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EVALUATING THE IMPLEMENTATION OF THE NEW MEDICINE SERVICE IN ENGLAND

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Abstract

Community pharmacies in England provide a variety of services including essential services such as the dispensing of medicines, advanced services such as Medicine Use Reviews, and enhanced and locally commissioned services, for example the minor ailments scheme. In October 2011 a new advanced service called the New Medicine Service (NMS) was introduced. It aimed to improve adherence to newly prescribed medicines for patients with certain long term conditions and reduce medicines wastage.

This thesis aims to evaluate the implementation of the NMS by exploring how the service was developed and implemented, identifying both potential and actual barriers and facilitators to NMS implementation, investigating the proportion of prescription items that are eligible for the service, and examining the uptake and provision of the service.

In order to achieve this several studies were carried out. Interviews were conducted with stakeholders involved in the service's development and implementation. Focus groups were conducted with community pharmacists complimented by interviews with superintendent pharmacists both before and after the introduction of the NMS. Data regarding the number of prescription items eligible for the service were collected in community pharmacies, and an analysis of service records for a large national chain of pharmacies was carried out.

The studies determined that there were four stages to the development and implementation of the NMS; pre-negotiation, negotiations, the launch phase, and post-implementation. Both community pharmacists and superintendent pharmacists were enthusiastic about the potential of the service prior to the introduction of the service and anticipated good uptake of the service which was confirmed by post-implementation results. Several barriers were identified prior to implementation, the most important of which was the payment structure. Post-implementation results confirmed that the payment structure had affected NMS implementation, and direct observations in pharmacies, that the opportunity rate to provide the service was nearly half of the payment structure's theoretical rate. Analysis of service data showed the uptake of the NMS was greater than the uptake of MURs in 2005.

The findings of this thesis provide policy makers, pharmacy stakeholders, community pharmacists, and researchers with knowledge of how pharmacy

services are developed. It also provides insights about factors that can facilitate or hinder service provision, including pharmacist attitudes towards a service, certain service and pharmacy characteristics (such as the ability to carry out telephone consultations), company encouragement to provide the service, the experience of conducting other pharmacy services, pharmacist workload, the accreditation procedure, and the services payment structure. These insights can be used to improve future pharmacy services' implementation.

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Wells KM, Boyd MJ, Thornley T, Boardman HF. What proportion of prescription items dispensed in community pharmacies are eligible for the New Medicine Service? *BMC Health Services Research.* 2014 14:115 doi:10.1186/1472-6963-14-115.

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M.J. Boyd, K.M. Wells, T. Thornley, H.F. Boardman, Views of community pharmacists regarding the New Medicine Service prior to its implementation. *International Journal of Pharmacy Practice.* 2012, 20 (Suppl. 1), p22

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The New Medicine Service: supporting patients with their medicines. *Pharmaceutical Care Network Europe – Medication Review Symposium* May 2012, Leuven, Belgium. *Oral presentation*.

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Views of Community Pharmacists Regarding the Implementation of the New Medicine Service. *International Pharmaceutical Federation (FIP) World Centennial Congress of Pharmacy and Pharmaceutical Sciences*. October 2012, Amsterdam, Netherlands. *Poster presentation.*

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Contents

List of Tables

List of Figures

Acronyms

AURs – Appliance Use Reviews

CCG- Clinical Commissioning Group

CI –Confidence Interval

COPD – Chronic Obstructory Pulmonary Disease

GP – General Practitioner

HbAlc – Glycated Haemoglobin

HLA – Healthy Living Advice

LAT – Local Area Team

MURs – Medicine Use Reviews

NHS – National Health Service

NICE – National Institute for Health and Care Excellence

NMS – New Medicine Service

PCT – Primary Care Trust

PMR – Patient Medication Record

PSNC – Pharmaceutical Services Negotiating Committee

QOF – Quality and Outcomes Framework

RCT – Randomised Controlled Trial

TPB– Theory of Planned Behaviour

TRA – Theory of Reasoned Action

Chapter 1: Introduction

The provision of advanced clinical services by community pharmacists is a relatively recent development with the first advanced service, Medicine Use Reviews (MURs), having been introduced in 2005. The introduction of MURs required pharmacists to get to grips with the new concept of providing formal NHS consultations as part of the community pharmacist role. With the MUR service being established and the change in pharmacist role accepted, the introduction of the New Medicine Service (NMS) provided an opportunity to understand how pharmacy services are implemented without the impact of culture change. This can be used to inform future service implementation. The introduction of the new service also allows us to see how culture within pharmacy has changed since the introduction of MURs and to compare the implementation of the two services.

When examining the implementation of a service it is helpful to identify barriers and facilitators to the process. Doing so means that barriers can be addressed and facilitators optimised to help the implementation of the service. Many barriers and facilitators to MUR provision and implementation have been published and it was thought interesting to find out what the pharmacy profession has learned from it and whether the same barriers and facilitators have affected the introduction of the NMS.

Whilst much research has been conducted examining the provision of MURs, there is still a lack of information about how services are developed. The introduction of a new pharmacy service is an opportunity to understand the process of service implementation. By understanding how services are developed and introduced, and what is important to stakeholders involved in commissioning new services, research can be focused on providing the evidence most valued by commissioners for future services.

In this chapter the background to community pharmacy services and the different tiers of services is set out. Adherence to medicines and medicines wastage are then introduced, focusing in particular on how to measure them, interventions that aimed to improve adherence and wastage, and the problems caused by non-adherence. I then examine the different models of health behaviour change and how they relate to non-adherence and the New Medicine Service (NMS). The NMS is then introduced, including the structure of the service and the research that underpins it. The existing body of

research that has looked at the NMS is described, as is research conducted concerning the implementation of the Medicine Use Review (MUR) service. I look at current research into the implementation of clinical services in order to identify facilitators and barriers to service implementation. I then consider different theories of service evaluation and relate them to evaluating the NMS. The different ways in which the NMS could be evaluated are described including descriptions of the different methods available. Finally the aims and objectives of this thesis are detailed.

1.1 National Health Service community pharmacy services

In England, community pharmacy services are not directly provided by the NHS but through an NHS contract with community pharmacies. This NHS contract has changed over time to move from being primarily based on prescription dispensing to one where pharmacies are paid for providing more clinical services in addition to the volume of dispensing. This report is concerned with community pharmacies only, therefore when this report refers to pharmacies, it refers to community pharmacies. Pharmacy businesses can be grouped by size. In this thesis pharmacies have been categorised using the definitions used by PwC in their cost of service inquiry for community pharmacy. Independent pharmacies are chains of 1-5 pharmacies, small chain pharmacies have 6 or more pharmacies (but do not including the 10 largest pharmacy chains in England), and larger chains are defined as being the 10 largest pharmacy chains in England.[1]

Pharmacists speak about 'The Pharmacy Contract'; however there is no one document that is the contract. Instead, what is required of a community pharmacist in England is outlined in several documents namely: (i) The National Health Service Act 1977, (ii) The National Health Service (Pharmaceutical Services) Regulations 2005[2], (iii) The Pharmaceutical Services (Advanced and Enhanced) (England) Directions 2005[3], and (iv) The Pharmaceutical Services (Advanced Services) (Appliances) (England) Directions 2009[4].

The contents of these documents differ in focus and hence appear to serve different purposes. The National Health Service Act 1977 provides a background for understanding the Pharmacy Contract. On the other hand The National Health Service (Pharmaceutical Services) Regulations No.641 2005 and The Pharmaceutical Services (Advanced and Enhanced) (England) Directions 2005 are useful consultation tools detailing what the NHS expects of a community pharmacy. The more recent publication, The Pharmaceutical

Services (Advanced Services) (Appliances) (England) Directions 2009, adds additional services that a community pharmacy can provide under the NHS.

There are three levels of services that pharmacies provide. These include (i) essential services, (ii) advanced services, and (iii) enhanced services and locally commissioned services; these are discussed in the sections that follow. Pharmacies are remunerated for the services they provide via the NHS-Business Services Authority Prescription Pricing Division (PPD).

1.1.1 Essential Services

Essential services are the core services that all pharmacies must provide. These first level services include;

- Dispensing of medicines – the supply of medicines against NHS prescriptions

- Repeat dispensing – the supply and management of medicines against repeat prescriptions

- Additional essential service requirements linked to the supply of appliances – for example, the measuring and fitting of stockings

- Waste management - collection and appropriate disposal of medicines returned by patients

- Public health – participation in health promotion and the provision of advice

- Signposting – directing customers to other sources of help and support

- Support for self-care – providing advice and supplying medicines over the counter

- Clinical governance – ensuring appropriate procedures and safety mechanisms are in place within the pharmacy.

1.1.2 Advanced Services

The second level of services is advanced services. They are nationally commissioned services and can only be provided by accredited pharmacists from premises that have been approved by the local Clinical Commissioning Group (CCG) or Local Area Team (LAT). One of the requirements for having a premises approved is that there is a consultation room where the services can be provided in private. The first advanced service to be introduced was

medicine use reviews (MURs), and the prescription intervention service in 2005. Since then two more advanced services have been implemented; appliance use reviews (AURs) and stoma appliance customisation services, although they are not widely provided. The latest advanced service to be introduced is the New Medicine Service (NMS) implemented in October 2011 and it is the implementation of this service that this thesis concerns.

MURs aim to address patients' use of their medicine and to improve their knowledge of the pharmaceutical treatments they are undergoing.[3] AURs are reviews for patients who use appliances (e.g. catheters) and so aim to improve the patients' knowledge and use of their appliances.[4] Stoma services are different from the other two advanced services and are provided by far fewer pharmacists. The stoma service provides custom fitting of stoma appliances for patients to ensure proper fitting and correct use as well as prolonging the duration of use of the stoma appliance and therefore reducing wastage.[4] Prior to the introduction of the New Medicine Service (NMS), advanced services have aimed to improve knowledge and use of medications and appliances and to reduce wastage of them. This contrasts with the NMS which was introduced explicitly to address patient adherence to medicines.

The most widely established advanced service is the MUR and prescription intervention service, therefore the majority of data available about uptake of advanced services are about MURs. The uptake of MURs was slow with 67% of pharmacies in England providing the service in 2009/10, four years after they were introduced.[5] Previous studies have found that the uptake of MURs was much greater by larger chains than by independent pharmacies.[6]

With over 1.8 million MURs conducted between April 2010 and February 2011 it is important to consider how acceptable the service is to both pharmacists conducting the service and patients that are experiencing it. Pharmacists have been found to have a positive attitude towards MURs and advanced services in general, with many seeing them as an opportunity to extend their role using their existing professional skills.[7] In general patients have been found to be positive about their MUR experience, although it should be noted that few patients had heard of MURs before receiving one, therefore their expectations were not high.[8] Patients are positive about the idea of pharmacists helping them to manage their medicines suggesting potential support for advanced services.[9]

1.1.3 Enhanced Services

The third level of services is enhanced and locally commissioned services. In the past they have been commissioned by Primary Care Trusts (PCTs) but changes to the NHS in the last few years mean that this has changed. There are now several ways these services can be commissioned. The Pharmaceutical Services (Advanced and Enhanced) (England) Directions 2012 set out 20 enhanced services that can be commissioned by NHS England Area Teams.[10] Examples of such services include needle and syringe exchange and the minor ailments service. Services can also be commissioned by Clinical Commissioning Groups (CCGs) and local authorities through NHS standard or local contracts. In addition, if CCGs or local authorities would like a service listed in the 2012 directions to be commissioned as a pharmaceutical service in their area, they can request it to be commissioned by the NHS England Area Team.[11]

1.2   Non-Adherence and Medicines Wastage

1.2.1 Adherence

There are three terms used to describe medicine taking. The different terms do have subtly different meanings however they are often confused. The first term is compliance. It has been defined as; *'The extent to which the patient's behaviour matches the prescriber's recommendations'.*[12] This term is seen as paternalistic and has fallen out of favour despite being commonly used until relatively recently.   The second term that has been widely adopted in preference to compliance is adherence. Adherence has been defined as: *'The extent to which the patient's behaviour matches agreed recommendations from the prescriber'.*[13]

Both of the above terms are about the patient following a health care professional's recommendation.   A more patient-centred approach is concordance.   It has been defined as: *'An agreement reached after negotiation between a patient and a health care professional that respects the beliefs and wishes of a patient in determining whether, when and how medicines are to be taken'.*[13]   Concordance therefore describes a process rather than an outcome.

Therefore, although concordance is the newest and most patient-centred term to describe medicine taking behaviour, it is adherence that is most widely used. It is the term used by the NHS, and the term that is referred to in the

service specification from the NMS. Therefore this is the term that will be used throughout this project.

In 2009 The National Institute for Health and Clinical Excellence (NICE) published guidelines regarding adherence to medicines. The existence of these guidelines demonstrates how important improving adherence is to the NHS. In the guidelines, NICE defines adherence to medicine as *'the extent to which the patient's action matches the agreed recommendations'*.[14] The guidelines explain the reason for the importance of improving adherence by stating that poor adherence (or non-adherence) leads to negative consequences for the patient, the NHS and society in general.

a) Cost to the individual patient;

Non-adherence is closely linked to treatment failure.[15] For example, if a patient with diabetes does not adhere to their treatment, their blood glucose levels will not reduce and this increases the risk of long-term complications.

b) Cost to the NHS;

It has been estimated that between 30% and 60% of medicines are not taken as recommended[13], costing the NHS £36m-£196m in hospital admissions that could be avoided.[14] In addition to the cost of hospital admissions, there is also the considerable cost of wasted medicine and a poorer quality of life for patients.

c) Cost to society

Society is also impacted by individuals not being adherent. There is evidence to support the idea that non-adherence contributes to the emergence and increase of drug resistant organisms within society.[15] An example of this is Tuberculosis treatment which requires strict levels of adherence to be effective[16] and a failure to complete the treatment course can lead to relapse and drug resistant pathogen strains emerging.[17] Society is also affected by employees missing work due to sickness contributed to by non-adherence.

1.2.2 Non-adherence

According to the definition accepted by NICE, anything less than a 100% match between the patient's actions and the agreed recommendations is classed as non-adherence. Non-adherence can be intentional or non-intentional. Intentional non-adherence is where a patient makes a decision not to take their medicine as prescribed. Non-intentional non-adherence is

where the non-adherence is not as a result of a conscious decision the patient has made, for example where a patient is forgetful.

There are many reasons for non-adherence, both intentional and non-intentional. The risk factors for poor adherence fall into three groups;

(i) Medicine-related factors:

These can be the patient experiencing distressing side effects or having complex regimens for taking the medicine.[18-20] Claxton, Cramer and Pierce found that *'the prescribed number of doses per day is inversely related to adherence'*.[21]

(ii) Emotional or physical factors such as beliefs the patient holds about their disease or the treatment and disabilities that may affect the patient's ability to take their medicine.

(iii) Clinical or social factors such as co-morbidities or lifestyle.[22]

It has been suggested that 30-60% of all medicines prescribed for long term conditions are not taken as prescribed.[13,23] Adherence appears to vary with;

- Age – Adherence seems to improve with age[24] however the relationship is not a simple one as there is higher prevalence of cognitive problems with increasing age[13]. The least adherent age group is adolescents.[24]

- Gender – Women appear to be less adherent to medicine regimens.[25,26]

- Marital status – There may be a correlation between being single and low levels of adherence although the evidence for this is not strong.[27]

- Ethnicity – There seems to be a connection between ethnicity and levels of adherence. The differences between ethnic groups seem to be based on cultural differences in beliefs about medicines and there is variation within groups.[13]

- Education – Higher levels of educational attainment seem to be associated with higher levels of adherence.[27]

- Social support – It has been suggested that social support can help some patients in overcoming barriers to adherence. However little is

known about what types of support are likely to be helpful to different individuals.[13]

- Presence of depression or a level of cognitive impairment – Kessels declared that recalling medicine-taking instructions accurately is necessary for adherence.[28] Therefore anything that impairs the recollection of instructions will reduce adherence. The link between depression and poor adherence is unclear, however depressed patients are three times more likely to be non-adherent than patients who are not depressed.[13]

It is important to note that these characteristics are viewed as factors influencing behaviour rather than explaining adherence or a lack thereof.[13]

1.2.3 Adherence in different medical conditions

Adherence levels tend to differ according to the nature of a patient's condition. Patients with acute conditions, such as a bacterial infection, tend to adhere to pharmaceutical treatments. Patients with long term conditions tend to have lower adherence, with some evidence finding that there is a significant drop in adherence after 6 months of taking a medicine.[29,30] It is also worth noting that there are no widely agreed acceptable levels of adherence.[30] There is also considerable variation in adherence rates in different long term conditions. Some conditions are associated with high adherence rates, such as HIV antiviral treatment (>80%)[31], whereas other conditions tend to have much lower adherence rates, such as asthma (around 50%).[32]

1.2.4 Measuring Adherence

Studies have used a variety of methods to measure or calculate adherence to medicine. The methods can be indirect or direct ways of measuring adherence. Adherence is difficult to measure because if the patient is aware that their adherence is being measured, adherence is likely to increase. Despite the large body of research into adherence, there is no gold standard for measuring it.[33] The different methods include;

- Self-report - This method involves the patient recalling how often they have taken their medicine. Self-report often over-estimates levels of adherence, however it has been found to be a good indicator of

adherence.[34] One such self-report method is the Morisky scale[35]; a validated questionnaire that is widely used to measure adherence.

- Doctors judgement - This method is not an accurate way of determining adherence as it has been found that doctors overestimate their patient's adherence.[36] Consequently this method is not commonly used.

- Pill counts – this involves counting the number of pills left after a period of time to estimate how many tablets the patient has taken during that time. This method makes the assumption that the pills that are not in the container at the end of the time period have been taken rather than wasted.

- Prescriptions - This method involves looking at either GP records to find the dates prescriptions have been written, or pharmacy records to find the date prescriptions have been dispensed. Calculating the intervals between prescriptions being written or dispensed (known as the prescription possession ratio) can be used as an estimate of adherence. This method does make the assumption that when a prescription has been written or dispensed the patient has taken the medicine as directed.

