists felt unable to take rest breaks. This inability to take a break due has been attributed to understaffing and pressure to meet financial targets, particularly in the area of medicines use reviews. However, two thirds of pharmacists believed they were putting patient safety at risk by not taking a break.

For a significant number of the profession the increased workload is leading to stress, dissatisfaction, anxiety and fatigue above the national average (Royal Pharmaceutical Society, 2010). Workforce studies from 2004 and 2008 found long hours and high levels of stress in pharmacy. This has been compounded by the community pharmacy contractual framework which has had a largely negative impact on job satisfaction (Bond et al., 2008) because it added new roles without removing those roles that were previously performed.

Long hours can lead to health problems for the individual, but also safety risks for consumers. Working beyond the 48 hours of the European Working time directive significantly increases the likelihood of mistakes. The challenge of long hours and shift work is relevant for all pharmacists, but perhaps to locums in particular as they have long travel times and erratic work patterns. Yet despite this, one response to the burdening administrative workload experienced by pharmacists is to become locums.

Prescription medicines supply workload

Of all of the drivers of pharmacy workload, prescription volume is often described as the greatest. Over the course of the last decade the number of prescriptions dispensed outside hospitals in England has risen almost 70 per cent. While in 2000 there were 552 million items dispensed, that rose to 927 million in 2010, of which 850 million were supplied from community pharmacies (figure 3.1). This is not a population effect because the average number of prescription items dispensed per person has also risen sharply, from 11.2 in 2000 to 17.8 in 2010 (The NHS Information Centre, 2011).

Putting these figures in context, there were 10,951 community pharmacies in England in 2010 (The NHS Information Centre, 2011). This suggests in the region of 77,680 prescription items per pharmacy each year, or 6473 prescription items per month. This is approximately 1,500 prescription items per week. If the average pharmacy opens for 65 hours per week (chapter 2), then 23 prescription items are dispensed every hour or one

every three minutes. The equivalent calculation for 2001 was 16 per hour. These calculations include several assumptions and averages. But they demonstrate that the pressure, in volume terms, to dispense prescriptions has markedly increased even though over one thousand extra pharmacies have opened over the last decade.

Appendix Conclusion - The Overall Nature of Work Load

Improvements in the regulation of pharmaceutical ingredients and controls have acted to reduce the time spent by pharmacists on assuring the quality of medicines. Yet this reduction has been countered by successive policies, which, coupled with a rising tide of prescriptions, have increased pharmacists' workload in the management of minor ailments and delivery of extended pharmaceutical services. Further administrative and regulatory changes, as well as an increasingly competitive market, have all added to the workload pressures that pharmacists experience. The increase in workload has led to continued complaints by pharmacists about the pressure they are facing in their working lives, resulting in a Royal Pharmaceutical Society campaign (Royal Pharmaceutical Society, 2010), which tried to identify the drivers and possible solutions.

The key workload drivers identified all relate to the financial rewards that support the pharmacy business. Inevitably financial income will drive the behaviour of those working in any commercial enterprise and community pharmacies are no exception. With this in mind, the next section of this chapter goes on to analyse the various community pharmacy income streams and explores the wider market trends in order to identify how these are likely to affect future workloads and, therefore by proxy, future roles.

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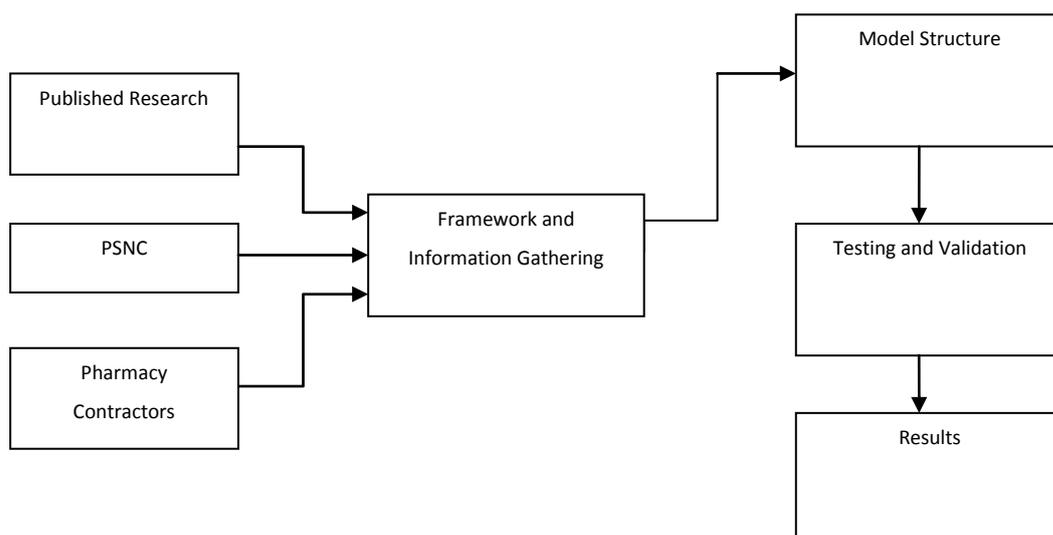
Appendix B - Developing an Ideal Type of Community Pharmacy

Community pharmacies are businesses. They operate in a commercial retail environment with an aim of making profit, without which, they would become economically unviable. This appendix seeks to present a simplified model of the community pharmacy business for the purposes of explaining how the functions of the business influence the activities of the pharmacist, and to provide a baseline for testing future projections of the business.

It is important to acknowledge that all models, no matter how complicated, are subjective approximations of reality. No model can be a perfect description of reality. But the very process of constructing, testing, and revising models forces policymakers to tighten their views about how aspects of the economy work.

The process of designing and developing a model of the ideal type community pharmacy is shown in figure B.1 below. The basis for the model is predicated on Albert Einstein's maxim that 'everything should be made as simple as possible, but not simpler'. Therefore simplifications have been made and assumptions to create the variables. These simplifications are described in the model below.

Figure B.1 – Model Development Framework



Framework development and information gathering

In order to develop the model, several literature sources relating to community pharmacy businesses were interrogated. In particular the PWC Cost of service inquiry, the PSNC website and the community pharmacy handbook(Waterfield, 2008). Certain aspects of the model required data not in the public domain. Where possible this was provided in confidence by pharmacy contractors or by the PSNC. The basic tenets and assumptions inherent to the model were confirmed with a group of community pharmacy contractors and superintendents in order to provide calibration. The basis of the model was one of the business logic models, where income goes in, costs go out, and outputs are created. These are described in table B.1 below. The construction of the model was aided by the use of Microsoft Excel.

Table B.1 – Ideal Type Business Model

Income	Costs	Outputs
NHS Supply Income	Staff costs	Profit
NHS Services Income	Property Costs	Prescriptions Supplied
Non NHS Income	Depreciation of Assets	Services Delivered
	Other Costs	
	Head office Costs	
	Cost of Capital	

Community Pharmacy Income

For the purposes of the ideal type model, there are effectively three main income streams into a community pharmacy: Non NHS income (including health and Beauty sales, private income and OTC medicines); NHS Supply Income (including purchase profit); and NHS Services Income. Each of these income streams is analysed in turn.

NHS Income – The National Contractual Framework

As described in chapter three, a significant proportion of community pharmacy income is drawn from the national contractual framework, principally for the supply of prescription medicines, although the framework also accounts for advanced and enhanced service (table B.2). The advanced services are negotiated nationally as part of the overall contractual framework budget, whereas the enhanced services are commissioned locally, currently by local primary care organisations.

Table B.2 – The 2005 pharmacy contractual framework

ESSENTIAL	ADVANCED	ENHANCED
NATIONAL CONTRACT		LOCALLY COMMISSIONED
Dispensing of medicines Repeat dispensing Promotion of healthy lifestyles Signposting Support for self care Disposal of unwanted medicines Support for disabilities Clinical governance	Medicines use review New Medicines Service	Medicines management Minor Ailment Pilot Needle & syringe exchange Supervised to drug misuse Intermediate care service Care homes advice Rota-out of hours Smoking Cessation Palliative care Weight management Emergency Contraception Long term Conditions management Chlamydia screening

Essential Services

All community pharmacy contractors must provide the essential services in order to dispense NHS prescriptions. The most dominant of these is the dispensing of medicines. At present contractors are paid a 90p professional fee for each item supplied under the terms of the contractual framework (Department of Health and the Welsh Assembly Government, 2012). In addition they also receive special fees and allowances in a range of instances where additional work is required such as record keeping for controlled drugs or where a formula must be prepared. On average this currently equates to about 8.69p per item (Pharmaceutical Services Negotiating Committee, 2011d). To support overheads contractors who dispense over 2240 items per month receive a practice payment (77.1p per item) which is conditional on minimum staffing levels for the number of items dispensed. These contractors also receive establishment payments of just over two thousand pounds per month (£2,092) to support the provisions of other essential services (Department of Health and the Welsh Assembly Government, 2012). Separate arrangements exist for pharmacies that dispense below this number. Pharmacies providing the electronic transfer of prescriptions are also entitled to a monthly payment of £200 (Department of Health and the Welsh Assembly Government, 2012). Table B.3 shows the indicative income per prescription supplied based on the October 2011 negotiations. This shows that the marginal income per prescription varies according to the number of items supplied. For the average pharmacy, dispensing in the region of 6000 items per month, this equates to just over two pounds per item dispensed (table B.3).

Table B.3 - Indicative Income from Prescriptions per month (October 2011)

Items per month	Item fee	Establishment payment	Special fees and allowances	Repeat dispensing set up fee	Practice payments (including contribution for DDA)	Total income from fees and allowances pcm	£ per item
1,000	900	–	87	125	50	1,162	1.16
1,100	990	-	96	125	627	1,838	1.67
1,600	1,440	-	139	125	878	2,582	1.61
2,300	2,070	-	200	125	878	3,273	1.42
2,600	2,340	1,940	226	125	1,911	6,542	2.52
3,000	2,700	2,092	261	125	2,205	7,382	2.46
4,000	3,600	2,092	348	125	2,940	9,104	2.28
5,000	4,500	2,092	434	125	3,675	10,826	2.17
6,000	5,400	2,092	521	125	4,410	12,548	2.09
7,000	6,300	2,092	608	125	5,145	14,270	2.04
8,000	7,200	2,092	695	125	5,880	15,992	2.00
9,000	8,100	2,092	782	125	6,615	17,714	1.97
10,000	9,000	2,092	869	125	7,350	19,436	1.94
11,000	9,900	2,092	956	125	8,085	21,157	1.92
12,000	10,800	2,092	1,043	125	8,820	22,879	1.91

Regardless of the drug supplied pharmacists will receive the amounts listed in the table B.2. In addition pharmacies can obtain a retained margin on the medicines supplied.

Retained Buying Income

There is an assumed income that can be made on the medicines margin between the prices the pharmacy contractors are reimbursed by the NHS for each drug supplied and the actual cost the contractor pays for the medicine from the wholesaler. Across the contractual framework this is targeted to remain at £500m per annum. However, this is not evenly distributed across contractors. Although on average this equates to buying profit of 55.63 pence per item.

Table B.4 – Estimated Average Buying Profit per month by Item volume

Average Prescription Volume (per month)	Estimated Average Buying Profit (per month)	Estimated Average Buying Profit (per annum)
3000	£ 1,669.00	£ 20,028.00
5000	£ 2,781.00	£ 33,372.00
6000	£ 3,338.00	£ 40,056.00
8000	£ 4,450.00	£ 53,400.00
12000	£ 6,675.00	£ 80,100.00

For the simplicity of the model the 55.63 pence per item is assumed. In reality some items have far greater buying margin than others. The national average cost per item of £9.04 is used for generating the total revenue. In total the additional fees, such as establishment payments, repeat dispensing fee and practice payments and well as prescription income are shown in table B.5 for pharmacies of varying prescription volumes.

Table B.5- Indicative revenue and income from prescription supply

Average Prescription Volume (per month)	Total Income from fees (per annum)	Total Income from Drugs costs (per annum)	Total Revenue (Income + Drug Costs per annum)	Estimated Average Income from prescriptions (per annum)
3000	£ 88,592.40	£ 325,440.00	£ 414,032.40	£ 108,620.40
5000	£ 129,918.00	£ 542,400.00	£ 672,318.00	£ 163,290.00
6000	£ 150,580.80	£ 650,880.00	£ 801,460.80	£ 190,636.80
8000	£ 191,906.40	£ 867,840.00	£ 1,059,746.40	£ 245,306.40
12000	£ 274,557.60	£ 1,301,760.00	£ 1,576,317.60	£ 354,657.60

Therefore NHS Supply income can be summarised as follows:

$$f(NHSSupply) = Establishment\ Payment + Repeat\ Dispensing\ Fee + (Items * [Item\ Fee + Special\ Fee + Practice\ Payment + Retained\ Buying\ Profit])$$

For those prescribing over 3,000 items the model is

$$f(NHSSupply_month) = 2092 + 125 + (Items * [0.9 + 0.0854 + 0.771 + 0.5563])$$

$$f(NHSSupply_month) = 2217 + (Items * 2.3127)$$

$$f(NHSSupply_year) = 12 * [2217 + (Items * 2.3127)]$$

NHS Services Income

The other element of the contractual framework that forms part of the national negotiations are cognitive pharmaceutical services. The contractual framework was intended to improve access to pharmaceutical services in local communities (Department of Health, 2003d). Through two categories of service - advanced and enhanced.