- Electronic measurement devices - This method involves an electronic device being associated with the container containing a patient's medicines e.g. Medication Event Monitoring System (MEMS).[37] The device notes when the container has been opened or activated and the data gained can be used to create a picture of the patient's medicine taking habits. This method makes the assumption that when the container is opened or activated the patient is taking a dose, and seems to give the most accurate adherence measurements, although there is the risk that patient awareness of being monitored could lead to an overestimate of adherence.[38]

- Outcome measures – These are the desired outcomes of successful treatment and are not a reliable way of estimating adherence as there is not necessarily a clear relationship between an outcome measure and adherence. It is based on the assumption that the improving adherence increases the likelihood of the desired outcome measures being achieved.

- Measuring blood serum levels or urinary excretion of the drug - This method allows the monitoring of whether or not a patient has taken any of the drug prescribed. It does not show how the patient takes their medicine, nor the frequency or quantity taken. This method is most commonly used to monitor long term adherence to a therapy. For example measuring glycated haemoglobin (HbA1c) levels (a long term measure of diabetic control) over time gives an indication of adherence to anti-diabetic therapy.

- Observation - This involves the patient attending a pharmacy or clinic to be observed taking their medicine. This method is an accurate way of ensuring adherence, however it is very inconvenient for the patient who must attend the pharmacy or clinic daily. This method is usually used to increase adherence rather to measure adherence. Observation has been used for methadone administration and anti-tuberculosis treatment.

1.2.5 Interventions to Improve Adherence

Measures to improve adherence to medicine aim to improve patient outcomes, reduce the financial burden on the NHS, and slow the increase in drug resistant strains of micro-organisms. Therefore there have been many attempts to develop interventions particularly for patients with long term conditions. In a review of interventions for enhancing medicine adherence, Haynes *et al.* found that the majority of studies of adherence interventions have very small sample sizes, reducing the likelihood of statistically significant findings.[39] Despite this studies have found that interventions can improve adherence. These interventions have at least one of the following characteristics;

- Improved convenience of care

- More information, including about the risk of experiencing side effects[40]

- Reminders to take the medicine(s)

- Self-monitoring by the patient

- Counselling by a health care professional

- Including the family in education about the therapy

- Telephone follow-up by pharmacists[40]

- Supportive care (treatment aiming to improve patients' quality of life by preventing, controlling or relieving complications and side effects from medicines). [39,42]

Much research has looked at targeting interventions to patients with specific conditions. One of these is HIV/AIDS, where high adherence rates are very important, 95% adherence or more is required to give the maximum effect of the antiretroviral therapy.[43] High levels of adherence in patients with HIV/AIDS are associated with lower levels of disease progression, hospitalisation and mortality.[44] In a review of support and education services provided to patients to promote adherence to antiretroviral therapy, several features were identified as related to improved adherence;

- Providing the service at an individual level compared with a group setting,

- Providing the service over an extended period (more than 12 weeks),

- Services aimed at improving practical medicines management skills.[45]

Another long term condition that has been widely researched with regards to improving adherence is type 2 diabetes mellitus, in particular aiming to reduce $HbA1_c$ levels. Interventions that have been shown to reduce $HbA1_c$ levels include a nurse-led telephone intervention[46], a comprehensive care model provided by pharmacists[47] and an intervention where pharmacists were able to make treatment adjustments[48].

Research has also been carried out in patients with psychological illness, chronic heart disease, dyslipidemia, and other chronic conditions such as asthma but relatively little research has been carried out with participants with multiple morbidities.[39] In a study carried out by Clifford *et al* a patient centred telephone-based intervention was found to improve adherence in patients who were 75 years old or over, and patients who have certain long term conditions (stroke, coronary heart disease, asthma, diabetes and rheumatoid arthritis), who were prescribed a new medicine. The intervention focused on providing information to patients about their new medicines and addressing any problems they may have encountered when taking them. The interventions were conducted from a central location by two pharmacists who

had received specific training.[41] This study is examined in further detail in section 1.4.1.

It has been suggested by Elliott that improving access to health care and encouraging interventions that are effective at promoting sustained behaviour change should be a priority for policy makers.[49] The research discussed above suggests that when designing an intervention to improve adherence, some characteristics associated with successful interventions should be incorporated to increase the likelihood of the service improving adherence.

1.2.6 Medicines Waste

The term 'medicines waste' refers to medicine that has been dispensed but that has not been and will not be taken. Medicines waste may be returned to a pharmacy or dispensing GP practice, disposed of via household waste, or retained in the home. Medicines waste can be divided into potentially avoidable waste and unavoidable waste. In good quality pharmaceutical care there is a level of inevitable waste, for example, a medicine may be stopped prematurely if a patient's condition does not respond to it. There are also components of medicines waste that are avoidable and it is here where savings can be made. However it has been argued that the most serious consequence of medicines waste is not the financial implications, but the loss of therapeutic benefit to patients.[50]

In 2004, 600 tonnes of unused medicines were returned to pharmacies to be destroyed.[48] In addition, a recent audit of community pharmacies found that returned medicines had a value of around £100 million, with half of that figure considered to be avoidable waste.[50] These figures represent conservative estimates of general medicines waste as excess medicines may be disposed of informally (e.g. via household waste) and so the exact figure is unknown. In a tough economic environment where savings need to be made, the NHS would be wise to look at affordable strategies to reduce medicines wastage, despite the UK's medicines waste problem being no greater than in comparable countries.[47] An economic evaluation found that £100-150 million could be saved for the NHS by reducing medicines waste.[50]

Medicines waste is often talked about in relation to adherence, however they are two different concepts. Whilst non-adherence may (or may not) lead to some waste, it is not the main cause of medicines waste.[50] Risk factors for waste fall into several categories;

- Individual level factors - These factors are the same as those for non-adherence and include lack of knowledge, experience of side effects and beliefs about medicines. Put simply, if the patient is non-adherent they are more likely to produce waste.

- Process and system causes - Included in this group are; complex treatment regimes, long prescription durations, and changes in treatment.

- Patient group and condition specific causes - Medicines waste tends to vary between different groups of patients and patients with different conditions.[50]

As discussed above, there is a level of inevitable waste involved in good pharmaceutical care. However there are significant savings to be made by reducing waste that is not inevitable. A public survey conducted by the York Health Economics Consortium and the University of London School of Pharmacy found that the most common reason for patients not completing a course of medicine (and therefore producing waste) was the disappearance of symptoms. The second most common reason was a change in medicine by the GP or consultant. Only 6.9% of participants reported not wanting to take the medicine as the reason for not completing a course of medicine.[50]

An audit of medicines returned to community pharmacies was carried out by the same group as the public survey described above. This audit recorded reasons for the medicine being returned. The most common reason was death (26.5%) with the second most common reason being that the medicine was stopped (25.0%). Only 4.78% of returned medicines were recorded as being due to non-adherence.[50]

1.2.7 Interventions to reduce wastage

There have been several interventions that aim to reduce medicines waste. They include restricting prescription length, medicine reviews, repeat dispensing schemes, and awareness campaigns. These are described below.

Restricting prescription lengths

One intervention used within the NHS to reduce medicines wastage was the recommendation from PCTs to reduce prescription lengths. Most commonly prescribers restrict their prescribing to only 28 days of medicines for patients.

Whilst this intervention may reduce the amount of unnecessary medicines prescribed, it may also cause additional problems. The majority of prescriptions written are repeat prescriptions for long term conditions. These medicines tend to be essential and missing doses can be potentially harmful. Reducing the prescription length for these essential medicines increases the likelihood of a patient running out of medicine, which may have the potential to impact on their condition.

In addition to a potential reduction in treatment benefit in patients with long term conditions, restricting prescription length reduces the payment per prescription dispensed for pharmacies as the fixed funding for pharmacy means that an increase in the number of prescriptions reduces the remuneration per prescription. Researchers in the US concluded that restricting the length of prescription was not a cost effective method of reducing waste because the increase in cost in pharmacy charges would outweigh the savings made by reducing waste.[51] However this does not necessarily mean that restricting prescription length is not cost effective in the UK as the US and the UK have different models for remuneration.

Medicine Reviews

One of the aims of conducting medicine reviews is to reduce medicines waste. Studies have found that pharmacists carrying out MURs can reduce the number of repeat medicines ordered and reduce the number of uncollected prescriptions at GP surgeries, thus reducing waste.[52,53] However these studies were highly structured with the pharmacists conducting the MURs adhering to pre-defined standards. In reality the quality of service provision varies with the ability of the pharmacist to conduct MURs, the accuracy of the patient's repeat medicine records and the relationship the pharmacy has with the patient's GP practice.[54] This could affect the likelihood of the MUR effecting change in medicines waste.

A review carried out on medicine reviews in a wider sense (i.e. differing interventions carried out by various health care practitioners) found no firm evidence that medicine reviews had a positive effect on reducing medicines wastage.[55]

Repeat dispensing schemes

Around 70% of all prescriptions written in primary care are repeat prescriptions for items to treat long term conditions.[50] A method of

pharmacist managed repeat dispensing has been introduced where a pharmacy holds batches of prescriptions for a patient who can come into the pharmacy to collect regular medicines, usually on a 28 day basis. The pharmacist confirms with the patient exactly what medicine is needed. This system should reduce waste by reducing the amount of unnecessary medicines collected by patients.

The repeat dispensing scheme is described by the 2008 white paper, Pharmacy in England, as being a proven method of reducing medicines waste.[55] However the paper also acknowledged that repeat dispensing prescriptions only make up 1.5% of all prescriptions issued in primary care. This poor uptake of the scheme, mainly driven by a lack of GP engagement, means that the service has not realised its potential to reduce waste and it has not been possible to assess the cost effectiveness of the service.[47,56]

Awareness campaigns

There have been many campaigns run by PCTs highlighting the cost of medicines waste. These campaigns often include the use of posters and leaflets in GP surgeries as well as community pharmacies. There is anecdotal evidence that these campaigns do reduce the amount of medicine waste within PCTs.[57] Oxfordshire PCT found that the awareness campaign they ran halved the amount of medicines returned to pharmacies.[58] This suggests that media campaigns explaining the cost of medicines waste to local health care are an effective method of reducing waste.

1.2.8 Why Non-Adherence and Associated Wastage is Still a Prevailing Problem

The Evaluation of the Scale, Causes and Costs of Waste Medicines report demonstrates that there is still concern regarding medicine wastage in the NHS, despite interventions having been introduced to reduce waste.[50] The interventions may have failed to reduce waste across the NHS due to the localised nature of the interventions. Another possible drawback to some of the interventions is that they didn't focus specifically on waste reduction. A report and action plan produced by the steering group on improving the use of medicines for better outcomes and reduced waste was published in October 2012.[59] The report detailed possible ways to address the problems identified in the Evaluation of the Scale, Causes and Costs of Waste Medicines report including targeted MURs and the provision of the NMS. Whilst levels of non-adherence and medicines waste in the UK is no higher than in other

countries[49], the publishing of the action plan suggests that non-adherence and associated medicines waste is a priority for the Department of Health.

Despite many attempts to improve the situation, the NHS still has a problem with patients being non-adherent to their medicine and producing waste. A reduction in non-adherence and waste production could lead to significant savings for the NHS in a time when funding is stretched. It has been suggested by Elliott that improving access to health care and encouraging interventions that are effective at promoting sustained behaviour change should be a priority for policy makers.[49]

Increasing levels of adherence requires behaviour change in those taking medicines. Therefore in the next section models of behaviour change are discussed.

1.3 Models of Health Behaviour Change

When considering how to change people's medicine taking behaviour it can be useful to look at models of individual behaviour change. In this section some of the most widely accepted models of individual behaviour change will be examined including; the Health Belief Model, the Transtheoretical Model, and the theories of Reasoned Action and Planned Behaviour, in an effort to understand how they might relate to adherence to medicines and the NMS. Models of social change have not been discussed here as they do not apply to changing an individual patient's medicine taking behaviour.

1.3.1 The Health Belief Model

There is evidence that a patient is more likely to stop taking a medicine if he or she has doubts about the importance of the illness.[60] How these factors are linked and affect a patients action is summarised by the Health Belief Model. Figure 1.1 shows the model in pictorial form.

The Health Belief Model was developed by Becker in 1974 and is a way to predict a patient's behaviour.[62] It acknowledges that there are many factors that influence a patient's decision making process and that ultimately the patient chooses whether or not to take action according to the balance between how the patient thinks the action will benefit them, and the barriers

they face when taking action.   There are four variables: individual perceptions, likelihood of action, cues to action, and modifying factors.

The Health Belief Model
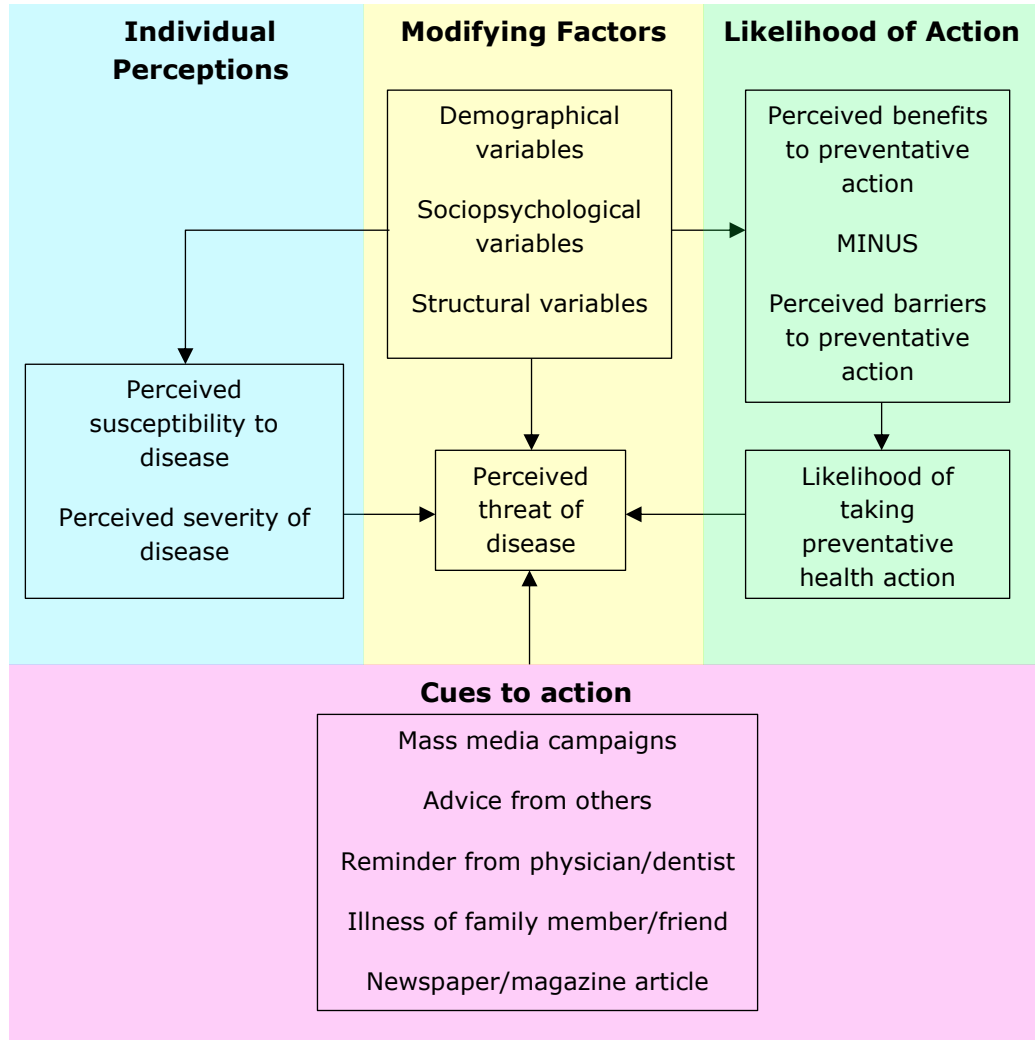
Figure 1.1: The Health Belief Model adapted from Janz and Becker [63]

Individual perceptions

An individual's perceptions are determined by the severity of the disease and how susceptible they believe they are to it. The combination of these factors is known as the perceived threat of the disease.

Likelihood of action

The likelihood that the individual will take action is determined by the balance between the perceived benefits associated with taking action and the perceived barriers to behaviour change.

Cues to action

The model suggests that an individual needs a cue before they will take action to change their behaviour. This can vary from reading a newspaper article encouraging behaviour change or a mass media campaign, to the illness of a family member.

Modifying factors

The health belief model acknowledges that there are factors that can modify an individual's beliefs and the perceived threat of the disease, and so affect their likelihood of action. These modifying factors include the individual's age, gender and socio-economical background as well as their personality and education.

The health belief model can be applied to medicine taking behaviour. It suggests that ideas about the possible benefits of a medicine versus the barriers to taking it are affected by how the patient sees their condition and what concerns they have about the treatment. Horne and Weinman describe this as the necessity-concerns differential, where the patient weighs up how necessary they believe the medicine is, against what concerns they have about taking it.[61] If the necessity score is greater than the concerns the patient holds, they are likely to take the medicine. If the concerns outweigh how necessary the patient believes the medicine is, they are unlikely to take it. These concerns may be specific to the medicine, for example; regarding possible side effects or developing dependence to the medicine, or they might be more general concerns about taking the medicine or the importance or severity of the disease. This is supported by a study carried out by Elliott *et al*. who found that a patient was more likely to stop taking a medicine if they did not believe that the illness was important.[60] From this we can see that the views a patient holds regarding his or her illness and the medicine they are taking can have a considerable influence on the patient's medicine taking behaviour.