Advanced services, are negotiated nationally by the PSNC. Currently there are only four such services: The Medicines Use Review (MUR) and prescription intervention service; The New Medicines Service (NMS); Appliance Use review (AUR); and Stoma appliance customisation service (SAC).

Medicines Use Review and Prescription Intervention - These interventions are paid on a fee-per service basis, with each pharmacy contractor limited to 400 MURs per annum. Achieving the full allocation in means an additional income of £11,200 per year (table B.6). From the 1st October 2011, at least half of all MURs are conducted in three national target groups. These being: patients on high-risk medicines; patients recently discharged from hospital; and patients with respiratory disease. (The barriers and drivers to the implementation of MUR services is discussed in greater detail in chapter 4).

Table B.6 – Medicines Use review Income

MURs (per month)	Value per annum
5	£ 1,680.00
10	£ 3,360.00
20	£ 6,720.00
30	£ 10,080.00
(max allowance) 33.33	£ 11,200.00

New medicines service - This service was launched on the 1st October 2011. The policy developments that led to its introduction are analysed in chapter 4. The essence of the service is to offer patients advice and follow up with their medications that have been newly prescribed. Pharmacies are offered an initial set up payment for providing the service, (£750). The funding is then based upon a matrix related to their prescription volume that equates to approximately £25 per NMS completed.

Table B.7 – Indicative Funding for NMS (October 2011)

Volume of	Number of NMS	Number of NMS	Number of NMS	Number of NMS
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prescription items per month	completions per month necessary to achieve 20% target payment	completions per month necessary to achieve 40% target payment	completions per month necessary to achieve 60% target payment	completions per month necessary to achieve 80% target payment
0-1500	1 (£25)	2 (£50)	3 (£75)	4 (£100)
1501-2500	2 (£50)	4 (£100)	6 (£150)	8 (£200)
2501-3500	3 (£75)	6 (£150)	9 (£225)	12 (£300)
3501-4500	4 (£100)	8 (£200)	12 (£300)	16 (£400)
4501-5500	5 (£125)	10 (£250)	15 (£375)	20 (£500)
5501-6500	6 (£150)	12 (£300)	18 (£450)	24 (£600)
6501-7500	7 (£175)	14 (£350)	21 (£525)	28 (£700)
7501-8500	8 (£200)	16 (£400)	24 (£600)	32 (£800)
8501-9500	9 (£225)	18 (£450)	27 (£675)	36 (£900)
9501-10500	10 (£250)	20 (£500)	30 (£750)	40 (£1000)
+1000	(+1) (£25)	(+2) (+£50)	(+3) (+£75)	(+4) (+£100)

Table B.7 above shows the target payments for the first year. After the second year of the service the lower target tier will disappear.

Appliance Use Review (AUR) and Stoma Appliance Customisation (SAC) - These services are less frequently undertaken. Contractors are paid £28 per AUR that takes place on a pharmacy premises or £54 if it takes place in a patients home⁶⁵ (Department of Health and the Welsh Assembly Government, 2012). Where the stoma appliance customisation service is provided, the contractor receives a payment of £4.32 for each item that qualifies for customisation. Qualifying items are listed in the drug tariff. The extent to which this adds a significant contribution to the income is limited by the number of applicable items and patients using these products.

Of these four advanced services the Medicines Use review (MUR) is the most prevalent, with the new medicines service (NMS) second. Together these two services can add an additional £18,400 to the average community pharmacy each year. Although this income acts as a driver to provide these services, the income gained must be off set against a counterfactual of dispensing prescription medicines.

⁶⁵ The fees and conditions associated with this service are set out in Part VIE of the drug tariff

Enhanced Services

According to the NHS Information Centre, 30,962 local enhanced services were provided by community pharmacies in England in 2010-11. Enhanced services have been developed to address a variety of healthcare problems, although the most frequently offered are Stop Smoking support, Supervised Administration, Minor Ailment Schemes and medicines supply via Patient Group Directions (The NHS Information Centre, 2011). The funding structure allows these services to be contracted out to private pharmacy contractors (Pollock et al., 2007), from local unified budgets, which are part of general primary care provision.

The ability to provide locally commissioned enhanced services varies between primary care organisations across the country. Even when a service is offered in a locality, there is competition between the different pharmacy contractors. The variation is not limited to location, but also ownership (Bush et al., 2009). This is partly because delivery of services are disproportionately more costly to smaller pharmacies who have less capital to invest in adequate facilities (Department of Health, 2009b). This unpredictability of income from service delivery has resulted in many pharmacies shying away from providing them. It is difficult to generalise about the income associated with these services as the payment structures are dependent on the local service specifications and the type of service. Generally most offer some sort of initiation payment to cover overhead costs and equipment, followed by a fee per service model. Given this spectrum of services and fees, it is approximated that enhanced services represent only a small proportion of a community pharmacies income. There were 30,962 enhanced services provided by pharmacies in the England (table B.8). On average enhanced services are negotiated locally, and represent £4,977 per pharmacy per annum (Hall, 2012), with large national variation.

Table B.8 – Community Pharmacy Enhanced Services

Services	Number Provided
Anticoagulant Monitoring	103
Care Home	647
Disease Specific Medicines Management	252
Gluten Free Food Supply	474
Home Delivery	960
Language Access	492
Medication Review	2,383
Meds Assessment & Compliance Support	691
Minor Ailment Scheme	3,686
Needle and Syringe Exchange	2,283
On Demand Availability of Specialist Drugs	1,102
Out of Hours	1,032
Patient Group Direction	3,552
Prescriber Support	13
Schools	0
Screening	1,737
Stop Smoking	6,104
Supervised Administration	5,385
Total services provided	30,962

Source: General Pharmaceutical Service 2010-11.

Estimating the services in the model is complicated by the wide range in the level of income that these provide to pharmacies. However £4,997 is the most reliable average estimate currently available (Hall, 2012). It was discussed with pharmacy contractors that on average services are worth about £25 per service delivered, comparable to the fees paid for advanced services and NMS.

NHS Services Income

Therefore services income is a function of the number of services performed. For simplicity, NMS fee, although on a sliding scale has been simplified to £25 per fee. Therefore NHS services income is

$$f(\text{NHSServices}) = [(MUR \text{ Fee} * \text{Volume}) + (NMS \text{ Fee} * \text{Volume}) + (AUR \text{ Fee} * \text{Volume}) + (SAC * \text{Volume}) + (\text{Enhanced Services})]$$

$$f(\text{NHS Services}) = [(28 * \text{mur_volume}) + (25 * \text{nms_volume}) + (\text{Enhanced Services})]$$

Non NHS Income

Private prescriptions are usually priced by applying a dispensing fee and the cost of the medicine plus a sufficient mark up. With the exception of pharmacies located close to private practices, this generally provides only a very marginal part of a pharmacies income.

According to the national prescribing centre, the proportion of prescriptions written for Controlled drugs privately is 0.45% of the NHS total, or about 50,000 private controlled drug items per year. Extrapolating this to the community pharmacy NHS total, would suggest that in the region of four million private prescriptions are issued in primary care each year, equivalent to 37 prescription per pharmacy per year, less than one a week (National Prescribing Centre, 2012).

Private services for which all of the cost is borne by the patient are becoming increasingly popular in community pharmacy. While no national statistics currently exist for these services, the extent to which they are provided by the large multiple organisations suggests that they are widespread. These services tend to address lifestyle challenges and include schemes such as hair retention clinics, weight loss clinics or cardiovascular risk assessments. The services are combined with patient group direction that allows the supply of a prescription medicine to patients with specific symptoms. While costs of these services vary, they are typically in the region of about £30 per consultation.

For the purposes of this model, the each private prescription is valued at £7.40, which is the standard prescription charge, as this is representative of the income received above and beyond that of the drug cost. Therefore, when complete 37 prescriptions a month, this is equal to about £275 of additional income per month. Therefore, based on 37 prescriptions per year, this represents £275 of private income per year.

By comparison, for most community pharmacies the largest private income stream is the retail sale of drugs and medicines, healthcare products and supplements, toiletries, perfumes and cosmetics. Based on figures from National Statistics' Annual Business Inquiry, Key Note estimates that retail sales by chemists and drugstores in the UK were worth £13.47bn in 2009 (Keynote, 2010). For some pharmacies, particularly those in high foot fall retail locations, such as shopping centres, retail sales are a large part of their business. Gross margins in this area are typically still around the 10%, but vary depending on the pricing policy of an individual pharmacy and the products sold.

Table B.9 – Annual Non-NHS Revenue

	Average total NHS Revenues from PwC Survey	Reported NHS Proportion of Revenue	Non NHS Revenue per annum	Income Value
Independent	£ 722,420.00	85%	£108,363.00	£10,836.30
Small Multiple (6-20 branches)	£ 827,833.00	90%	£82,783.30	£8,278.33
Small Multiple (>20 branches)	£ 1,086,992.00	90%	£108,699.20	£10,869.92
Non Retail Driven Large Multiple	£ 910,222.00	88%	£109,226.64	£10,922.66
Retail Driven Large Multiple	£ 863,214.00	23%	£664,674.78	£66,467.48
Supermarket	£ 874,715.00	85%	£131,207.25	£13,120.73

Source: Estimations based on PwC survey and discussion with pharmacists.

Incomes from health and beauty sales is highly variable, and is a function of the type of pharmacy. For the majority, the NHS sources represent between 80-90% of revenue, but for retail driven multiples, revenue from external sources represents a considerable proportion of income.

This revenue includes the costs of:

$$f(\text{NonNHS Income}) = [(\text{Total Revenue} - \text{NHS Revenue}) * 0.1]$$

where total revenue is a factor of pharmacy type. This represent and annual figure.

This model assumes that pharmacies on average make a 10% margin on all non NHS sales. In reality this will have a wide variation, with some expensive perfumes sold at higher margins, and some medicinal products sold at a smaller margin.

Incomes into Community Pharmacy

For the purposes of modelling, the incomes into community pharmacy are from NHS Supply, NHS service or from Non NHS sources.

$$f(\text{Pharmacy_Income}) = (\text{NHSSupply_year}) + (\text{NHS Services}) + (\text{NonNHS Income})$$

where

$$f(\text{NHSSupply_year}) = 12 * [2217 + (\text{Items} * 2.3127)]$$

$$f(\text{NHS Services}) = [(28 * \text{mur_volume}) + (25 * \text{nms_volume}) + (\text{Enhanced Services})]$$

$$f(\text{NonNHS Income}) = [(\text{Total Revenue} - \text{NHS Revenue}) * 0.1]$$

The Nature of Community Pharmacy Costs

The NHS income into community pharmacies does not discriminate between ownership or business model within the pharmacy. The national framework applies in the same way to all pharmacies dispensing over 2,300 prescriptions per month. However, the natures of the costs of running the pharmacy are variable based on a number of factors. For example, Retail driven large multiples tend to have higher costs due to their location in prime retail areas such as shopping centres and high streets (£577 per m² for retail driven large multiples and £238 to £288 per m² for all other pharmacy types)(PricewaterhouseCoopers LLP, 2011).

There are a diverse range of providers that have each carved out their niche within the community pharmacy market in England. Using a nomenclature based on ownership, these providers can be defined as Large retail driven multiples; Non-retail driven multiples; Supermarkets; Independents; and Small multiples(PricewaterhouseCoopers LLP, 2011). *Independents* are considered to be those pharmacies in chains of less than six, *small multiples* are groups of six or more pharmacies, but not one of the six large entities (Boots, Lloyds, Rowlands, Co-op, Day Lewis and Superdrug). *Retail Driven Multiples* represent branches from the six big entities that focus on retail services, and *Non-retail driven large multiples* which focus on NHS services. *Supermarkets* are in-store pharmacies from Sainsburys, Morrisons, Asda and Tesco.

The Department of Health modelling of services categorised pharmacies using a similar approach: local independent pharmacies; Specialist pharmacy chains; Pharmacy-led health and beauty retailers; and Supermarket pharmacies(Department of Health, 2009a).