Janz and Becker write that patients *'need to have some kind of cue to take action'*. They suggest that this prompt may be a conversation with a *'significant person'*.[63] In the case of the NMS, the pharmacist would hope to be the 'significant person' causing the patient to take action. The health belief model would suggest that the service should address a patient's concerns about the new medicine as well as emphasising the potential benefits in order to improve adherence. The model does acknowledge, however, that whether or not to be adherent is ultimately the patient's decision, and whilst the pharmacist providing the service can hope to influence the decision by altering the beliefs the patient holds, there will be other factors outside of the pharmacists influence.

The health belief model can be used to explain both adherent and non-adherent behaviour. The model would suggest that adherent behaviour results from the individual viewing the threat of disease as significant and deciding that the potential benefits of taking the medicine outweigh the perceived barriers. Non-adherence could be explained by the individual perceiving the threat from the disease as low and the barriers to becoming adherent as greater than the potential benefits to taking the medicine.

A major criticism of the model is that there is a lack of clarity regarding the definitions of the factors and the relationships between them, making the model difficult to apply. This results in the model having weak predictive power.[64,65] Zimmerman and Vernberg conducted a review that found that the health belief model had a lower predictive power than the theory of reasoned action and concluded that the health belief model is really a list of variables affecting behaviour.[66] Another review of the health belief model found that as the model has such weak predictive power with factors difficult to define, it should not be used to inform the structure of new interventions being developed.[65] The implication for the NMS is that if the service is found to improve adherence, it is unlikely to be the result of the health belief models influence on the development of the service.

The health belief model takes social, economic and environmental factors as well as cognitive factors into account. However, past use of this model to examine the relationships between factors has often not included social, economic or environmental factors, therefore the relationships between these factors and the likelihood of behaviour change is largely unknown.[65] Yarbrough and Braden found that the predictive power of the model was improved by including an individual's socio-economic background.[67]

Therefore, when applying the health belief model to the NMS, it may help increase the likelihood of improving a patient's adherence if pharmacists consider the social, economic and environmental situation of the patient and how these factors may affect their perception of the threat of disease, the benefits of and barriers to medicine adherence.

There is some evidence that emotional reactions can be a predictor for behaviour change[68], however the health believe model does not take emotions into account; it assumes that health behaviour is rational. It is possible that by changing the model to include an individual's emotional response, the power of the health belief model to predict behaviour could be increased. Whilst there is no scope in the model to include emotions, there is potential for pharmacists conducting the NMS to take patients' feelings into account in order to help them overcome perceived barriers to becoming more adherent to their medicines.

Whilst the predictive power of the health belief model is weak and is unlikely to facilitate the NMS in causing behaviour change, it is possible that pharmacists may be able to use some of the factors described in the model to improve the likelihood of a patient changing their medicine taking behaviour. It may be helpful for pharmacists to understand what the patients believe are barriers to medicine taking, and by addressing these barriers influence patients to be more likely to become adherent.

1.3.2 The Transtheoretical Model and Stages of Change

The transtheoretical model was developed after comparing the leading theories of psychotherapy and behavioural change.[69] It takes the processes and principles of the major theories of intervention and integrates them into stages of change. The model views behaviour change as a process involving 5 stages.

Stage 1: Pre—contemplation

At this stage people are not planning to change their behaviour. They typically avoid reading, talking or thinking about the behaviour such medicine taking.

Stage 2: Contemplation

At the contemplation stage people are considering changing the behaviour and are weighing up the pros and cons of changing.

Stage 3: Preparation

At the preparation stage people are planning to change their behaviour in the immediate future and may be making preparations to do so, for example they may make an appointment with their GP to discuss the action they wish to take.

Stage 4: Action

This stage is characterised by people having made changes in their lifestyle within the last six months. Not all behaviour changes count as action in this model. In order for the change to class as action the individual must reach the standard agreed by health professionals as sufficient to reduce the risk. For example, adherence to HIV medicines must be greater than 95% in order for them to be most effective.[43]

Stage 5: Maintenance

At this stage people have made the behaviour changes and are working to prevent relapse to the undesirable behaviours.

There is a sixth stage that applies to some behaviours. This stage is called termination and at this stage people are no longer tempted to return to the old behaviours. This stage does not apply to non-adherent patients becoming adherent to their medicines. It has been suggested that as a rule of thumb in a population displaying the undesirable behaviour 40% will be in the pre-contemplation stage, 40% will be in the contemplation stage and 20% will be in the action stage.[69]

The transtheoretical model points out that when a person is considering changing an undesirable behaviour they will weigh up the pros and cons of making that change before coming to a decision. Research suggests that to progress from pre-contemplation to contemplation the pros of the behaviour change must increase, and to progress from contemplation to action the cons of the behaviour change must decrease.[70] The model also sets out activities that people use to move through the stages of change by altering the balance of pros and cons. These activities are called processes of change. The ten processes that have the most support from research are[69]:

- Consciousness raising: this is where the person is made aware of the consequences of the undesirable behaviour.

- Dramatic relief: this activity is one that provokes an emotional experience that can be reduced by taking appropriate actions providing a sense of relief.
- Self re-evaluation: this activity involves the person assessing how they view themselves with and without the undesirable behaviour.
- Environmental re-evaluation: this activity involves the person assessing the impact of the presence or absence of the undesirable behaviour on the people around them.
- Self-liberation: this is the belief that the person can change and has the commitment to do so.
- Helping relationships: relationships between the person wishing to change a behaviour and the people around them can support the individual in changing their behaviour.
- Counter-conditioning: this activity involves replacing the undesirable behaviour with a healthy behaviour.
- Contingency management: this is where consequences to making progress toward changing the undesirable behaviour are introduced. They can be rewards or punishments.
- Stimulus control: This activity involves the person removing cues to the undesirable behaviour and introducing prompts for the healthy behaviour.
- Social liberation: this involves increasing social opportunities or alternatives available to the individual.

The transtheoretical model proposes ways of changing an individual's undesirable behaviour and therefore could only be useful for patients that the NMS identifies as non-adherent. Whilst the model may not apply to adherent patients, by using the model to establish whether an individual is prepared to change their medicine taking behaviour and by using some of the processes of change to increase an individual's readiness to change, patients identified by the NMS as non-adherent could be encouraged to become more adherent to their medicine. There are, however, several concerns that should be considered.

Whilst the transtheoretical model has enjoyed popularity, there have been several criticisms made. It has been suggested that applying the stages of change to complex behaviours is particularly difficult because there maybe a variety of specific behaviours within a complex behaviour and an individual may be in different stages of change for each specific behaviour.[71] Adherence

to medicines could be seen as a complex behaviour as individuals are often taking multiple medicines and have varying levels of adherence to the different medicines. For example, people are more likely to have higher levels of adherence to acute treatments compared with long term preventative medicines. The transtheoretical model would suggest that the NMS avoids this pitfall because it focuses on adherence to an individual medicine but that the NMS would not necessarily improve an individual's adherence to all their medicines and therefore potentially have a lower impact on the desired outcome of the medicines.

In addition, it has been suggested that the pre-contemplation stage actually contains two separate groups of individuals who would benefit from being treated differently; aware pre-contemplators and unaware pre-contemplators. Aware pre-contemplators know that their behaviour is undesirable but do not intend to change, whereas unaware pre-contemplators do not know that their behaviour is undesirable so see no need to change.[72] This would suggest that when conducting the NMS with an individual in the pre-contemplation stage, a pharmacist needs to establish whether the patient is aware of how they should be taking their medicines to determine whether they are an aware pre-contemplator or an unaware pre-contemplator, in order to know how best to encourage the patient to change their medicine taking behaviour.

There are also criticisms made regarding the algorithms for determining which stage of change individuals are in. The algorithms are often based on self-assessment which is a problem because studies have shown that people believe they are far more compliant with behavioural recommendations than their behaviour demonstrates.[72,73] In addition, as there is no accepted method of comparing different staging algorithms, the validity of the algorithms has not been demonstrated. It has also been suggested that there could be problems with the reliability of staging algorithms because transition between stages of change are common and can occur over a very short period of time.[74,75] The structure of the NMS does not include an algorithm for determining a patient's stage of change, however if this was included it would be based on self-assessment and pharmacists would need to be aware that patients may be less compliant with recommendations than their answers would suggest.

Whilst the transtheoretical model is not appropriate for all patients who receive the NMS, I believe that some aspects of the model could help pharmacists encourage non-adherent patients to change their medicine taking

behaviour. The idea that some people are more prepared to change their behaviour than others and the ways suggested by this model to encourage people to become more ready to change could be utilised by pharmacists when conducting the NMS in its current structure.

1.3.3   The Theory of Reasoned Action and The Theory of Planned Behaviour

The Theory of Reasoned Action (TRA), set out in Figure 1.2, was developed in order to understand the relationship between attitudes and behaviour. The theory states that that an individual's behavioural intention is the biggest predictor of their behaviour.

The Theory of Reasoned Action
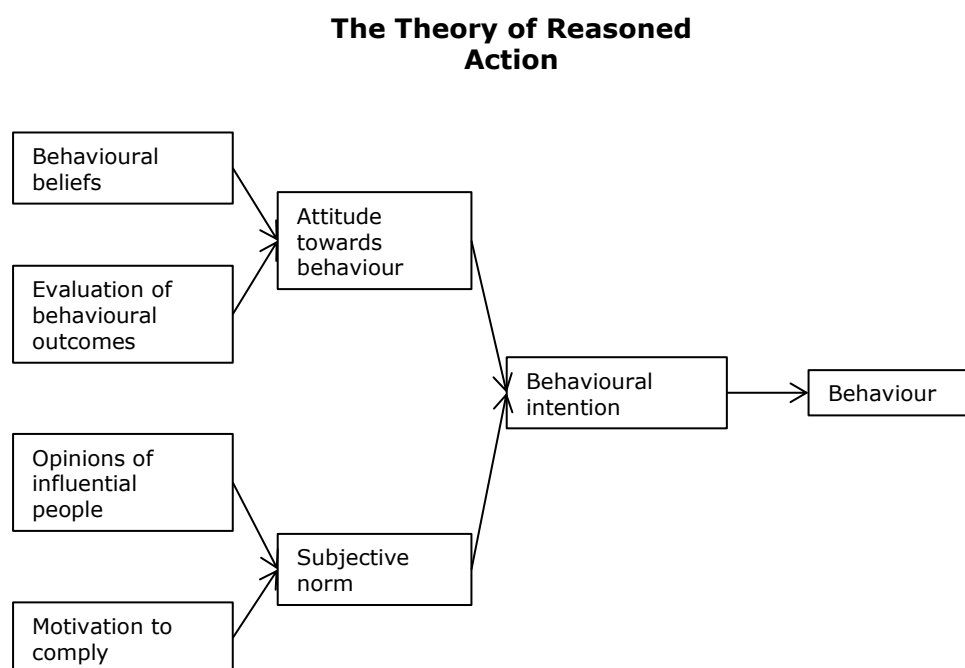
Figure 1.2: The theory of reasoned action, adapted from Health Behaviour and Health Education [69]

An individual's behavioural intention is determined by their attitude towards the behaviour and the subjective norm associated with the behaviour. In turn the individual's attitude towards the behaviour is dictated by their behavioural beliefs and their evaluation of the outcomes associated with the behaviour. The subjective norm is determined by the opinions of people important to the individual towards the behaviour, and the individual's motivation to comply with their opinions.

The theory of planned behaviour (TPB) (Figure 1.3) is a development of the TRA in an effort to account for factors that may affect a person's intention and behaviour but are outside of the person's control. The theory introduces the idea of perceived control that is determined by the person's beliefs about the presence or absence of factors that could facilitate or inhibit the behaviour, and the power of such factors to facilitate or inhibit the behaviour.[66]

**The Theory of Planned
Behaviour**
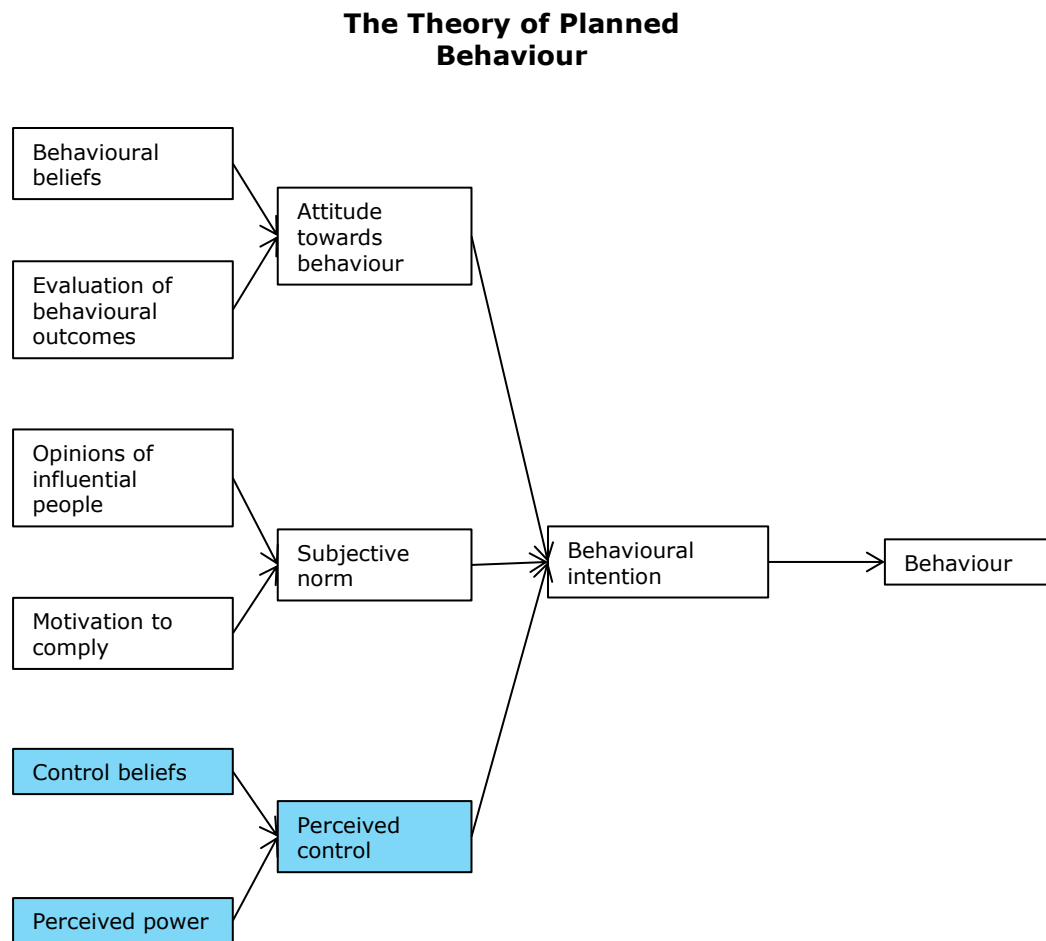
**Figure 1.3 The Theory of planned behaviour adapted from
Health Behaviour and Health Education** [69]

For the theories of reasoned action and planned behaviour the model components and the relationships between them are clearly defined and can have mathematical values assigned in order to determine the impact of the component on an individual's behaviour.[76] This clarity results in the models having a greater predictive power than the health belief model.[66]

The theories of reasoned action and planned behaviour have been widely used, mainly to predict and understand exercise, dietary, addiction and HIV prevention behaviours.[65] However, the theories' high level of generalisability means that it is possible to relate them to medicine taking behaviour.[75] Poor adherence could result from a negative attitude towards medicine taking, a belief that influential people disapprove of them taking medicines, and a desire to comply with their views, and/or a belief that the individual does not have the power to control their medicine taking behaviour. Conversely, an individual may be adherent to their medicine if they have a positive attitude towards taking the medicine, believe that the people around them encourage them to be adherent and have a desire to comply, and/or believe that they have to power to become more adherent.

A criticism of the theory of reasoned action is that it is individualistic; relying on an individual's interpretation of factors and does not take external variables outside of the individual's control into account.[77] The addition of the perceived behavioural control component in the theory of planned behaviour goes some way to addressing this problem. It is possible that these factors are already addressed within the structure of the NMS as during the consultations pharmacists should ask patients about all barriers to taking their medicines, whether within the patient's control (such as remembering to take the medicine) or outside of their control (struggling to take the medicine in tablet form), in order to resolve problems where possible.

The theories of reasoned action and planned behaviour have primarily been used to understand behaviour retrospectively rather than used to develop interventions to change behaviour.[67,78] This may be because the theories allow prediction and understanding of behaviours rather than explain ways to encourage behaviour change. This means that the theories of reasoned action and planned behaviour may be less useful to pharmacists conducting the NMS than the transtheoretical model because they do not suggest mechanisms for making patients more likely to change their medicine taking behaviour.

Whilst the theories of planned behaviour and reasoned action have greater predictive power than the health belief model, I would suggest that the health belief model is more helpful in relation to improving adherence as it provides ways for pharmacists to influence patients' beliefs and make them more likely to take their medicines. However, its weak predictive power and lack of clarity means that the success or failure of the health belief model based NMS

is very unlikely to be due to the model's influence. I would suggest a pragmatic approach, incorporating some aspects of the transtheorectical model into the current structure of the NMS. By understanding that some patients may be more prepared to take their medicines than others, and using some of the processes of change derived from the transtheoretical model, it is possible that pharmacists could improve the likelihood of improving patients' adherence to medicines.

1.4   The New Medicine Service

In 2008 the Government released a white paper entitled 'Pharmacy in England; Building on strengths – delivering the future'. This document detailed the Government's vision for pharmacy, including introducing a *'new service for those who are starting to take regular medicines to treat their [long term] condition for the first time'*[79]. In March 2011 the Pharmaceutical Services Negotiating Committee (PSNC) and the NHS Employers announced that funding had been agreed for this new advanced service, called the New Medicines Service (NMS) with the aims of increasing adherence and reducing wastage of newly initiated medicines in patients with long term conditions.