Local independent pharmacies are built on their strong community connections, often located in rural or deprived areas. They are perceived to be difficult to navigate, often being cluttered; missing a clean clinical environment; and lacking the privacy and anonymity afforded by other pharmacy types(Department of Health, 2009a). *Specialist pharmacy chains* offer a clinical, efficient environment. However the sterile environment inhibits the same continuity provided by local independent providers(Department of Health, 2009a). The *pharmacy-led health and beauty retailers* offer a large range of products to consumers building their business on retail. Although they lack the personal service and relationships provided by independent and specialist providers, they are perceived to offer appropriate levels of privacy and a clinical environment for services(Department of Health, 2009a). *Supermarket pharmacies* are located in-store and

offer anonymity and convenience, particularly appealing to men due to their non-feminised environment. Consumers felt that there was a long way to go for these pharmacies to develop the on-going personal relationships required in the clinical environment (Department of Health, 2009a).

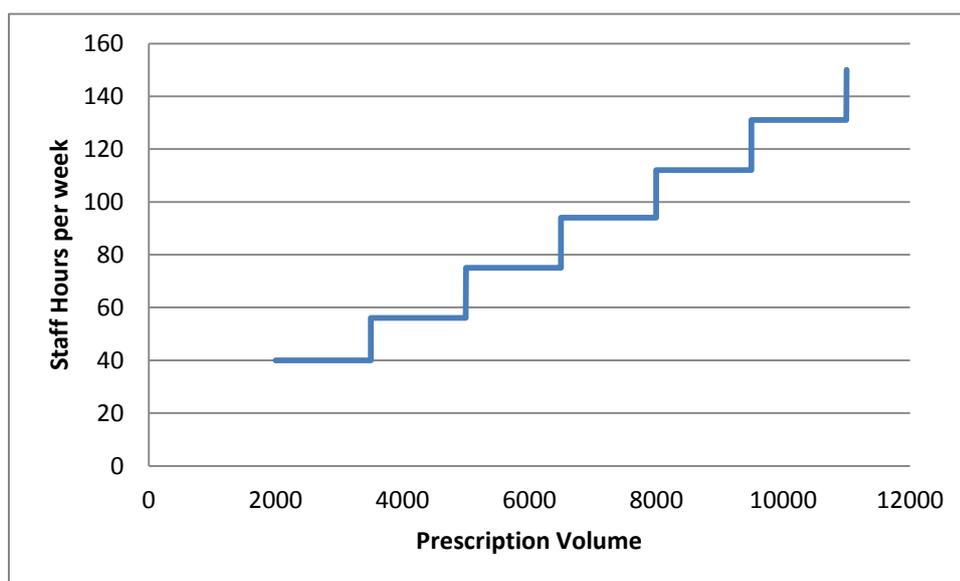
It is important to consider this nomenclature when considering the costs associated with running a community pharmacy. Broadly speaking the costs of running a community pharmacy can be separated into staff costs, property costs, depreciation of asset costs, other costs, value, office costs and value of asset costs. Managing the property cost which consist of rents, including utilities and business rates are important to the business profitability. Other costs include, professional fees, staff training, insurance, cleaning, postage and printing and bank charges (PricewaterhouseCoopers LLP, 2011).

Breakdown of the Costs

Staff Costs represents the largest element of cost incurred by a pharmacy business. The figures shown in table B.10 have been calculated based on the staff costing provided to the PwC cost of service inquiry. This includes all costs at the branch level including accountants, cleaners and delivery and distribution staff. For non retail driven enterprises this constitutes an average cost of approximately £150,000 per annum on average.

However, staff costs are related to the workload within the pharmacy, and the productivity of that labour source. For those pharmacies dispensing large volumes of prescriptions, or opening for extended hours, there is a requirement for more labour and therefore further costs. How pharmacies manage these costs is complex, but for the most part related to the work undertaken. The drug tariff sets out the number of staff that a pharmacy must have present for the full practice payment to be claimed based on volume (figure B.2).

Figure B.2 – Required dispensing staff hours per week for practice payment



Beyond 11,000 items, 19 hours of dispensing staff are required for every extra 1,500 prescriptions dispensed. Appropriate dispensing staff includes a pharmacist; a non-practising pharmacist working as a dispenser; a pre-registration trainee (only half of the pre-registration trainees hours should be counted for this purpose) or an assistant trained to undertake the functions being performed.

Behind the variable functions of staff costs, some remain static including the work of cleaners, accountant which remains constant across the different pharmacies.

$$f(\text{Staff Cost}) = f(\text{Volume of Prescriptions}) + f(\text{Non NHS Revenue}) + f(\text{Opening Hours}) + f(\text{overhead staff})$$

Table B.10 – Average Staff Costs

	Total Staff Costs
Independent	£ 152,660.81
Small Multiple	£ 153,813.79
Non Retail Driven Large Multiple	£ 154,023.38
Retail Driven Large Multiple	£ 428,214.29
Supermarket	£ 192,854.29
Overall	£ 189,333.33

Source: PwC Cost of Service Inquiry

Property Costs

The cost per square metre are similar for all pharmacy types; between £238 to £288 per m². Retail driven large multiples are £577 per m². These higher total property costs may in part be due to higher costs locations (table B.11).

Table B.11 – Property Costs

	Mean rent (per sq metre)	Mean floor area (sq metre)	Mean Cost (per annum)
Independent	258	101	£ 26,058.00
Small Multiple	197	109	£ 21,473.00
Non Retail Driven Large Multiple	228	105	£ 23,940.00
Retail Driven Large Multiple	370	619	£ 229,030.00
Supermarket	170	49	£ 8,330.00

Source: PwC Cost of Service Inquiry survey of contractors with DH/PSNC assumptions

The main factor in the property costs is the type of pharmacy. For the purposes of the model, the main rent is averaged to £263 per sq metre, with an assumed average size of 105 sq metres. This equates to an annual cost of £27,615.

$$f(\text{Property Costs}) = f(\text{mean rent}) * f(\text{floor area})$$

$$f(\text{Property Costs}) = [263 * \text{floor area}]$$

Depreciation of Assets

Depreciation of assets is the operating costs based on average refit costs of the pharmacy using estimates of refit/replacement provided by the PwC survey. This includes the shop, IT, consultation room shelving and other pharmacy assets. This is based on average depreciation per branch. Each asset was weighted based on likely time to require replacement⁶⁶.