1.4.1 Introduction of a New Advanced Service

The NMS has been developed by the PSNC and NHS employers. When planning this service, they focused on five articles about three studies from one research group.[41,80-83]   These articles describe: a telephone-based pharmacy intervention service that aimed to improve adherence to newly prescribed medicines; literature around education, policy and research about adherence and community pharmacy in England; and beliefs held by patients about their medicines. The findings of the five influential papers are summarised in Table 1.1.

Table 1.1: Summary of the five articles that influenced the PSNC and the NHS employers when developing the NMS (page 1 of 2).

Article Title	Authors	Year	Study Population	Methods	Main Findings
Patients' problems with new medication for chronic conditions	N. Barber, J. Parsons, S. Clifford, R. Darracott, R. Horne.	Participants recruited March 1999 to February 2000. Article published 2004.	258 participants prescribed a new medicine and aged 75 years or over or with at least one of the following conditions: stroke, coronary heart disease, asthma, diabetes. Recruited from 23 pharmacies.	Longitudinal survey using semi-structured telephone interviews at 10 days and 4 weeks, and a questionnaire at 4 weeks. Measuring self-reported adherence, causes of non-adherence, problems with medicines and information needs	30% of participants still taking medicines at 10 days were non-adherent. This dropped to 25% at 4 weeks. 66% of patients taking their medicines at 10 days experienced problems. Over half of participants wanted more information at both time points.
Understanding different beliefs held by adherers, unintentional non-adherers, and intentional non-adherers: Application of the Necessity-Concerns Framework	S. Clifford, N. Barber, R. Horne.	Participants recruited Mar 1999 - Feb 2000. Article published 2008.	As above	Using 10 day telephone interview data from above study to measure necessity-concern differential (BMQ) and self-reported adherence.	Of the non-adherent participants, 30/67 were intentionally non-adherent and 37/67 were unintentionally non-adherent. There was a significant difference in necessity-concern differential between adherent and non-adherent participants.
Medication adherence and community pharmacy: a review of education, policy and research in England	S. Clifford, S. Garfield, L. Eliasson, N. Barber.	Article published 2010	13 of 21 pharmacy schools in England.	Literature review to understand current policy, education and research related to community pharmacy and adherence in England.	All pharmacy schools that responded included adherence in the undergraduate teaching. Improving adherence is a priority for policy. Research centred on compliance aids, patient education, community pharmacy involvement in discharge planning and patient centred interventions.

Article Title	Authors	Year	Study Population	Methods	Main Findings
Patient-centred advice is effective in improving adherence to medicines	S. Clifford, N. Barber, R. Elliott, E. Hartley, R. Horne.	Article published 2006	500 participants prescribed a new medicine and aged 75 years or over or with at least one of the following conditions: stroke, coronary heart disease, asthma, recruited from 40 pharmacies. 237 control and 255 intervention participants.	Randomised control trial with telephone interviews at 2 and 4 weeks and questionnaire at 4 weeks. Measured self-reported adherence, problems with medicines, and beliefs about medicines.	At 4 weeks non-adherence in the intervention group was lower (9% vs 16%), fewer problems were experienced by the intervention group (23% vs 34%) and the necessity-concerns differential was higher in the intervention group.
The cost effectiveness of a telephone-based pharmacy advisory service to improve adherence to newly prescribed medicines	R. Elliott, N. Barber, S. Clifford, R. Horne, E. Hartley	Article published 2007.	As above	Questionnaire at 2 months after starting medicine. Measured cost to UK NHS using incremental cost effectiveness ratios.	The mean cost for the intervention group was £187.70 per patient compared to £282.80 per patient in the control group.

The first two papers listed in Table 1.1 describe a longitudinal study looking at patients who were 75 years old or over, or had one or more of the following conditions: stroke, coronary heart disease, asthma, diabetes and rheumatoid arthritis, and had been prescribed a new medicine. The study measured: self-reported adherence, as well as recording the causes of non-adherence; problems participants experienced with the new medicines; and the participants' information needs at 10 days and 4 weeks after receiving the new medicine. The study also used the Beliefs about Medicines Questionnaire in order to determine the necessity-concerns differential for participants at 10 days. The results of the study showed that at 10 days 30% of participants still taking the medicines were non-adherent. This figure dropped to 25% at 4 weeks. The study also found that two-thirds of participants still taking their new medicines at 10 days were experiencing problems and at both time points over half of the participants wanted more information. A significant difference in beliefs about medicines was found between adherent and non-adherent participants, with adherent patients having greater necessity scores and lower concern scores than non-adherent patients. Of the non-adherent patients, 45% were intentionally non-adherent and 55% were unintentionally non-adherent.[80,81]

The implications of this study are that there is a problem with non-adherence to new medicines in that population combined with a majority of patients experiencing problems. The study also shows that there is a significant desire for more information about new medicines. This suggests that adherence to medicines in the elderly or patients with long term conditions may be improved by intervening when a medicine is newly prescribed, to provide information about the new medicine and to address any problems patients may be experiencing. The results of the Beliefs about Medicines Questionnaire show that there is the potential to encourage non-adherent patients to become more adherent by addressing their beliefs about the necessity of taking the medicine and their concern regarding the treatment.

The third paper in Table 1.1 by Clifford et al. details the results of a study conducted in order to understand the policy, the education provided to pharmacists, and research conducted in relation to adherence and community pharmacy in England. The review found that tackling problems with non-adherence was seen as important and guidelines had been issued suggesting that adherence could be promoted by involving patients in decision making, by supporting patients in their medicine taking, and by regularly reviewing

patients' medicines. In terms of education, the study found that all of the schools of pharmacy that responded included teaching regarding adherence in the undergraduate curriculum as well as in postgraduate training, suggesting that pharmacists have knowledge about adherence and may be under-utilised in addressing the problem of non-adherence. The study found that research regarding community pharmacy and adherence mainly focused on compliance aids, patient education, hospital discharge and some patient tailored interventions. The authors concluded that more research was needed in order to be able to identify a successful as well as cost-effective way of improving adherence. The study demonstrated that there is scope for community pharmacists to be involved in supporting patients in their medicine taking in order to improve adherence.[82]

The last two articles included in Table 1.1 describe an intervention conducted by community pharmacists aiming to improve patient adherence. The randomised control trial involved patients who were 75 years old or over, or had one or more of the following conditions: stroke, coronary heart disease, asthma, diabetes and rheumatoid arthritis, and had been prescribed a new medicine. Of 500 participants recruited, 255 received the intervention and 237 received usual care (8 participants withdrew from the study). The intervention consisted of a telephone call conducted by one of two specially trained community pharmacists two weeks after the patient had received the new medicine using an interview schedule developed in the first study. All participants then received a telephone call at four weeks in order to assess adherence as well as problems experienced by participants and their beliefs about medicines. Participants also completed a questionnaire after two months that was used to calculate incremental cost effectiveness ratios in order to assess the cost to the NHS.[41,83]

The study found that the intervention group had a lower level of non-adherence (9% compared to 16%), fewer problems experienced (23% compared to 34%) and a higher necessity-concern differential than the control group. The economic evaluation found that the intervention had a lower cost to the NHS than usual care (£187.70 per patient compared to £282.80 per patient.[41,83] The results from this study suggest that pharmacists can improve adherence in elderly patients and patients with long term conditions in a cost effective way by providing advice soon after they are first prescribed a medicine.

The articles suggest that there is a need for a patient centred approach to improving adherence, that non-adherence is more of a problem in patients with long term conditions than patients with acute illnesses[80], and that the first few days of taking a medicine are critical for developing adherence[41]. The studies show that a patient-centred intervention conducted by pharmacists soon after the prescribing of a new medicine can improve adherence in a cost effective manner and on this basis the NMS was developed.

1.4.2 Description of the New Medicine Service

In documents published by the PSNC in May 2011 and August 2013, the PSNC and NHS employers set out the aims and outcomes of the NMS. They stated that '*the service should;*

- *Help patients and carers manage newly prescribed medicines for a long term condition and make shared decisions about their condition*
- *Recognise the important and expanding role of pharmacists in optimising the use of medicines*
- *Increase patient adherence to treatment and consequently reduce medicines wastage and contribute to Quality, Innovation, Productivity and Prevention agenda*
- *Supplement and reinforce information provided by the GP and practice staff to help patients make informed choices about their care*
- *Promote multidisciplinary working with the patient's GP practice*
- *Link the use of newly prescribed medicines to lifestyle changes or other non-drug interventions to promote well-being and promote health in people with long term conditions*
- *Promote and support self-management of long term conditions, and increase access to advice to improve medicines adherence and knowledge of potential side-effects*
- *Support integration with long term condition services from other providers and provide appropriate signposting and referral to the services*
- *Improve pharmacovigilance*
- *Through increased adherence to treatment, reduce medicines related hospital admissions and improve quality of life for patients.*[84,85]

The New Medicine Service (NMS) is specifically for four long term condition groups.   It   targets   asthma   and   COPD,   type   2   diabetes,

antiplatelet/anticoagulation therapy, and hypertension. The majority of these conditions are widely accepted as having low adherence rates. COPD, type 2 diabetes and antiplatelet/anticoagulant therapy mainly affect adults with few children being affected.[86-88]

Figure 1.4 shows the structure of the NMS as proposed by the PSNC.[84] The NMS consists of three parts; patient engagement, intervention and follow-up. The first part, patient engagement, involves the existing practice of providing appropriate advice regarding how to take the medicine and possible side effects the patient should be aware of, followed by identifying the patient as eligible for the service and gaining written consent from the patient to enter the service. The intervention stage occurs seven to fourteen days later and consists of a consultation with a pharmacist which can be conducted either by telephone or face-to-face in the pharmacy consultation room. The pharmacist uses a semi-structured questionnaire to identify any problems affecting adherence that the patient may be experiencing. Two to three weeks after the intervention, the follow-up stage of the service occurs again either by telephone or face-to-face in the pharmacy consultation room. The follow-up consultation with the pharmacist also uses a similar semi-structured questionnaire to assess adherence, whether recommendations made at the intervention stage have been successful, and whether the patient is experiencing any new or further problems with their new medicine. If the pharmacist judges that the patient is experiencing significant problems at the intervention and follow-up stages, the patient can be referred back to their prescriber. At each stage of the service the pharmacist can make public health and lifestyle interventions. Patients can be recruited into the service in several ways: the patient may request the service, a pharmacist may offer a patient the service, or the patient may be referred into the service by a health care professional in primary or secondary care. There is no compulsory training required to provide the NMS, however a pharmacist must be accredited to provide MURs and must declare themselves competent to provide the new service.[89]

The Structure of the NMS

Patient is prescribed a new medicine for one of the following conditions and is identified by the pharmacy or referred by a prescriber:
- Hypertension
- Asthma/COPD
- Type 2 diabetes
- Anti-platelet/Anti-coagulant

First stage: Patient engagement
- Initial advice given
- Agreement on time and method of follow-up

7-14 days later

Second stage: Intervention
- Semi-structured interview
- Face-to-face or telephone consultation

Problem identified

Referred to prescriber and exit service

14-21 days later   Adhering to regimen

Third stage: Follow-up
- Semi-structured interview
- Face-to-face or telephone consultation

Pharmacist and patient agree solution and time and method of follow-up

Adhering to regimen:
- Exit service

Problem identified:
- Referred to prescriber
- Exit service

Figure 1.4: The structure of the NMS

Remuneration for providing the NMS is allocated from the global pharmacy sum. Initially the service had funding until 1st April 2013 but funding has been extended pending the results of an evaluation of the NMS. The payment structure introduced for the NMS in October 2011 linked the number of services that could be claimed for with a pharmacy's dispensing volume; a novel concept for pharmacy. The expectation was that 0.5% of all prescription items dispensed would be eligible for the service and the

structure allowed payment to be triggered by reaching 20%, 40%, 60% and 80% of expected opportunities within tiers of dispensing volume. These thresholds meant that a maximum of £25 would be paid per NMS. The complex nature of the payment structure meant that it was difficult to predict how much a pharmacy would be paid for providing the service in a given month. This payment structure was amended in May 2012 and, whilst the structure retains the percentage targets, it now means that a pharmacy will be remunerated for each completed NMS.[90]

The recording requirements for the NMS allowed pharmacies to record the services completed in a variety of ways. One tool available to pharmacists via the PSNC was PharmaBase (now PharmOutcomes) which is a national web-based program which has the facility to record NMS as well as other services. The PharmaBase NMS module was made available for NMS recording at the same time as the launch of the service.

Earlier the characteristics of interventions associated with improved adherence were discussed. The NMS has four of the characteristic associated with successful interventions: providing more information (including information about possible side effects), counselling by a health care professional, telephone follow up by pharmacists, and supportive care. These characteristics may improve the likelihood of the NMS improving adherence.

1.4.3 Existing NMS Research

In an editorial De Simoni *et al* set out the potential, evidence and challenges facing the NMS.[91] They suggested that the new service had the potential to improve long term health as well as save the NHS money, but this potential would only be realised if the NMS was implemented successfully. The article reported the evidence base for the service as '*sparce*' and noted that systematic reviews of community pharmacy interventions had mixed findings. The article set out several challenges that the NMS faced, including the time pressures experienced by pharmacists and the need to organise appointments for NMS consultations. They also questioned whether GPs were likely to refer patients into the service.

An analysis of the national PharmaBase database (now PharmOutcomes) was published in the form of a report by the PSNC in November 2012 for the first year of the NMS.[92] It reported that of the 418,744 completed NMS claimed for from the NHS Precription Authority between October 1st 2011 to July 31st 2012, 43.1% had been recorded on PharmaBase. They reported that the

proportion of male and female patients were similar and that 99.6% of NMS were recruited by the pharmacy, with just 0.4% being referred by GPs or practice nurses. The most common condition was hypertension (54.4%), followed by asthma/COPD (26.4%), type 2 diabetes (11.3%), and anti-platelet/anti-coagulants (7.9%). The also reported that where the consultation method was reported, over two-thirds of intervention and follow-up consultations were conducted by telephone. The results showed that pharmacists provided healthy living advice (HLA) at each stage of the service with advice regarding diet and nutrition being the most common HLA offered and sexual health advice the least common.

The analysis of the PharmaBase records suggested that nearly a third of patients reported as non-adherent at the intervention stage became adherent at the follow-up stage, and this rate of adherence change improved rapidly over the first few months of the service. However the questions used in NMS consultations do not include a validated adherence measure, therefore the data captured using PharmaBase cannot reliably be used to calculate adherence or non-adherence. Instead it gives only an indication of adherence, so one must be careful when drawing conclusions from this data. In addition, the report does not detail the methods used during the analysis of the data and has not been peer-reviewed, so it is not possible to conclude whether the methods used are valid or reliable.

Due to the fact that the NMS was introduced so recently (October 2011) there is little published data about the service. One effect of the service that has been reported in the press is that the service has lead to an increase in reporting of adverse drug reactions through the Yellow Card scheme which has been hailed as proof that the service is meeting its objective of improving pharmacovigilance.[93]

One small survey of community pharmacists in Cornwall, conducted after the implementation of the NMS, found that respondents held broadly positive views of the service. They reported that the majority of services conducted were opportunistically initiated by pharmacy staff and more than half of respondents said that the majority of interventions and follow-ups were conducted by telephone. Twenty-two respondents suggested that more training on the conditions eligible for the NMS would be beneficial whilst only two of the pharmacists surveyed reported that they would find further training regarding communication skills helpful.[94] This survey was very small with only 39 pharmacists responding from one area of England and the results

were published without peer review, therefore it is unclear how robust the survey was and the degree to which the results are generalisable is questionable.

The Department of Health funded a national evaluation of the NMS conducted through a collaboration between the University of Nottingham and University College London. The evaluation comprised of a health technology assessment in the form of a RCT, an economic evaluation and a qualitative stream. The RCT aimed to find out if the NMS affects adherence and involved patients being randomised into either receiving the NMS, or usual care and were followed up for 6 months. The economic evaluation aimed to determine the cost of the NMS to the NHS relative to the cost of 'usual care'. The qualitative stream explored the patient experience as well as profiling pharmacies and eliciting stakeholder perspectives regarding the service. The protocol for the RCT has been published but the results of the study have yet to be published however.[95]

1.5 Community Pharmacy Research Identifying Barriers and Facilitators to Service Implementation and Provision

Understanding factors that affect implementation and provision of new services has become more important as the role of community pharmacists has expanded to include more clinical services. Numerous literature searches were conducted throughout the four years of this PhD using the PubMed and Scopus databases, looking at factors affecting the uptake and implementation of pharmacy services. Search terms used included 'pharmacy services', 'Medicine Use Reviews', and 'pharmacy implementation'. Whilst papers published before 2005 were reviewed, the majority of papers deemed relevant to the implementation of pharmacy services in the UK, and therefore included in this review, were published after the introduction of the revised NHS pharmacy contract in 2005. The reference lists of papers included in this review were examined for further papers that may have been relevant.

Since 2005 much research has been conducted investigating the uptake and introduction of MURs as well as examining the MUR service itself. The results of such research may be used in to give an indication of factors that may affect NMS provision.

MUR activity was initially slow after its introduction in April 2005 with just 18% of MURs for which funding was available being conducted in its first year.[8]   A study by Bradley *et al* found that uptake of MURs was greater in multiple pharmacies (chains with 6 or more pharmacies) compared with independent pharmacies.[6]   This trend has been confirmed by other studies[8] and several reasons for this have been suggested.   The MUR service was introduced at the same time as major contractual changes for community pharmacy and this may have disproportionally affected independent pharmacies because they do not have corporate support for implementing changes.[8]   In addition it has been suggested that company pressure facilitated provision of MURs in volume[6,8], although this has been linked to MURs of questionable quality.[96]   The findings from these studies suggest that the uptake of the NMS may be greater in multiple pharmacies as the NMS was introduced at the same time as other contractual changes and the pressure from companies to provide advanced services is likely to remain the same.   It is less likely that the NMS will experience the same problems with quality as MURs as the eligibility criteria are much narrower.

A commonly identified barrier to MUR uptake was the requirement that pharmacies providing MURs must have an approved consultation room.[6-8] This is unlikely to affect NMS implementation because pharmacies wishing to offer the new service are likely to already be providing MURs and will already have an approved consultation room.   Another barrier associated with consultation rooms is the lack of access to patient medical records (PMRs) in consultation rooms without IT access.[8]   This barrier may affect the provision of the NMS as some consultation rooms still lack access to PMRs.   As the number of services requiring consultation rooms increases, the need for PMR access in the consultation room grows.   Therefore providing PMR access in these rooms may facilitate not only the NMS service, but other services as well. Whist there appears to be very little literature about how PMR systems can affect the provision of pharmacy services, an international study found that IT solutions are important to the provision of professional services and that a lack of IT solutions could threaten pharmacy's role in patient centred care.[97]

Studies in Australia and Sweden have found low GP awareness and a lack of interest and participation in pharmacy services.[98-101]   However, where GPs can see the potential benefits of a pharmacy service to patients, they are more likely to engage with it and collaborate with pharmacists.[102]   In the UK a

widely reported barrier to MUR implementation and provision was a lack of GP support for the service.[6-8,94] It has been suggested that poor communication between pharmacists and GPs regarding the service had led to GPs being unclear about the purpose of MURs and therefore not seeing value in the service.[6.8] That, in combination with the volume of paperwork associated with MURs during early implementation, had aggravated GPs[6] and may have led to very few patients being referred into the service by GPs[8]. This was supported by reports of better GP support for the service where good relationships between pharmacies and practices already existed.[8] This suggests that if pharmacy is to avoid this pitfall when implementing the NMS, pharmacists and GPs must communicate to ensure that GPs understand the purpose of the new service. Pharmacists should also avoid sending unnecessary paperwork to GPs if they are to avoid aggravating them. It also emphasises the importance of good relationships between pharmacies and GP practices and suggests that pharmacists should endeavour to foster good relationships if they want GP support for the services they provide. It has also been proposed that one way to build trust between GPs and pharmacists would be to introduce a service for one condition and establish that it is beneficial for that condition before including other conditions.[9] This suggests that the introduction of the NMS may help to build trust between GPs and pharmacists if it is found to be helpful in the four disease areas eligible for the service.

A facilitator to the provision of MURs identified by the national evaluation of the new community pharmacy contract was the location of community pharmacies. It was found that pharmacies located close to GP practices conducted more MURs.[8] It is possible that proximity of GP practices may affect NMS provision more greatly than MUR provision as the eligibility criteria for MUR states that the patient must have been receiving prescriptions from the pharmacy for three months whereas a NMS may be provided to any patient receiving an eligible medicine; they do not need to be a regular patient. I would suggest that some patients receiving a prescription for a new medicine are likely to get that first prescription dispensed at the nearest pharmacy rather than their regular pharmacy which may be located further away from the GP practice. This would mean that pharmacies co-located with GP practices may have more opportunities to provide the NMS than pharmacies further away.

An increase in pharmacist workload is often cited as a barrier to service provision and a commonly reported obstacle to MUR provision along with a

lack of support staff.[6-8,96,103] However in situations where there was sufficient support staff effectively used to free the pharmacist to conduct MURs, this was found to facilitate MUR provision.[8,96] Concerns have been raised that the increasing workload on pharmacist could affect patient safety.[104-108] Since 2005 and the introduction of MURs a pharmacist's potential workload has increased with the expansion of services they can provide, therefore the effective and efficient use of support staff had become increasingly important and it is likely that pharmacists' workload may be proposed as a barrier to NMS implementation.

Previous studies have shown that a health care professional's knowledge of a service and their attitude and confidence towards providing it can affect service implementation.[96,109-111] In addition, several studies have found that positive pharmacist attitudes facilitated MUR implementation and provision.[6,8] It has been suggested that this positive attitude towards MURs stems from pharmacists seeing the service as an opportunity to use their professional skills.[7] A study in New Zealand suggested that pharmacists see service provision as crucial to the future of pharmacy as a profession which may also contribute to pharmacists' motivation to provide services.[112] This suggests that pharmacists' attitudes towards the NMS could facilitate or hinder the implementation of the new service. The NMS service is an opportunity to further use pharmacists' professional skills so it is possible that pharmacists may welcome the new service.

In order to provide MURs, pharmacists must undergo training in order to become accredited to provide the service. This need for accreditation has been identified as a barrier, and good consultation skills and the provision of training opportunities as facilitating MUR implementation and provision.[6,103] Whilst good consultations skills facilitated MUR implementation, it has been found that pharmacists do not always demonstrate these skills in MUR consultations and that specific training in conducting patient-centred consultations may be beneficial.[113] A potential way to facilitate NMS provision would be to ensure that there are opportunities for pharmacists to undergo training in patient centred consultations. However, an Australian study found that pharmacists perceived training in communications skills as less necessary than training in other areas for the provision of extended pharmacist roles, supporting the idea that pharmacist see themselves as already possessing good communication skills.[111]

There seems to have been a further barrier to pharmacists conducting MURs as several studies identified that a proportion of accredited pharmacists were not providing the MURs in the first and second year of the service.[8,103] Bradley *et al* found that pharmacists' lack of confidence in providing MURs acted as a barrier to MUR implementation.[6] This may explain why some pharmacists do not go on to provide MURs after becoming accredited. In the case of NMS implementation, accreditation is very unlikely to act as a barrier because the process is very different, with pharmacists having to complete a declaration of competence. Good consultation skills and the provision of training opportunities are still relevant to the NMS therefore it is likely that they could facilitate the implementation of the new service. However, the findings from MUR research suggest that pharmacists need to be confident in providing the new service if they are to move from being accredited to actually providing the NMS to patients.

A study by Latif *et al* found that pharmacists reported that personal financial incentives would facilitate MUR provision.[7] In addition research into other UK services and a Finnish pharmacy service found that inadequate remuneration is viewed as a barrier to service implementation.[115-117] This suggests that the payment structure of the NMS has the potential to facilitate or hinder the implementation of the new service and therefore needs careful consideration.

Several studies examining medicine review services found that patients see pharmacists as a source of reassurance for their medicine taking behaviour.[118,119] The NMS is specifically designed to offer patients reassurance and support for medicine taking provided by pharmacists, and therefore does not represent a change in role of the pharmacist as viewed by patients. This could potentially facilitate the provision of NMS as patients may be more willing to consent to the service.

In order to identify barriers and facilitators to NMS implementation and provision, the service needs to be evaluated. The next section discusses how the NMS could be evaluated.

1.6 Service Evaluation

When evaluating a service, the investigations can be formative (aiming to use the results to develop or improve the service) or summative (aiming to produce results to inform a decision as to whether the service should be

continued).[120]   Traditionally health services have been evaluated using Donabedian's Structure, Process and Outcome model. 'Structure' refers to *'the conditions under which care is provided'*[118] which include material resources, human resources and organisational characteristics.   'Process' refers to the activity of health care and 'Outcome' covers all changes that can be attributed to the health care. These outcomes can be clinical, physical, social or psychological as well as patient opinions of the service.[121]

When assessing the quality of the structure in place for the provision of the NMS one could look at the availability of a consultation room, whether the pharmacist is able to conduct telephone calls in the consultation room, and the mechanism in place for recording the consultations. Human resources could also be examined; whether or not the pharmacist conducting the NMS is the sole pharmacist and what support is provided by other pharmacy staff. The remuneration paid to pharmacies for the provision of the NMS, and the suitability of the payment structure could be investigated as part of an assessment of the quality of the structure.

The process of a service should be assessed *'in relation to deviation from pre-defined standards'*[120]. Therefore what happens in each of the three stages of the service should be examined when assessing the process of the NMS. This could include investigating whether pharmacists use the consultation schedules provided and how pharmacists complete records of the consultations, for example, do pharmacists fully complete the consultation records?

An assessment of the outcomes of a service should look at the effectiveness of the service in achieving its goal.[121] In the case of the NMS, the goal of the service is to improve adherence to medicines and therefore reduce medicines waste. Therefore to assess the outcomes of the NMS one would need to find out whether the NMS improves adherence.

This doctoral project evaluates the implementation of the NMS, therefore some aspects of the structure-process-outcome model are not appropriate. Whilst it remains helpful to consider the structure and processes in place for the provision of NMS, outcomes are less relevant when considering the implementation of the service and I would suggest that investigating barriers and facilitators to NMS implementation would be more informative at this stage.

Chapter 2: Methods Overview

2.1 Aims and Objectives

The overall aim of this project was to evaluate the implementation of the NMS in community pharmacies in England.

The objectives were to:

- Investigate how the NMS was developed and introduced into community pharmacies
- Identify potential barriers and facilitators to NMS implementation prior to the services introduction
- Identify actual barriers and facilitators affecting NMS implementation
- Investigate the proportion of prescription items that are eligible for the NMS
- Investigate the uptake of the service
- Understand the types interventions pharmacists make when providing the NMS

2.2 Available Methods

When assessing the implementation of the NMS it would have been possible to use quantitative methods ('*the measurement and analysis of observations in a numerical way*'), qualitative methods ('*social research which is carried out in the field and analysed largely in non-statistical ways*'), or a combination of the two.[120]

Quantitative methods can be used to test hypotheses and include randomised controlled trials, surveys and numerical analysis of collected data. Qualitative methods include gathering data through conducting interviews and focus groups, or through observations. As these methods are used to explore and understand phenomena they do not require hypotheses, therefore are suited to exploratory research.[120]

2.2.1 Qualitative Methods

Although often associated with quantitative research, one method available for qualitative research is the use of questionnaires. This is generally a list of open-ended or closed questions for participants to answer. The advantage to using a questionnaire method would be that it would be possible to gain information from a large sample of participants relatively easily with minimum cost. It would be convenient for participants, requiring them to give up less of their time and allowing them to answer the questions at a time of their

choosing. However questionnaires often have low response rates and require focussed questions, whether open or closed, so are less suited to exploratory studies.[120]

Focus groups are commonly used to explore views of participants through the discussion of topics so are an excellent way of generating information regarding exploratory areas. The format of focus groups allows researchers to tailor the discussion topics to the participants, taking in to account varying levels of understanding. The disadvantages to this method are that it is relatively labour intensive and so not practical if information from a large sample of participants is desired, and that it requires participants to attend a session at a fixed time and date. In addition, whilst the discussion generated by focus groups can be useful for exploratory subjects, a group setting may prevent some participants from expressing their true thoughts or experiences, either through a fear of judgement, or an awareness of commercial sensitivities.[120]

Interviews are a flexible method for qualitative research, allowing researchers to make them as structured or unstructured as the topic requires. They have many of the same advantages as focus groups in that they can be tailored to individual participant needs and can be employed to investigate exploratory topics. Similarly, they share some of the disadvantages of focus groups; they are labour intensive and require participants to give up more of their time than for a questionnaire. However, conducting individual participant interviews is more flexible than focus groups, allowing the interviews to be conducted at a time and place of the participant's choosing. Interviews also provide a greater level of participant anonymity and allow conflicting viewpoints to be expressed more easily than in focus group settings.[120] Therefore interviews are a useful tool for eliciting information from participants for whom focus groups are not practical.

Another qualitative method that can be used is observations. This method involves systematically observing a phenomena and making detailed field notes. Like interviews, observations can be conducted with varying levels of structure. Highly structured observations are generally used to gain quantitative data whereas more unstructured observations are used to generate qualitative information. The advantage of observation studies are that results closely reflect reality, however the presence of a researcher in an environment may affect the results gained. Observational studies are very time consuming and therefore expensive, so only a small number of

environments can be sampled meaning that the results would be less generalisable than a study sampling more environments.[120]

2.2.2 Qualitative Analysis

Once data has been produced using a qualitative method, it needs to be analysed to produce results. Thematic analysis is a way of breaking down qualitative information into themes using codes. The code may be a list of themes or a more complex model of themes relating to each other. The code can be created inductively from the raw data or deductively using theory or prior research. Inductive thematic analysis is particularly useful in exploratory research where there is no prior research to base the analysis on. There are 3 stages when using thematic analysis: stage 1, sampling and design issues; stage 2, developing themes and a code; stage 3 validating and using the code.[123]

Stage 1: Sampling and Design Issues

This stage occurs during the design of a study requiring the method of sampling as well as the unit of analysis and unit of coding to be decided on. The unit of analysis is *'the entity on which the interpretation of the study will focus'*[124]. For example if a study wanted to investigate the relationship between the size of a pharmacy chain and uptake of the NMS by interviewing individuals from different pharmacy chains, the unit of analysis would be the pharmacy chain. The unit of coding is *'the most basic segment of the raw data'*. In the example above, the unit of coding would be the individual participants.[124]

Stage 2: Developing Themes and a Code

It is at this stage that the themes and code are established. In a deductive approach to thematic analysis the code is derived from theory or from previous research. This code will need to be reviewed and amended to make it applicable to the raw data. In an inductive approach, a code is developed from the raw data. First it is necessary to become familiar with the data by reading the transcripts or listening to the audio recordings repeatedly for each unit of analysis (subsamples). The information should then be summarised and themes within subsamples identified. The themes can then be compared across subsamples and the differences between the subsamples' themes should be used to create statements that differentiate the two subsamples. These statements, or themes, become a code. Each theme should have a

label, a description, indicators, examples and exclusions.[123] The last step in developing themes and a code is to ensure reliability. The code should be applied independently to another subsample of data by the researcher who developed the code, and by a second researcher, to determine the consistency of the themes being applied.

Stage 3: Validating the Code

At this point the code developed in stage 2 should be applied to the rest of the sample of data. Then the code can be validated statistically or qualitatively in order to determine the differentiation of the subsample for each theme. The themes that show differentiation become the validated code.

The Hybrid Inductive Approach to Thematic Analysis

In some studies there is only one unit of analysis, therefore a true inductive approach is not possible as there are no subsamples. In these cases a hybrid inductive approach can be used. For example, if a study aims to find out if there is a difference in the views of employee pharmacists and locum pharmacists regarding the NMS, there are two subsamples (employee pharmacists and locum pharmacists) therefore a true inductive approach can be used. However, if a study just aims to understand the views of pharmacists regarding the NMS there are no subsamples to compare and a hybrid inductive method must be used. In this method of analysis themes are developed in the same way as the pure inductive method described above, but the step in stage 2, where the themes from subsamples are compared is omitted. The code is derived from the themes identified and applied to the rest of the raw data and reliability determined in the same way as for the pure inductive method. The validation of the code described in stage 3 of the inductive method cannot be conducted if there is only one unit of analysis.[123]

2.2.3 Quantitative Methods

Quantitative methods are used when the desired data is in numerical form. Quantitative methods can be used to answer several types of research questions, including questions that demand a numerical answer (for example, the number of pharmacies providing the NMS), questions about numerical change (for example, did more pharmacies provide the NMS in October 2011 or December 2011?), questions about phenomena (for example, did the introduction of the NMS affect MUR provision in October 2011?), and

questions testing hypotheses (for example, hypothesis: pharmacies co-located with GP practices have more opportunities to provide the NMS than pharmacies located further away, question: is this true?). These questions can be answered using several different methods.

A common method used in quantitative research is the survey. They can be designed to ask specific questions in order to gain numerical data that can be used to answer research questions. Surveys allow large populations to be sampled relatively cheaply. Surveys can be administered through questionnaires and interviews but have more structured questions, often with a predetermined choice of answers, than qualitative questionnaires or interviews.[120] There are many validated questionnaires available in published literature, such as the Morisky scale[35] which is used to determine adherence.

Randomised controlled trials (RCTs) are most commonly used to compare effectiveness, whether that is of interventions or drugs, and are the gold standard for clinical trials. An important feature of RCTs is that participants are randomly allocated to a group and they should ideally be unaware of which group they are in (although this isn't always possible). The second important characteristic of RCTs is that the variables that could potentially affect the outcome are controlled meaning that the different groups within the trial should be treated identically except for the variable being tested. Whilst RCTs are seen as the gold standard for determining effectiveness of interventions, a criticism of the method is that it is an artificial environment due to all bar one variable being controlled. They also require very clear and specific research questions and therefore are inappropriate for most exploratory research. A third drawback to RCTs is that they are relatively expensive to run.[120]

Another way of answering research questions quantitatively is through audit. Audit can be defined as '*A procedure whereby an independent third party systematically examines the evidence of adherence of some practice to a set of norms or standards for that practice and issues a professional opinion'.*[124] For example, if the research question was 'do pharmacists use the questions provided for NMS consultations as they are written?', an audit could be carried out where a researcher observed NMS consultations and recorded whether each question in the services specification had been asked.

Quantitative data is analysed mathematically with statistical tests used to determine the significance of the results. There are rules governing what

each statistical test can be used for and when they are not appropriate. When designing a quantitative study it is important to calculate the sample size needed to allow the statistical analysis to detect a change in the variable.

2.3 Study Designs

2.3.1 Understanding the development and introduction of the service

After examining the different ways the implementation of the NMS could be investigated, I decided that it would be important to understand how the service was developed and introduced into pharmacies because there is so little literature on the subject. One way to find this out would be to explore the experiences of individuals involved in the process of developing and implementing the service. Individual interviews were chosen as the most appropriate method to use as the number of people involved in the development and introduction of the NMS was small. In addition, interviews can be tailored to meet the participants' or study's needs making them particularly suited to exploratory studies with heterogeneous populations like this one.

2.3.2 Identifying Potential and Actual Barriers and Facilitators to NMS Implementation

An examination of the literature revealed many barriers and facilitators that had affected the implementation and provision of other services. Therefore I decided to explore what barriers and facilitators affected NMS implementation, what barriers and facilitators were anticipated prior to the introduction of the NMS and whether they were actually experienced in practice. As the barriers and facilitators to the implementation of other services could all be found in pharmacies it would make sense if an investigation of NMS barriers and facilitators was conducted in pharmacies, or using pharmacists as participants.