Table B.12 – Depreciation of Assets

	Average depreciation per branch per annum
Independent	£ 13,000.00
Small Multiple	£ 14,000.00
Non Retail Driven Large Multiple	£ 17,500.00
Retail Driven Large Multiple	£ 44,000.00
Supermarket	£ 8,000.00

Source: PwC Cost of Service Inquiry

⁶⁶ This is based on the calculations used in the PwC cost of service inquiry.

This feature is a function of the type of pharmacy and the ownership. The larger size and organisation of the large multiples leads to additional refit costs.

$$f(\text{Depreciation of Assets}) = f(\text{pharmacy type})$$

Other Costs

There are other additional operating costs in the pharmacy. These include costs that the pharmacy may face, including delivery, professional fees, insurance, stationary, IT, mixed financials, Bank charges etc.

Table B.13 – Other Costs

	Other Costs	
Independent	£	17,767.00
Small Multiple	£	14,498.00
Non Retail Driven Large Multiple	£	20,776.00
Retail Driven Large Multiple	£	43,547.00
Supermarket	£	7,265.00

Source: PwC Cost of Service Inquiry survey of contractors with DH/PSNC assumptions

These operating costs are again a function of pharmacy type and ownership. On average these were reported to the PwC to be about £20,909 per annum.

$$f(\text{OtherCosts}) = f(\text{Pharmacy Type})$$

Head Office Costs

The costs of the running and maintaining the head office need to be accounted for in the operating costs of the pharmacy. Head Office costs have been allocated on a per branch basis, distribution by revenue per pharmacy. Some head office costs are universal, some redistributed. Independents have very low head office costs, and represent a cost of less than £2,600 per branch per annum (table B.14).

Table B.14 – Head Office Costs

	Head Office Costs	
Independent	£	2,600.00
Small Multiple	£	38,000.00
Non Retail Driven Large Multiple	£	85,000.00
Retail Driven Large Multiple	£	141,000.00
Supermarket	£	68,000.00

Source: PwC Cost of Service Inquiry survey of contractors with DH/PSNC assumptions

As with other costs, these remain to a large extent driven by the structure and nature of the pharmacy business.

$$f(\text{HeadOfficeCost}) = f(\text{Pharmacy Type})$$

Value of Assets

The return on assets represents the return that a company should earn on invested capital in order to provide sufficient return to the investors who are financing the business, categorised by tangible and intangible assets. This includes the tangible assets: working capital, fixtures and fittings, IT assets and stock holdings of the pharmacy; and the Intangible Assets, which have been calculated through the Greenfield Modelling approach. This is an estimate of intangible assets as a proportion of revenue, made by comparison of a hypothetical new pharmacy and an existing pharmacy. This provides an estimate of the value of the assets in a community pharmacy business (table B.15)

Table B.15 - Value of Assets

	Total Assets	Cost of Capital	Fair Return on Assets
Independent	£ 254,671.00	15.7%	£ 39,983.35
Small Multiple (6-20 branches)	£ 270,732.00	17.2%	£ 46,565.90
Small Multiple (more than 20 branches)	£ 367,432.00	15.2%	£ 55,849.66
Non Retail Driven Large Multiple	£ 398,746.00	9.1%	£ 36,285.89
Retail Driven Large Multiple	£ 703,377.00	9.1%	£ 64,007.31
Supermarket	£ 326,284.00	9.1%	£ 29,691.84
Overall	£ 372,810.00	12.3%	£ 45,855.63

Source: PwC Cost of Service Inquiry survey of contractors with DH/PSNC assumptions

A fair return on these assets was then calculated using the WACC methodology to demonstrate the value of the capital, in the PwC cost of service inquiry. The cost of equity has been calculated using a standard capital asset pricing model (CAPM). Based on various assumptions the PwC best estimate for average pre-tax real WACC is 12.3%. Therefore the calculated Fair return on investment is the WACC (12.3%) multiplied by (Tangible and intangible assets) minus the tax benefit.

The fair rate of return represents the return that a company should earn on invested capital in order to provide sufficient return to investors who are financing the business. Essentially this is the cost of the capital invested in the business.

In the model this is a factor of pharmacy type as larger business are able to access capital at comparable cheaper rate.

$$f(\text{Cost of Capital}) = f(\text{pharmacy type})$$

Overall Costs

In this the largest factor is the value of the total assets.

$$f(\text{Costs}) = [\text{Staff Cost} + \text{Property Cost} + \text{Depreciation of Assets} + \text{Other Costs} + \text{Head office Costs} + \text{Cost of Capital}]$$

where

$$f(\text{Staff Cost}) = f(\text{Volume of Prescriptions}) + f(\text{Non NHS Revenue}) + f(\text{Opening Hours}) + (\text{overhead staff})$$

$$f(\text{Property Costs}) = [263 * \text{floor area}]$$

$$f(\text{Depreciation of Assets}) = f(\text{pharmacy type})$$

$$f(\text{Other Costs}) = f(\text{Pharmacy Type})$$

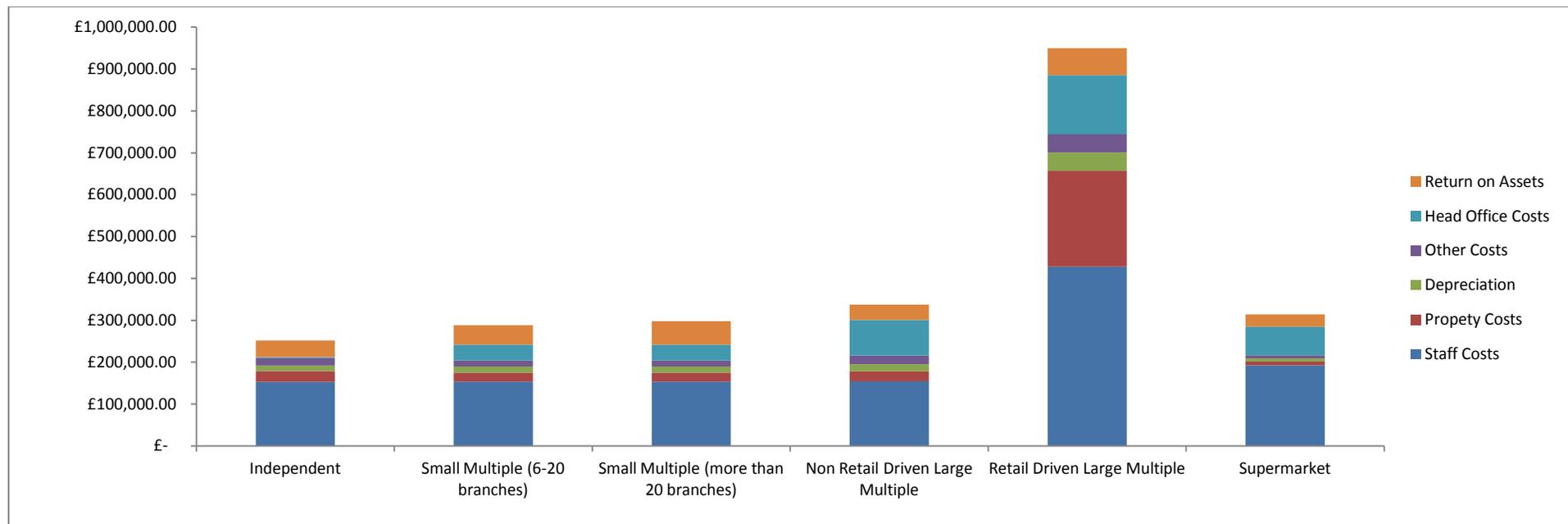
$$f(\text{Head Office Cost}) = f(\text{Pharmacy Type})$$

$$f(\text{Cost of Capital}) = f(\text{pharmacy type})$$

The relative value of these overall costs is shown in table B.16.

	Staff Costs	Property Costs	Depreciation	Other Costs	Head Office Costs	Return on Assets	Total
Independent	£ 152,660.81	£ 26,058.00	£ 13,000.00	£ 17,767.00	£ 2,600.00	£ 39,983.35	£252,069.16
Small Multiple (6-20 branches)	£ 153,813.79	£ 21,473.00	£ 14,000.00	£ 14,498.00	£ 38,000.00	£ 46,565.90	£288,350.70
Small Multiple (more than 20 branches)	£ 153,813.79	£ 21,473.00	£ 14,000.00	£ 14,498.00	£ 38,000.00	£ 55,849.66	£297,634.46
Non Retail Driven Large Multiple	£ 154,023.38	£ 23,940.00	£ 17,500.00	£ 20,776.00	£ 85,000.00	£ 36,285.89	£337,525.26
Retail Driven Large Multiple	£ 428,214.29	£ 229,030.00	£ 44,000.00	£ 43,547.00	£ 141,000.00	£ 64,007.31	£949,798.59
Supermarket	£192,854.29	£ 8,330.00	£ 8,000.00	£ 7,265.00	£ 68,000.00	£ 29,691.84	£314,141.13

The total costs are higher than those reported by PwC as there calculation include the value of total assets of the business, not just NHS business.



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Appendix C - The 'Value' added by the Pharmacy Business

A business model depicts an organisation's value creation, proposition and capturing. It is a meaningful concept for explaining the relationship between strategy and the skills of the pharmacist. The same pharmacist 'commercialised' in different ways may result in a different commercial outcomes. Hence the business model can be understood as a mediating constant between the profession and its economic value.

It is the profession's social 'value' that has allowed pharmacy businesses to acquire premium incomes in excess of those observed in other sectors of the retail. Different aspects of the community pharmacy business operate different business models, but to a large extent pharmacy has provided an 'advice based' model, where the value creation has been as a result of the knowledge and skills of the pharmacist. Consumers utilise their 'clinical' skills to provide them with a diagnosis, without a direct financial charge. This can, in some cases, provide early diagnosis and referral for more serious medical conditions. The 'value' of the advice is recouped through the sales of a product to accompany that diagnosis.

Such a model relies on people needing and requiring advice and then subsequently purchasing suitably priced products. However, as a model it is in threat. In the first instance, consumer perceptions of advice have changed. Customer service is something that is expected, even demanded. In pharmacies the boundary between good customer service and health advice is blurred. This leads to a perception of pharmacists' counselling and diagnosis skills as being part of a customer service role, rather than a 'clinical' healthcare role. As such, it becomes harder to present a case for premium incomes as a result of this advice. Yet, evidence suggests that one in seven consultations results in advice without a sale (FIP Pfizer, 2010). Coupled to this, the value of each sale has decreased. The abolition of re-sale price maintenance in 2001 further reduced the margins on OTC medicines, exacerbated recently by tightened consumer spending.

Pharmacies, in a similar way to post offices, create 'value' beyond those typically associated with retail activities. Central to developing a strategic future for community pharmacy is

understanding which of these 'values' and societal functions are considered worth preserving in future business models.

Consumers 'value' the fact that pharmacists are the most accessible health care professional. This offers a large social support network for many people with long term conditions. Changing the structure of supply to 'hub and spoke' or 'mail order' models may threaten this 'value' and therefore reduce the premiums that are paid for medicines supply.

The accessibility of 'advice' to a large population was central to the creation of the 'healthy living pharmacy' initiative. The 'healthy living' pharmacy concept, developed by NHS Portsmouth and the local pharmaceutical committee, aims to use pharmacies to promote good health and provide proactive health advice. It built upon the pharmacy White Paper call for pharmacies to become healthy living centres, promoting health and self care (Department of Health, 2008a). In contrast to previous pharmacy innovation, such 'advice' is not only provided by the pharmacist, but by the whole pharmacy team. Pharmacies receive income for providing this 'advice' rather than providing a specific product. The evidence base behind this initiative has been broadly positive, and their government is seeking to gather further evidence of the effectiveness of community pharmacies through pathfinder sites.

Other schemes have shown potential to develop a system where the 'value' provided by the pharmacist is separated from supply of a product. Doncaster PCT developed a quality and outcomes framework (QOF) for community pharmacy in 2007. The scheme aimed to financially reward pharmacists based on outcomes, whereby pharmacies could earn 100 points a year with an average pay of £90 per point, totalling £9,000 in potential annual earnings. Within its third year, the QOF had secured universal participation in the area and helped to achieve targets such as raising pharmacies' safety alert response rate from 40 to 90 per cent.

These two different examples both provide business models where the 'value' of the pharmacist is integral to the business. From a professional perspective this addresses the 'under-utilisation' accusation that is described in policy. However, these models separate the remuneration for advice from the supply of a product.

Developing business models for the future require an acknowledgement of where the funding streams for this value added by the pharmacists come from. A 'weak' future for

community pharmacy would be one where the profession continues to become consumed by supply, with other groups, such as medicine and nursing incorporating the clinical aspects of pharmaceutical care and medicines management into their roles. Indeed, less expensive (and experienced) technicians and assistants could assume the majority of the supply of medicines to the public. In such a scenario the ‘value’ that supports the business is a technical and logistical supply function as opposed to a ‘clinical’ knowledge and advice function. As such the economic rewards for the former are likely to be far less than those of the later.