A possible way of investigating the barriers and facilitators to NMS implementation would be to ask pharmacy staff and others involved with implementing new services in community pharmacies. As the literature identified community pharmacist attitudes to a service as facilitating the implementation of the service[5,8,109,110], it would be sensible to use pharmacists as representatives of pharmacy staff. Superintendent pharmacists could be included in the study as they play a strategic and an administrative role, taking ultimate responsibility for pharmacists employed by their organisations, and the services they provide.[121] The implementation of a new service will

therefore be heavily influenced by them and their views will impact on the attitudes and opinions of the pharmacists they employ.

In this study the views of community pharmacists and superintendent pharmacists were elicited through focus groups and interviews respectively. Using a combination of methods allows the advantages of each method to be utilised. Focus groups can be used to generate discussion which is particularly useful for exploratory research and interviews can be tailored to an individual's needs and could take place at a time and place convenient to the participant.

2.3.3 Investigating the proportion of prescription items that are eligible for the NMS

The literature from other pharmacy services suggested that adequate remuneration is an important factor in the success or failure of a service.[115-117] The payment structure is unusual for pharmacy services as it links service provision to dispensing volume. As the payment structure is based on the assumption that 0.5% of all prescription items dispensed are eligible for the service, it was deemed important to find out whether the assumption is accurate. Therefore this evaluation will investigate the proportion of prescription items dispensed in pharmacies that are eligible for the NMS.

The method chosen for this study is an audit in a sample of community pharmacies, looking at the opportunities for providing the NMS as well as the numbers of prescription items dispensed. This method could collect more information with less impact on a pharmacy's workload, and would not be affected by pharmacy staff not identifying every NMS opportunity. However, this method would be time consuming and therefore the number of pharmacies that could be sampled would be less than a questionnaire could sample.

2.3.4 Investigating the uptake of the NMS and the interventions pharmacists make when providing the NMS

The uptake of MURs was gradual, linked to identified barriers to MUR implementation.[8] Therefore as well as investigating barriers and facilitators to NMS implementation, it would be important to understand the uptake of the service. In addition the structure-process-outcome model would suggest that an evaluation of a service should include an investigation into how the service is conducted.

NMS service records will be analysed in order to understand the uptake and provision of the NMS service. Service records contain information specified by the data recording requirements set out in the service specification, therefore they could be used to understand the numbers of NMS being conducted as well as the number and types of interventions pharmacists make during the consultations. Service records can be accessed through a pharmacy chain's head office, allowing all pharmacies within a chain to be sampled. However, using data from one chain may lead to the results being less likely to be generalizable as factors related to the chain will have influenced the uptake. A disadvantage to using service records is that it relies on pharmacists completing records of the NMS consultations so the quality of the data may be variable.

After careful consideration of the different methods available I decided that in order to meet the objectives, the following studies would be carried out:

- Stakeholder interviews regarding the development and implementation of the New Medicine Service
- Pre-implementation focus groups and interviews exploring the views and opinions of community pharmacists and superintendent pharmacists regarding the New Medicine Service
- Post-implementation focus groups and interviews exploring the views and experiences of community pharmacists and superintendent pharmacists regarding the New Medicine Service
- Quantitative study investigating the proportion of prescriptions dispensed that are eligible for the New Medicine Service
- Statistical analysis of service records from a large pharmacy chain

2. Ethical Approval

The research team were advised by National Research Ethics Service and the local PCT Research and Development department that the stakeholder interview, pharmacist focus group and superintendent pharmacist interview studies fell into the category of service evaluation, therefore ethical approval was not required. The studies' protocols were reviewed by a senior academic in the School of Pharmacy at the University of Nottingham.

The research team were also advised by University Research Governance and the local Primary Care Trust Research and Development leads that ethical

approval was not required for the study investigating the proportion of NMS eligible patients as it was classified as an audit - the researcher conducting the study was a part time employee of the pharmacy chain from which the data was collected and there was no intervention. The study protocol was reviewed by a senior academic at the University of Nottingham and approval gained from the pharmacy chain head office and relevant area managers.

The study exploring the PharmaBase service data was also determined as not requiring external ethical approval because the data were anonymised, the researcher was an employee of the chain providing the data, and the study was classified as service evaluation. The protocol was reviewed and approved by senior managers of the pharmacy chain and acedemic supervisors at the University of Nottingham.

Chapter 3: Stakeholder Interviews Regarding the Development and Implementation of the New Medicine Service

3.1 Introduction

The purpose of this study was to develop and understanding of how the NMS was developed and implemented. As there is no published literature on the subject, key stakeholders involved in the development and implementation were interviewed.

3.2 Methods

In this study participant views and experiences of the development and implementation of the NMS were sought in individual semi-structured interviews. This method of data collection was chosen for two reasons. Firstly the stakeholders we wished to sample were spread out nationally so focus groups would have been difficult to arrange and could have prevented some individuals participating. Secondly it was felt that these participants would be more open in individual interviews compared with in a focus group setting, as they may have had concerns regarding inter-participant confidentiality due to their roles within the organisations.

Data Gathering

Stakeholders involved in the development and implementation of the NMS were identified through informal conversations with individuals already known to have been influential in the development of the service. Participants were recruited through email invitations and personal contacts and an effort was made to include participants from each organisation known to be involved in the development and implementation of the NMS. The number of participants in this study is low due to the limited number of organisations and individuals involved in the service development process.

Six interviews were conducted with a total of seven participants. Two of the interviews were conducted face-to-face and the remaining four interviews were conducted by telephone according to participant preference. All interviews were conducted by KW and averaged 52 minutes in length.

The interview schedule used in this study has been included in Appendix 1. The schedule included questions regarding the involvement of the participant and their organisation in the development of and preparation for the NMS, the implementation of the service, the payment structure and the effect of the

introduction of the NMS on the participant and their organisation as well as on the pharmacy profession.

Analysis

All interviews were audio-recorded and transcribed verbatim and the transcripts read repeatedly before analysis began. The transcripts were analysed to produce a chronological narrative of the process of developing and implementing the new service. It was felt that this would be more helpful to understanding the process than using thematic analysis. In order to produce the chronological narrative of the development and implementation of the NMS, the analysis involved each of the transcripts being read and summarised focussing on the activity at time points throughout the development and implementation process. These summaries were then consolidated to produce a coding framework of events and activities over time. This coding framework was applied to the transcripts to ensure that no important activities were missed.

3.3 Results

The six interviews were conducted between February and May 2012, several months after the introduction of the NMS, so that participants could be questioned about the implementation of the service. The seven participants in this study represented a number of different organisations who were involved in the development and implementation of the NMS including the PSNC, NHS Employers, Company Chemists' Association, National Pharmacy Association, Numark as well as pharmacy contractors. Some individuals represented more than one organisation. Demographics of the participants have not been reported in order to protect their anonymity. Due to the restricted number of potential participants, the individuals in this study were not promised complete confidentiality, however an effort has been made to reduce the likelihood of being identified wherever possible. In particular, no demographic or interviewee status information has been reported with quotes.

The study aimed to question participants about their involvement with the development and implementation of the NMS. Data saturation (the point at which no new themes emerge)[120] was unlikely to be reached due to the limited number of potential participants and their different roles in the

development and introduction of the service. However data saturation was not required as this study did not use grounded theory, there was however consensus regarding some details.

The analysis of the interviews found 4 key phases in the development and implementation: pre-negotiation, negotiations, the launch and the post-implementation phases.

3.3.1 Pre-negotiation phase

The NMS is based on research conducted by a team at the London School of Pharmacy, led by Professor Nicholas Barber. The original study was conducted in the late 1990s and early 2000s and the results published later. One participant reported that the PSNC were aware of the results of the study by 2005 at the latest.

Early in 2008 it was widely discussed that a new white paper was being drafted that would look at the contribution of pharmacy to the NHS. As a result of this, a meeting was held in February 2008 between pharmacy stakeholders (including members of the CCA and Prof Barber), and the Department of Health (including the Director General of Commissioning, Mark Britnell, and the Chief Pharmaceutical Officer, Keith Ridge). During the meeting the pharmacy stakeholders presented their ideas of how pharmacy services could be developed which included the original research conducted by the London School of Pharmacy.

> *'So we presented our ideas of what…we thought community*
> *pharmacy could do to improve the health of the public and because*
> Nick [Barber] *was there we talked about this service that we'd*
> *worked on…and we presented some of the evidence.'* SH1

Participants reported that the Department of Health were interested in the original research and saw published research evidence for the service as desirable. As a result of this the 2008 white paper included what participants saw as a reference to a service based on the study conducted by Prof Barber's team.

3.3.2 Negotiation Phase

After the publication of the 2008 white paper NHS Employers entered discussions with the Department of Health about potential new services that would result in *'an increased patient facing role for community pharmacists using more of their skills'* (SH6). At this time some representatives of NHS Employers attended a meeting where Prof Barber spoke about the original research his team had conducted. Whilst the NHS Employers were interested in the potential of a service based on the published study, it was the economic evaluation that particularly caught their attention as it was important that any new service had a *'business case in order to get any money through the finance department and the treasury, and Nick made a very convincing case for investment in this service.'* (SH6).

At this stage NHS Employers were given a mandate from the Department of Health to negotiate changes to the pharmacy contract with the PSNC. The negotiations were conducted by NHS Employers and the PSNC in a series of closed meetings. As well as the service that would become the NMS, changes to clinical governance and MURs were also discussed. On entering negotiations NHS Employers had three requirements for the new service; it must be based on evidence, it must be evaluated and that it should be within a funding envelope without risk of overspend.

There were three main areas for negotiations; the service specification, the disease groups that would be included, and the funding for the service. Initially discussions focused on the structure of the service with both parties keen to make the new service as similar to the original research as possible, as that is where the evidence for benefit lies;

> *'We decided to keep quite closely to the proof of concept research, the rationale for that being that you need an evidence base to get the money out of the Treasury, and there was a risk that if we changed the service too much from that point they could say 'you can't apply that proof of concept research because it's completely different.'* SH5

A key detail discussed was whether the service should be conducted by telephone or in face to face consultations. The interventions and follow-up consultations in the original research had been conducted by telephone using two pharmacists located at a pharmacy chain's head office. When considering the method of conducting consultations the PSNC and NHS Employers had a

concern that allowing the consultations to be conducted by telephone only may lead to the setting up of NMS 'call centres' (SH3). They spoke to members from the team that conducted the original research who reported that the study had used centralised pharmacists conducting telephone interviews for practical reasons and that it was their view that face-to-face consultations would be even more beneficial to patients. Therefore whilst making provision for consultations to be conducted by telephone, the PSNC and NHS Employers stressed that face to face consultations should be the norm. It is worth noting that some participants had the perception that the PSNC and NHS Employers did not ask for any guidance from stakeholders until after the service had been approved by the Minister for Health, but the information gained from the PSNC and NHS Employers contradicts this. It is an example of a misconception due to rumour.

One aspect of the service specification that received complete consensus was that the service should be recorded electronically. The reason given for this was that in the case of MURs, there is little evidence of what happens in the consultations as many are recorded on paper, or are recorded on patient medical records (PMRs) that are not accessible outside the pharmacy chain. Therefore the PSNC and NHS Employers were keen that NMS consultations should be recorded electronically on a national database. PharmaBase (now called PharmOutcomes) was the preferred electronic database.

The second distinct area of negotiation was the disease groups that would be eligible for the service. Once again the negotiators were keen to stick closely to the original research:

> 'There were similarities between the conditions in research and
> what the conditions for the service are now' SH7

As well as considering the disease groups included in the original research (patients aged 75 years old or over, or had one or more of the following conditions: stroke, coronary heart disease, asthma, diabetes and rheumatoid arthritis), negotiators were keen for the included disease groups to be ones that pharmacists were confident they could make a difference to and that were relatively common. There was always an intention that the service would be extended to include more disease groups but that the 'first tranche' (SH6) of disease groups were chosen to provide the best opportunity for evaluation of the service. Some disease groups were excluded from the service not because there was a belief that they would not benefit, but that

the conditions were so complex that it would be difficult to evaluate the effect of the service. Individual drugs eligible for the NMS were chosen later, after some analysis of one pharmacy chain's patient medical records to identify commonly initiated drugs for the included disease groups.

The last area of negotiation was the funding of the service and how pharmacy contractors would be remunerated for providing the NMS. It was clear that the NHS Employers were not prepared to negotiate a pay per item of service structure and that the remuneration for the NMS should not be greater than for providing MURs. Participants explained this as part of a move towards target payments for bundles of care:

> 'If it were possible to have a system where it's not straight item of service linked, which was a strong desire from the NHS, because ultimately the direction of travel…with contractual funding is more around fees per package of care' SH5

The negotiators had a desire to incentivise pharmacists to capture as many eligible patients as possible and it was important to them to minimise any risk to the NHS of overspend. With these principles in mind a payment structure was developed that linked remuneration to the volume of prescriptions dispensed. The targets for pharmacies required an opportunity rate to be calculated. This was conducted using a national chain of pharmacies' PMR database and a preliminary list of eligible medicines to examine the number of new prescriptions versus dispensing volume. The analysis found that the average opportunity rate was 0.5% of dispensing volume, but this rate decreased in pharmacies with very low or very high dispensing volumes. The results also showed some monthly variation in the opportunity rate and dispensing volume, therefore the PSNC proposed a quarterly payment scheme that would mean that the effect of variation would be reduced. This was not included in the final payment structure. At this point some concerns were raised about factors that may potentially affect the opportunity rate, including the level of 'patient churn' (patients who do not use a regular pharmacy but who present prescriptions at many different pharmacies). However it was decided that these factors would have minimal impact on the opportunity rate.

As well as incentivising pharmacists to provide the NMS at every opportunity, the negotiators were also keen to encourage quick uptake of the service. Therefore they introduced an implementation payment into the funding

structure that pharmacy contractors would be able to claim after completing six NMS. It was reported that the funding allocated for the NMS had been taken from the dispensing margin and was not additional money for pharmacy:

> 'It was margin that was being taken away [from dispensing] and they would re-invest [it in the NMS]' SH3

During the development and negotiations for the service there was a change in government and therefore the Minister for Health also changed. Participants reported that this caused a delay in approval for the NMS. The service was approved by the Minister in February or March 2011 and a smaller team made up of representatives for the PSNC, NHS Employers and the Department of Health addressed the fine detail for the NMS service specification. This marked a move from the negotiation phase to the launch phase of the service.

3.3.3 Launch Phase

The launch of the NMS was coordinated by an oversight group made up of the PSNC, NHS Employers and the Department of Health. They created working groups, collaborating with pharmacy stakeholders, to address certain areas of the service. Examples given included a group set up to look at competency and training and a group that decided on the final list of medicines eligible for the service. Stakeholders from across the pharmacy sector were involved. They included representatives from training bodies, academia, the pharmaceutical industry, as well as representatives from community pharmacy.

All participants reported that stakeholder engagement with the service had been good and that there had been more stakeholder involvement in the launch of NMS than the implementation of MURs.

> 'Some of the work between the pharmacy stakeholders was particularly impressive' SH7

> 'This time round there was learning from MURs, I think stakeholders were more involved [with the NMS]' SH2

One key factor suggested as facilitating stakeholder engagement was the communication of the importance and purpose of the NMS by the members of

the oversight group. Participants reported that this had been done well. An example given of good communication and collaboration with stakeholders were the roadshows carried out in August and September 2011. These events provided information describing the structure of the new service as well as the purpose of the NMS and where it came from. The roadshow events were a collaborative effort between the PSNC, NHS Employers, Local Pharmaceutical Committees and a member of the team that conducted the original research. In addition, the pharmaceutical industry was involved by providing financial support for the events.

Whilst many stakeholders were aware that a new service was likely to be introduced, one participant stated that their body had first heard of the service when it was announced by the PSNC and NHS Employers in May 2011. This meant that when workload and budget had been planned for the 2011/2012 financial year, allowances had not been made for the introduction of a new service. However, in common with other stakeholders, there was a feeling that it was very important to engage with the service and support its introduction.

Whilst the participants were impressed with the level of stakeholder engagement with the service, it was also suggested that the launch of the NMS could have been further facilitated by a greater degree of stakeholder involvement at an earlier stage. It was suggested that involving stakeholders by giving them a specific role in introducing the NMS '*binds all the stakeholders to the success of the project*' (SH1) and this did not happen.

> '*The signal failure in all of this was that [the oversight group] didn't ask other organisations what they thought their role was in making [the NMS] a success'* SH1

The engagement of PMR suppliers was given as an example of stakeholders who could have facilitated the implementation of the NMS had they been involved in the launch sooner. PMR suppliers were not engaged until July 2011 which meant that they had very little time to develop modules for recording the service in the PMRs before the NMS was implemented.

Another criticism reported by participants was that the length of the implementation period was too short. This meant that all stakeholders involved in the launch of the NMS were under considerable pressure and made the implementation of the service 'challenging'. However participants

were impressed with how quickly stakeholders engaged with the service and *'got the message out about the new service'* (SH6). Whilst the short launch phase was mainly viewed as a challenge, one participant suggested that it facilitated the implementation of the NMS;

> *'It did mean that there was a certain energy that we could have lost if there had been a longer implementation period'* SH6

3.3.4 Post Implementation

3.3.4.1 Engagement and Uptake

Participants reported that they saw their role in supporting uptake and engagement in community pharmacies as on-going. Many suggested that it was important for them to continue to encourage their members to provide the NMS and had dedicated resources to this end. Support was provided through the sharing of good practice and telephone support as well as by providing practical tools to facilitate the provision of the service.

The implementation of the NMS was described as 'good' and as being quicker than the implementation of MURs with the provision of the NMS being fairly consistent. Participants gave many reasons for the successful implementation. It was felt that good communication of the purpose of the service and pharmacists seeing a clear potential benefit to their patients had been important.