On this basis the challenge for both the business and the profession is to demonstrate that the current ‘value’ that community pharmacies apply to the supply chain is worthy of future investment and support. This begs the question of where is the ‘value added’ by community pharmacy, and where is likely to be in the future.

The most obvious ‘value’ is the supply of nearly a billion prescription items to patients across England, and this should not be underestimated. Yet it represent as technical and logistical supply function, rather than a ‘clinical’ addition of value. Table C.1 describes the main areas where ‘value’ is added and therefore the main basis upon which future business model could develop.

Table C.1– Value added by Community Pharmacy

‘Value’ Model	Evidence Base
Supply of Medicines	The supply of nearly a billion prescription items each year. This is the essence of the current supply based model. Funding model for community pharmacy currently supports the community pharmacy business (Pharmaceutical Services Negotiating Committee, 2011d)
Safety	1% of GP prescriptions have serious error on them (Shah et al., 2001). Pharmacists prevent serious harm being caused in a limited number of patients (Dornan et al., 2009). The Department of Health pays for this ‘risk management’ through the contractual framework. Future models could adopt a primary care based approach where pharmacists are located in the surgeries
Advice on Prescription Medicines Taking	Pharmacists can aide in the adherence of medicines to patients. This provides the basis for the models behind the New Medicines service (Clifford et al., 2006) and MURs
Accessibility, Social Support, Self Care Management.	1.6 million visit pharmacy daily; accessible to population (Department of Health, 2008a). Pharmacies provide reassurance to patients (Harding and Taylor, 1997). Over a billion packs of medicines were purchased in the UK (The Proprietary Association of Great Britain, 2010), at least half of which were purchased in community pharmacies. The social support and advice is recouped through the sale of OTC medicines. Yet one in seven consultations without a sale (FIP Pfizer, 2010)
Early Diagnosis and Health Checks	Early diagnosis during health checks (Department of Health, 2008b) and disease awareness programs are supported by direct payments from the health service. Under this model advice is directly remunerated
Referral and Signposting, Lifestyle Support	Pharmacists reassure and allow access to other providers (Carroll et al., 2010). Examples of specific schemes include Alcohol reduction (Watson et al., 2011; Dhital et al., 2010)The Healthy Living pharmacies program aims to provide additional income for the advice provided in these circumstances. However traditionally this was included within the income for product supply
Individual Pharmacy Services	Evidence of beneficial outcomes in a variety of services (Burnham, 2011). In these cases the pharmacy is remunerated for advice directly

The 'new' income streams into community pharmacy represent a change in the way pharmacists are remunerated. Previously advice and supply cost were entangled in the physical object, the medicine, whereas these new services provide support and advice, but without the physical object. As such they are less tangible and therefore easier to discredit. To some extent this explains why pharmacists hold onto the tangible product of supply as being so important to their identity.

Indeed the 'value' of capturing prescription errors is one of economic utility (Dornan et al., 2009). Yet the payment for this 'service' is captured within the price paid for the supply of the medicine⁶⁷. This is the same for other 'intangible' benefits that pharmacies provide. For example, patients often consult the pharmacist for reassurance to justify visiting the general practitioner (Harding and Taylor, 1997; Harding and Taylor, 1994) and for advice on accessing other parts of the healthcare service (Carroll et al., 2010), are also included in the payments for prescription supply.

Extrapolation of the 'value' of local pharmacies can be taken from the social support provided by other retail outlets, in particular Post Offices. For example, the post office network of approximately 14,000 outlets is believed to offer wider social benefits in terms of social cohesion in the region of between £1.232 billion and £5.344 billion out of an overall estimated total social value of between £2.3 billion and £10.2 billion (NERA Economic Consulting, 2009). In the case of post offices there was a large difference observed between the social values for the network as a whole, and the values associated with the specific services provided by post offices, which was interpreted to represent the value that consumers to the wider social role of post offices. It is hypothesized here that community pharmacy would reflect a similar pattern. Particularly as pharmacies operate in contrast to the inverse care law (Hart, 1971; Hart, 2000) showing a greater density of pharmacies in areas of deprivation.

The same 'value' principle applies in the supply of OTC medicines, where the cost of advice is recouped through supply. Overall an estimated 1.6 million people visit a pharmacy every day (Department of Health, 2008a). Most patients with long-term conditions regularly visit the same pharmacy to seek healthcare advice (Continental Research and Solutions Research, 2008). One in seven pharmacy consultations fails to result in a sale (FIP Pfizer,

⁶⁷ The safety role that pharmacists play should not be overstated. They, in turn also introduce errors as the dispensing error rate in community pharmacy is 3.3%, although only one error in a hundred was found to be severe - **Dean Franklin B and O'Grady, K.** 2007: Dispensing errors in community pharmacy: frequency, clinical significance and potential impact of authentication at the point of dispensing. *International Journal of Pharmacy Practice* 15: 273-281.

2010). For example, £23.8 million was spent in the UK in 2010 on head lice and worm treatments (The Proprietary Association of Great Britain, 2010). Using a counterfactual of GP care (£36 per consultation before prescribing costs) (PSSRU, 2011), then a conservative estimate of £10 per treatment from a pharmacy suggests £72 million in savings by using community pharmacy. Although a crude estimate, this demonstrates how the advice of pharmacists is comparatively cheaper than GPs.

By contrast the more recent developments for community pharmacy have adopted a 'fee per service' approach, where the 'value' of the pharmacist's advice and support is paid for directly. Medicines Use Reviews and NMS are two examples. In some cases these have been shown to be economically viable. For example the NHS health checks delivered through community pharmacy, are designed to diagnose conditions such as diabetes, heart disease and chronic kidney disease early. The impact assessment showed that the NHS health check program would cost around £3,500 per QALY gained (Department of Health, 2008b).

The Healthy living pharmacy program adopts an approach where advice is remunerated. Early positive results from the Healthy Living Pharmacy program suggest that advice provided by health trainers is beneficial (Watson et al., 2011; Dhital et al., 2010).

In the future the amount that health care planner pay for the 'value' of the pharmacy business will likely move towards a transparent advice based model. Making the payment structure more transparent will require better evidence of outcomes in order to support the continued investment. At present the economic evidence to support such transparency is in the main weak. Creating this political and social justification for the payments will have large impact on the future path that community pharmacy takes.

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