> *'The overall implementation has been great. I think pharmacists have understood what we were trying to achieve and have bought into that vision'* SH5

It was also suggested that by following up patients after the intervention consultation, pharmacists were seeing the effect of their intervention and this was an important motivation for providing the NMS. Participants reported that aspects of the service structure had facilitated implementation. Clear eligibility criteria for the NMS and the provision of suggested consultation questions were suggested as making the service easier to provide and thereby facilitating its provision and uptake.

A key factor that allowed quicker uptake of the NMS compared to MURs was the accreditation process. The process for MUR accreditation took much longer as it required the provision of evidence of competencies to a higher

education institution, whereas in order to provide the NMS a pharmacist who had previously been accredited to provide MURs merely needed to complete a self-declaration of competence. This meant that there was no delay whilst pharmacists became accredited between the introduction of the service and it being provided in community pharmacies, except where MURs were not already being provided. The process of accreditation for the NMS was also described as recognising pharmacists as professionals and marking a move towards giving responsibility to pharmacists to ensure they are competent:

> '*Rely on us as regulated health professionals. We have a duty to not operate outside of our own sphere of competence. We've moved to that model and I hope it will help us move to that more grown up model*' SH5

3.3.4.2 Challenges Encountered

Another reason suggested by participants for the implementation of the NMS being more successful than the implementation of MURs was that fewer barriers were encountered in the introduction of the NMS. The challenges cited by participants included the pressure faced by pharmacists, a lack of GP and hospital pharmacist engagement, the need for pharmacists to develop different skills, data capture, and the payment structure. Consent was also mentioned as an initial barrier but was quickly overcome.

Participants reported that community pharmacists are under increasing work load pressure with dispensing volumes growing year on year and the introduction of the Responsible Pharmacist Regulations (regulations setting out the level of supervision required for operational activities within a pharmacy)[125]. The target culture in some pharmacy chains was also described as adding to the pressure pharmacists are under and there was some concern that there may be understaffing in some pharmacies meaning that there was not the support available to allow pharmacists to conduct clinical services. It was suggested that the increasing work load pressure on pharmacists meant that '*most of them will be feeling they have got enough workload already*' (SH5) and this could have affected the uptake of the service.

Another challenge experienced was the lack of GP and hospital pharmacist engagement resulting in fewer referrals into the service than hoped for. Local relationships between GPs and pharmacists were cited as the factor determining GP engagement with the service whereas a lack of awareness

was suggested as the reason for the lack of hospital pharmacist engagement. It was also mentioned that the lack of consistency in hospital discharge procedures could be a problem and that the rate of hospital referrals into the NMS could be increased by pharmacies and hospitals finding solutions locally.

> *'We've always struggled to work out how we can help improve relationships locally…ultimately it comes down to how people get on locally'* SH6

Participants highlighted that whilst pharmacists have been conducting face to face consultations for several years, this is the first pharmacy service that can be conducted by telephone. There was a view that different skills were needed for telephone consultations and this was a challenge pharmacists had to overcome during early implementation of the NMS.

It was suggested that the introduction of the NMS has highlighted the need for consistent data capture at a national level as a condition for it receiving funding was that it would be evaluated. This was described as a huge challenge as pharmacies use a variety of different PMR systems rather than using a universal system to record services. PharmaBase was introduced as a solution to this problem, the idea being that any pharmacy would be able to record their NMS consultations on this database that would provide national data allowing evaluation of the service. However participants suggested that the uptake of PharmaBase was much lower than the uptake of the service and that many pharmacies were not recording the consultations on the database. Several reasons for this were proposed. It was suggested that communication from the PSNC about the purpose of the database could have been better and had led to PharmaBase being viewed as competing with PMR systems. A second reason for the slow uptake in using the database was that recording the service on PharmaBase often resulted in double entry of data as it is not integrated with PMR systems. It was also reported that there had been some functional problems with the database but that this had been addressed soon after implementation.

The largest reported obstacle to the successful implementation of the NMS was the payment structure. The move away from a pay per item remuneration structure to a target based payment was described as necessitating a mind-set change for pharmacists and was described as the way future services are likely to be funded.

'Where we are going with contractual funding is more around fees per packages of care' SH5

However it was recognised that there were problems with the payment structure (detailed in Chapter 1) with pharmacies struggling to meet the 20% target. Rather than encouraging uptake of the NMS, the payment structure was described as dis-incentivising and impacting on enthusiasm.

Participants reported multiple reasons for the failure of the payment structure which focused on the assumption that 0.5% of prescription items dispensed would be eligible for the NMS. It was reported that the calculation of the opportunity rate was carried out using a preliminary list of medicines which could have affected the result; however one participant said that the rate had been re-calculated with the final list of medicines and was not significantly different. Another potential limitation of the calculation was that it could not allow for 'patient churn' (patients who do not have a regular pharmacy they use but have their prescriptions dispensed at a variety of pharmacies and so would appear to be presenting prescriptions for new medicines at each pharmacy they visit). Without knowing what the rate of patient churn is, it is possible that the opportunity rate of 0.5% could be artificially high. Stakeholders also reported that the rate varies between different types of pharmacies with pharmacies co-located with GP practices seeing more eligible items. Therefore the mean opportunity rate nationally may be 0.5% but pharmacies located further away from prescribing practices may see a lower rate of opportunity. Other factors affecting the accuracy of the calculated opportunity rate include changing prescribing patterns, and the inclusion of titration doses and paediatric prescriptions.

Another concern was that fluctuating monthly dispensing volume means that the opportunity rate in pharmacies could vary each month. This could cause a problem because the targets in the payment structure make no allowance for fluctuations and could lead to pharmacies losing out financially. The PSNC had proposed the inclusion of a quarterly averaging system during the negotiations to address this problem however it was not included in the final payment structure.

3.3.4.3 The Effect of the NMS

Participants reported that the number of MURs dipped temporarily after the introduction of the NMS as pharmacists focused on the new service. However

the dip in MURs quickly resolved itself and the NMS does not seem to have adversely affected the provision of other services in the long term.

It was also suggested that the process of implementing the NMS had built relationships, not only between pharmacists and patients, and pharmacists and GPs, but also between stakeholders. Participants suggested that this would facilitate the introduction of pharmacy services in the future. It was also reported that outside the pharmacy profession the NMS has helped to increase awareness of pharmacy as a service provider. This combined with the evidence that pharmacy is keen to provide services and engaged with the NMS quickly could give pharmacy a good sales platform when negotiating future services.

3.4 Discussion

This study aimed to understand how the NMS was developed and implemented by interviewing key stakeholders involved in the process. The information gained regarding the development and implementation of the NMS can be broken down into four stages; the pre-negotiation phase, negotiations, the launch phase and the post-implementation phase.

When asked about the pre-negotiation phase participants talked about the inclusion in the 2008 white paper of a proposed new service based on the original research carried out by the London School of Pharmacy. Whilst the white paper does not mention the original research it does state that the Government's vision for pharmacy includes a new service that provides support for patients prescribed new medicines for their long term conditions which could be seen as a reference to the NMS service.[55] It was also noted that some participants had misconceptions regarding how the negotiations were conducted and who was consulted. This could be due to the closed nature of negotiations meaning that information was not made public, allowing rumour to flourish.

The participants described the uptake of the NMS as good, and better than the uptake of MURs had been in 2005. It was suggested that learning had been gained from the MUR experience so there were fewer barriers to NMS implementation. An example of this was the introduction of self-accreditation which all participants saw as facilitating the implementation of the NMS. Participants also agreed that pharmacists were motivated to provide the NMS by seeing the difference the intervention makes to patients at the follow-up stage of the service, and this positive attitude towards the service reportedly

facilitated its implementation. This is supported by the results of the study conducted with community pharmacists that found that pharmacists recognising the potential benefit to patients contributed to a positive view of the NMS. There is also evidence that a positive view of a service facilitates its implementation.[110-112]

When discussing the post-implementation phase the participants identified several barriers affecting the NMS. It was suggested that telephone consultations use different skills to consultations conducted face to face and that therefore pharmacists needed different communications skills to provide the NMS compared to conducting MUR consultations. Community pharmacists seem to disagree with this view as a study conducted prior to NMS implementation found that pharmacists were confident that they had the necessary communication skills for conducting consultations both face-to-face and by telephone from conducting MURs (Chapter 4). However there is evidence to suggest that pharmacists do not always display good communications skills in MUR consultations and that training in conducting patient centred consultations may be beneficial.[7,113]

Another identified barrier to NMS implementation was a lack of GP involvement. This is supported by the findings of the study with community pharmacists that found that good local pharmacist-GP relationships would facilitate NMS provision but that where GPs had not engaged with the service it was acting as a barrier to NMS implementation (Chapter 4). In addition, MUR research found that the greatest barrier to MUR implementation was a lack of GP participation.[6] The problem of poor GP engagement with pharmacy services is not unique to England with a lack of GP interest and participation in pharmacy services being reported by studies in Australia and Sweden.[98,99]

All participants identified the payment structure as a key barrier to NMS implementation with particular concern that the actual figure of prescription items eligible for the service was lower that the estimated 0.5%. The payment structure was revised with effect from 1st May 2012. The modified payment structure still includes the 0.5% assumption; however its importance has been decreased by ensuring that pharmacies will be remunerated for each NMS conducted.[12]

Chapter 4: Pre-Implementation Views and Experiences of Community Pharmacists and Superintendent Pharmacists Regarding the New Medicine Service

4.1 Introduction

This chapter presents the results of a study exploring the views of community pharmacists and superintendent pharmacists regarding the introduction of the NMS, through focus groups and interviews, prior to the implementation of the service.

4.2 Methods

As this study was exploratory in nature and it was unclear how familiar participants would be with the new service, the views and experiences of pharmacists were explored in focus group settings in order to facilitate discussion. Focus groups are a method of collecting qualitative data from several participants at once. They involve multiple participants being asked questions by a facilitator (usually a member of the research team) and their answers being recorded. Focus groups can generate discussion between participants which is beneficial when conducting exploratory research.

It was decided that it would be inappropriate to include superintendent pharmacists in the pharmacist focus groups as there was a concern that their presence could affect the willingness of employee pharmacists to participate in the discussion. Therefore superintendent pharmacist opinions regarding the service were sought separately in semi-structured interviews. Interviews are a method where qualitative data is collected usually from individual participants in conversation with a researcher. It was decided that interviews were preferable to a focus group setting for superintendent pharmacists for two reasons. Firstly, the superintendent pharmacists were recruited nationally so arranging a mutually convenient time and location for a focus group would have been difficult. Secondly, it was felt that discussion was unlikely to be generated between superintendent pharmacists from competing companies and conducting individual interviews would prevent concerns around commercial sensitivities reducing the quality of the data gained. Interviews can be unstructured, structured or semi-structured. Semi-structured interviews were chosen as they allow a degree of flexibility in the interviews whilst still providing enough structure to ensure the topics I wanted to cover were discussed.

Data Gathering

Using the NHS choices website I identified that there were 98 pharmacies in Nottingham. Before contacting pharmacies, approval for us to contact them was gained from the head offices of the pharmacies belonging to pharmacy chains. Permission was not given to contact 18 pharmacies as some head offices did not respond to the request and one chain asked that their pharmacists not be contacted as the head office felt their pharmacists should concentrate on the imminent contractual changes. Pharmacists were initially recruited for focus groups by sending invitation letters to the 80 community pharmacies in Nottingham that we had received permission for. Due to poor recruitment rates, further participants were recruited by inviting pharmacists whilst at an NMS and MUR training event provided by their employers, and using personal contacts. The superintendent pharmacists were recruited for interview nationally by sending email invitations to participate in the study. The number of participants recruited was limited by a low recruitment rate and the short period of time between the provisional service specification publication in May 2011 and the implementation date of the 1st October 2011. The questions used in the focus groups and interviews were developed with reference to literature including the provisional service specification and in discussion with the research team.

A pilot focus group was conducted in August 2011 to test the validity of the questions being asked. The focus group topic guide was then adjusted according to the feedback given. The pharmacists attending the pilot focus group had very little understanding of the NMS, and therefore a pack of information about the service was put together for pharmacists to refer to during the main study.

In addition to the pilot focus group, three focus groups were conducted during September 2011, making a total of 15 participants. All pharmacist participants were UK registered pharmacists accredited to provide MURs (a pre-requisite for delivering the NMS) and represented locums, as well as employee pharmacists from across the sector. The pilot and two focus groups were conducted at the University of Nottingham, and one focus group was conducted after a company training event which included some training on the NMS. Each focus group was facilitated by one of my PhD supervisors whilst I observed and made notes. The focus groups averaged 70 minutes in length. Semi-structured interviews were conducted with five superintendent pharmacists during September 2011 to explore their views and experiences of

the introduction of the NMS. The superintendent pharmacist participants represented a range of pharmacies including independents, small chain pharmacies, larger chains and supermarket pharmacies.[1] All interviews took place at the superintendent pharmacists place of work for their convenience. The interviews averaged 48 minutes in length.

The topic guides and interview schedules have been included in Appendices 2 and 3. They were designed to cover the same topics but the focus group topic guide focused more on the practical implementation of the service in pharmacies whereas the superintendent interview schedule focused more on the implementation of the NMS across chains of pharmacies, to reflect the different roles played by the two groups of participants. The focus group topic guide covered awareness and understanding of the service, training and the self-accreditation procedure, NMS eligible medical conditions, practically providing the service and how the service would be recorded. The interview schedule was similar to the focus group topic guide, covering awareness and understanding of the service, learning from the introduction of MURs, preparing for implementation, the payment structure, training and the self-accreditation procedure and recording the service.

Analysis

All focus groups and interviews were audio-recorded with permission and transcribed verbatim. Thematic analysis was chosen as a way of analysing the data collected. Thematic analysis is a method of breaking the data down into themes in order to understand the information collected. In this study an inductive approach was chosen as the study is exploratory in nature and there was no prior research on which to base the analysis. A pure inductive method requires two groups separated by a criterion variable therefore a hybrid inductive method of thematic analysis was used as a criterion-referencing method was not appropriate for this study as there was no desirable criterion variable. The transcripts were read repeatedly and the audio-recording of the focus groups and interviews were listened to several times in order to summarise the information given. These summaries were then used to identify themes across the focus groups and interviews and the themes were used to create a coding framework. The developed coding framework was then applied to the transcripts and revised as necessary to include any missing themes.[123] The transcribed data was analysed by one researcher (KW) and the coding and analysis verified by an academic supervisor (HB) for

reliability and to ensure that no themes were excluded. The analysis was facilitated by using NVivo 9, a data management software for qualitative data.

4.3 Results

The 15 community pharmacists who took part in the focus groups represented a range of ages and were almost evenly distributed across genders. The majority of participants were employee pharmacists but locum pharmacists were also represented. The participants worked in a range of pharmacies including independents, small chain pharmacies, large multiples and supermarket pharmacies. The demographics of the community pharmacy participants are set out in Table 4.1.

Table 4.1: Demographics of the community pharmacist participants (n=15)

	Gender		Age					Employee/Locum	
	Male	**Female**	**22-25**	**26-30**	**31-40**	**41-50**	**51+**	**Locum**	**Employee**
Pilot focus group	2	1	-	2	-	-	1	2	1
Focus group 1	2	2	-	1	-	3	-	1	3
Focus group 2	3	2	1	1	1	-	2	-	5
Focus group 3	1	2	1	1	1	-	-	1	2
Total number of participants	8	7	2	5	2	3	3	4	11

Five superintendent pharmacists took part in the study. Two superintendent pharmacists represented independent (1-5 pharmacies) or small chain pharmacies (6 or more pharmacies not including the 10 largest pharmacy chains in England), and three represented larger chains (the 10 largest pharmacy chains in England).[1] Demographics have not been reported to prevent identification of participants.

The focus groups and interviews were carried out between five weeks and three days before the NMS was implemented. As the NMS was introduced very quickly, with key pieces of information being released throughout September 2011, the understanding of the NMS and how to provide it varied across the focus groups. The pilot focus group, carried out five weeks before implementation, displayed a lack of understanding and high levels of confusion around the NMS, whereas the focus group conducted three days before the launch of the service expressed greater understanding of the NMS and how to conduct the service. One focus group was conducted after a company training event that included training on the NMS. It could be reasonably expected that understanding would be greater in this group; however some confusion between the NMS and targeted MURs was still expressed.

The focus groups and interviews aimed to explore participant's views about the NMS before implementation, and to identify potential barriers or facilitators to its successful implementation. As this study did not use grounded theory, data saturation was not required, however by the fourth focus group no new themes regarding the implementation of the NMS emerged. Four main themes arose from the four focus groups and five interviews; participant awareness and understanding of the NMS, benefits of providing the NMS, potential facilitators to service provision and potential barriers to service provision.

4.3.1 Participant Awareness and Understanding of the NMS

Most pharmacist participants reported first hearing about the introduction of the NMS in July 2011, with a couple of participants having become aware of the service earlier through involvement with politics or pharmacy bodies. Pharmacists became aware of the service mostly through reading the Pharmaceutical Journal (the journal of the Royal Pharmaceutical Society), emails from the Centre for Pharmacy Postgraduate Education or through their employer. Whilst all pharmacist participants had heard about the service and

most had undergone some training, there was some confusion between the NMS and the changes to MURs that were being introduced at the same time.

The superintendent pharmacists interviewed had become aware of the service in different ways and at different times. The majority of participants had heard of the NMS through positions in various pharmacy bodies 12 to 18 months before implementation, however one superintendent pharmacist had only become aware of the service through the local Primary Care Trust four months before implementation.

4.3.2 Benefits of Providing the NMS

Participants described their views and experiences of providing existing pharmacy services. The introduction of clinical pharmacy services such as MURs in 2005 had been welcomed and pharmacists expressed enthusiasm towards this latest role extension. Both pharmacists and superintendent pharmacists expressed the opinion that providing pharmacy services improved job satisfaction. One pharmacist described it as;

> *'When I first qualified and I remember working in the dispensary where we were doing nearly up to 3000 items a week and I felt like I was in a production factory just checking scripts…I wanted to be challenged more. This is doing exactly that and I love my job now, I love doing all these services and I love the patient interaction.' P9 (Female, large multiple, age 41-50 yrs)*

Participants were generally very positive about the service and enthusiastic about the large potential benefit to be had from the service. All participants thought that the most important benefit would be to the patient. Potential patient benefits described by participants included improved clinical outcome and increased understanding of their condition and its treatment. Participants anticipated a positive reception to the service from patients who were seen as appreciating additional care. One participant described a patient being prescribed a new medicine as:

> *'A time when I think patients can be really quite confused and scared actually. So there's a real role for pharmacists here to help take some of the mystique away, give them practical help on how to look after their condition and deal with their medicines, and ultimately to make sure that any ill health or*

inconvenience that they're suffering as a consequence of that, is minimised.' SP4

'It sounds as though it's something that people will probably appreciate' P11 (Male, large multiple, age 41-50 yrs)

Potential benefits for the pharmacy profession were also identified. The NMS was seen as an opportunity for the profession to demonstrate its worth as a service provider and possibly increasing the level of respect for pharmacists. The NMS was also described as an opportunity for pharmacists to use their clinical knowledge to benefit patients. Commercial benefits from the new service was identified however this was seen as '*a bonus*' (P14). Superintendent pharmacists saw this benefit as more important than the pharmacists did.   Superintendent pharmacists saw income from clinical services as becoming increasingly important as remuneration for dispensing reduces:

'The additional income is significant for us when income around dispensing is dropping.' SP2

4.3.3 Potential Facilitators to Service Provision

The only other comparable service, MURs, were introduced to community pharmacy in 2005. Both pharmacists and superintendent pharmacists saw the introduction of MURs as a significant change in direction for pharmacy as a profession;

'It fundamentally changed the way pharmacists perceived themselves, how they work in their own dispensary, how the support staff actually support' SP1

This cultural change within the profession was cited as the main reason for the slow uptake of MURs with the attitudes of individual pharmacists determining the speed of service implementation. Participants thought that the change in how pharmacists perceived their job role would enable quicker uptake of any new service introduced;

'This is building on the MUR's service that already exists so…the expectation will be that this is the sort of thing you do.' P9 (Female, large multiple, age 41-50yrs)

When asked about how the NMS would affect the role of the pharmacist, participants responded saying that '*it is something we are already doing*' (P3

male, small chain, age 51+yrs) albeit in a less formalised and structured way. Therefore participants did not feel that it would significantly change the role of the pharmacist;

> *'I don't see it being any different because part of the role at the moment, it may not be in a formalised way, is to make sure people use their medicines correctly.' P11 (Male, large multiple, age 41-50yrs)*

All participants bar one pharmacist expected to be offering the NMS from 1st October 2011. The pharmacist who did not expect to be offering the service explained that the pharmacy they work in does not offer MURs so were unlikely to offer the NMS. All superintendent pharmacist participants expected every pharmacy in their companies to offer the service from October 1st. This suggests that pharmacies are expecting to provide this service immediately after implementation and this could facilitate the quick uptake of the NMS.

When asked about the selected conditions included in the NMS, participants acknowledged that the chosen medical conditions represented a large proportion of the patient population. This was seen as being important to the success of the service:

> *'They cover enough of our patients to be worthwhile doing. If you're just going to do the odd person here and there then it's not worth your while.' P6 (Female, large multiple, age 51+ yrs)*

Participants suggested that patients with asthma/COPD, type 2 diabetes or patients taking warfarin already received more support than other conditions through nurse-led clinics, but still saw a role for pharmacists in providing advice when a patient is newly prescribed a medicine.

Some participants felt that limiting the NMS to certain conditions was unhelpful. One pharmacist said that including all long term medical conditions '*would make more sense' (P9 Female, large multiple, age 41-50 yrs)*. A superintendent questioned limiting the eligibility for the NMS asking:

> *'Why are we being selective? Why is one patient's condition more valuable? Why is that patient with that condition more important than helping this patient who is not on the list but the outcome could be much more beneficial?' SP5*

Participants suggested medical conditions where patients would benefit including depression, rheumatoid arthritis, chronic pain and skin conditions such as psoriasis. Participants felt that the NMS could especially benefit patients with asymptomatic conditions. One participant did observe that the conditions chosen may have been chosen because they would allow the profession to prove the effectiveness of the NMS more easily than other conditions:

> *'If we wanted to prove that we are effective at what we're doing I suspect that something like antidepressants would not be a good choice for us.' P10 (Male, locum pharmacist, age 26-30 yrs)*

The service specification allows the intervention and follow-up consultations to be carried out in the pharmacy consultation room or by telephone. Participants were concerned that patients would be unwilling to return to the pharmacy for the consultations:

> *'I can't see why patients would want to come back specifically to have an interview with the pharmacist.' SP1*

Although most participants would prefer to conduct face-to-face consultations, they thought it was likely that most intervention and follow-up consultations would occur by telephone according to patient preference. Participants reported that ultimately the method of follow-up would be determined by patient choice.

There were other factors identified by participants as affecting the choice of follow-up method. It was suggested that where patients do not live close to the pharmacy, telephone consultations might be preferable. Telephone consultations may also be more preferable in busier pharmacies, where telephone consultations could be carried out at less busy times. The nature of the patient's medicine could also affect the choice, for example giving advice about inhaler technique may be easier in a face-to-face consultation. One participant pointed out that:

> *'Face-to-face allows me to use a translation service and I've got a large proportion of non-English speaking patients.' P3 (Male, small chain, age 51+ yrs)*

Therefore it was suggested that having the option to conduct the intervention and follow-up consultations by telephone would facilitate the provision of the NMS.

Pharmacist participants reported that as the advice given during NMS consultations reflected current practice, the only area they needed training on was the logistics of service provision;

> *'I think the only thing I would be confused about is how I claim payment for it.' P12 (Female, large multiple, aged 41-50 yrs)*

Both pharmacist and superintendent participants were positive about the accreditation process for the NMS. For previous services pharmacists have had to prove competence in order to become accredited to provide the service, a process that takes several months. The accreditation for the NMS requires pharmacists already accredited to provide MURs to self-certify that they are competent to provide the service. This change was welcomed by the participants as recognition of pharmacists as professionals:

> *'I think the self-assessment gives us a brain for once where is the MUR accreditation was a little bit ridiculous.' P13 (female, small chain, aged 26-30 yrs)*

> *'I think that comes from the slight ethos change around the GPhC that as a profession we are allowed to say yes I know I've done it and I stand behind that and that should be enough.' P6 (female, large multiple, aged 51+ yrs)*

The self-accreditation process was seen as facilitating the early implementation of the service:

> *'There's no more external accreditation with the self-assessment so that will make [the service] get off the ground a lot faster.' SP3*

Participants also felt that self-accreditation was appropriate for this service because *'it is something we are already doing'* (P3 male, small chain pharmacy, aged 51+ yrs) so did not require any up-skilling.

> *'We are not being asked to do anything that we don't do already, anything that we not professionally qualified to do…we can make a statement that we are up to doing this and not be*

asked to prove it. We are professionals and qualified to do this.'
SP5

Both pharmacists and superintendent pharmacists saw interview technique and communication skills as being important in the successful delivery of the NMS but not something requiring further training, with one pharmacist commenting:

> *'It's all about communication skills, if you can't sign to say that*
> *you have sufficient communication skills, you shouldn't be doing*
> *the job in the first place'. P6 (female, large multiple, aged 51+*
> *yrs)*

Superintendent pharmacist opinions on the necessity of training for their pharmacists also varied. Some felt that formal company training was unnecessary because their employee pharmacists already possessed the skills required and that;

> *'It's the mechanics and the practicalities of the service that I*
> *need to check with each manager that they're going to be ok*
> *with.' SP1*

4.3.4 Potential Barriers to Service Provision

The study participants perceived general practitioners (GPs) as having a low awareness of pharmacy services. In the case of MURs, there was a feeling that most GPs had not accepted them and that GPs were unlikely to accept any new services. Similarly, patients were seen as having a poor awareness of what pharmacists can offer;

> *'We just count tablets and sell shampoos. That's how people see us.'*
> *SP3*

Both pharmacists and superintendent pharmacists saw GP awareness and involvement in the NMS as important; however there was a general feeling that GPs were unaware of the NMS despite briefings from Local Medical Committees and Primary Care Trusts. One participant suggested that the NMS was unlikely to be a priority for most GPs due to the coincident restructuring of the NHS in England:

> *'If I am honest I think the GPs certainly have many other issues*
> *at the moment around the changes within the NHS that they are*

> *far more concerned about' P8 (Male, large multiple, age 31-40*
> *yrs)*

There is provision in the service for patients to be referred into the service by prescribers in primary and secondary care however participants saw patient engagement initiated by the pharmacist as the main entry route into the NMS due to the perceived low prescriber interest and awareness of the service.

> *'It should be [that] the general practitioner sends the patient to*
> *us…but I imagine that 90% of the consultations are going to be*
> *initiated by the pharmacist. I don't think we're going to get*
> *many people referred to us.' SP1*

Participants thought that patients were unlikely to be referred into the service from secondary care but were more optimistic about referrals from GPs. Local relationships between GPs and pharmacists were seen as being key to gaining primary care referrals and good relationships were seen as being more likely for pharmacies co-located with GP surgeries:

> *'It depends if you manage to get the right relationship with*
> *them. It just depends whether you're getting prescriptions from*
> *a wide range of surgeries where you can't have a close*
> *relationship, or whether you're in a health centre' P12 (Female,*
> large multiple, age 41-50 yrs)

Participants saw value in pharmacists personally briefing local GP practices in order to raise awareness and promote GP involvement but were not particularly optimistic about the reception they would receive.

There were concerns raised by both superintendent pharmacists and community pharmacists around the speed of introduction of the NMS and the lack of clarity regarding details of service provision. The wording for the consent form was not published until two weeks before implementation and the online recording system for national recording of NMS data was not released until the day before the implementation of the NMS. Participants were concerned about the administrative requirements for the intervention and follow-up consultations. There was a lot of uncertainty around what the recording requirements would look like. One superintendent pharmacist commented:

> *'It's probably going to be paper-based…at the beginning, again like MURs we started that on paper then moved onto computer. It's a bit of a shambles really; we're in no way prepared for it on the 1st of October.'* SP1

The speed of implementation led to some materials being made available close to the date for implementation and the final service specification being published one month after the introduction of the service. This was seen as potentially hindering the uptake of the service.

The pharmacists were concerned that the introduction of a new service may lead to increased management pressure. Participants described experiences of management pressure to perform MURs and expected pressure to be exerted to encourage them to provide the NMS. This was seen as inappropriate as pharmacists felt they had no control over the number of eligible patients they would see:

> *'The only concern that creates is...because I work for a company, will I get pressure from above?…I can't manufacture patients if they are not on a new medicine. If they don't meet the criteria I can't manufacture people to do it.'* P12 (Female, large multiple, age 41-50 yrs)

The payment structure raised concerns with both pharmacists and superintendent pharmacists. Pharmacist participants were confused by the payment structure and were unclear how they would be remunerated for the service. Pharmacists were concerned that the payment structure could lead them to provide services for which they will not be paid:

> *'Just pay us for every one we do, it's just ridiculous to say I can do 10 and not be paid.'* P9 (Female, large multiple, age 41-50 yrs)

Superintendents were less confused by the payment structure but like the pharmacists they had serious concerns about what it would mean in practice. One superintendent pharmacist was concerned that the payment structure could adversely affect the implementation of the service. Both pharmacists and superintendent pharmacists were keen to point out that the payment structure would not prevent them offering the service to patients because they saw the potential value in the service for patients:

'Obviously we'll put the interests of our patients first so where we can, we will offer this service.' P9 (Female, large multiple, age 41-50 yrs)

'I think our pharmacists will go for it. They see value in this service and see themselves having a role in helping patients. I think despite the payment structure we'll make this a success, but we won't be getting paid in some instances where we should be getting paid. And that's not fair. It's not fair remuneration for the work we've put into this.' SP3

4.4 Discussion

This chapter explores pharmacists' and superintendent pharmacists' views of the NMS prior to implementation and experiences of preparing to offer the service. Themes emerging from the participants' responses included: participant awareness and understanding of the NMS, benefits of providing the NMS, potential facilitators to service provision and potential barriers to service provision. Participants identified pharmacists' positive attitudes towards the NMS, good pharmacist and GP relationships, and the ability to conduct the intervention and follow-up stages of the NMS by telephone as potential facilitators to the successful implementation of the NMS. Participants were concerned that a lack of GP enthusiasm for pharmacy services and the payment structure could act as barriers to service implementation. Another potential barrier to the successful implementation of the NMS is pharmacist confusion regarding the eligibility criteria for the service.

The superintendent pharmacists in this study agreed that attitudes and beliefs about a service are key factors in motivating their pharmacists to provide services. The pharmacist participants held positive attitudes towards the NMS and all bar one pharmacist expected to offer the service from the first possible day. Previous studies have shown that a health care professional's knowledge of a service and their attitude and confidence towards providing it can affect service implementation.[109,110] Bradley et al. investigated factors affecting the uptake of MURs and found that pharmacists motivated to provide MURs facilitated MUR provision.[6] This suggests that pharmacists motivated to provide the NMS would facilitate the implementation of the service.

The results from this study suggest that pharmacists have a positive attitude to providing services, seeing it as an opportunity to use their clinical skills to

benefit patients. A study exploring the attitudes of pharmacists towards MURs found that pharmacists saw them as a chance to make better use of their professional skills and to help patients' make better use of their medicines.[7] My study also suggests that the provision of services is viewed as an increasingly important role of the community pharmacist. This is not unique to the UK; a study in New Zealand suggested that pharmacists see service provision as crucial to the future of pharmacy as a profession.[112] The enthusiasm for providing services found in this study is very different to the views expressed by Australian pharmacists regarding new roles, where pharmacists were hesitant to play a patient-care role despite seeing it as important.[126] This difference may be explained by participants in this study viewing the NMS as a formalisation of advice already provided by pharmacists and not a completely new role.

The study conducted by Clifford et al required pharmacists carrying out telephone interviews to receive training that included telephone communication skills whereas pharmacists wishing to provide the NMS are not required to undergo any training.[41] This study found that the participating pharmacists felt that they only required training regarding the service structure and did not need further training in communication skills, as all competent pharmacists should possess good communication skills. An Australian study found that pharmacists perceived training in communication skills as less necessary than training in other areas of the provision of extended pharmacist roles, supporting the idea that pharmacist see themselves as already possessing good communication skills.[114] However studies investigating pharmacist consultations in England have found that pharmacists do not always demonstrate good communications and further training may be beneficial specifically in conducting patient-centred consultations.[113,127]

Several potential barriers to service implementation were identified, the first being that pharmacists were confused between the NMS and targeted MUR services. Even those pharmacists who had received training from employers on both services immediately prior to the focus groups still appeared confused. This was not wholly unexpected as the NMS and changes to MURs were introduced concurrently and there are some similarities in eligibility criteria for the services, but does raise concerns about how ready the pharmacists were to provide both services from October 2011.

Participants were concerned that the payment structure for the NMS could act as a barrier to service implementation. Other research in the UK has found that inadequate remuneration is viewed as a barrier to service implementation.[115,116] Since collecting the data for this study, a revised payment structure was introduced in May 2012 that addressed many of the concerns raised by participants in this study regarding the lack of remuneration for service provision.[90]

Another potential barrier that participants in this study identified was a lack of GP awareness of the service and a lack of interest in the NMS despite briefings from the local medical committees. This seems to be a common situation worldwide for pharmacy services. Studies in Australia and Sweden have found low GP awareness and a lack of interest and participation in pharmacy services, but where GPs can see benefits to pharmacy services, they are more likely to participate and GP involvement with pharmacy services leads to an increase in GP-pharmacist collaboration.[98-102] This is a concern for the implementation of the NMS as Bradley et al found that the greatest barrier to the implementation of MURs was a lack of GP participation.[6]

There are several opportunities to further facilitate the implementation of the NMS. Participants in this study emphasised the importance of making pharmacists aware of the benefits to patients that the service can provide in order to motivate them to provide the service. Another concern voiced by participants was the lack of awareness or interest in the service held by GPs. The findings of this study would suggest that increasing GPs awareness of the potential benefits of the NMS to their patients and practice could help facilitate the implementation of the service. Pharmacists need to be proactive and work to publicise the service locally to both GPs and patients if the NMS is to realise its full potential.

The results of this study would suggest that pharmacists believe that patients are not aware of the expertise of a pharmacist, seeing them as shopkeepers more than health professionals. This is important because the NMS is based on the health belief model which was developed by Becker in 1974 and is a way to predict patient's medicine taking behaviour.[62] When attempting to alter a person's beliefs and therefore actions, Becker states that the patient 'needs to have some kind of cue to take action', that is, the patient needs to be prompted before they will take any kind of action.[63] He suggests that this prompt may be a conversation with a 'significant person'. In the case of the

NMS, the pharmacist would be the 'significant person' causing the patient to take action. This would suggest that the success of the intervention depends to an extent on whether the patient views pharmacists as 'significant'.

Chapter 5: Post-Implementation Views and Experiences of Community Pharmacists and Superintendent Pharmacists Regarding the New Medicine Service

5.1   Introduction

This chapter presents the results of a study exploring the views and experiences of community pharmacists and superintendent pharmacists regarding the implementation of the NMS. This study follows on from the study reported in the previous chapter.

5.2   Methods

The views and experiences of the community pharmacists were sought in focus groups and interviews. Focus groups were initially chosen to allow discussion of topics and experiences, and the opportunity to participate in interviews was offered when a pharmacist was unable to attend a focus group session.   It was decided that it would be inappropriate to include superintendent pharmacists in the focus groups as their presence may affect what their employees said. In addition the idea of a focus group consisting of only superintendent pharmacists was dismissed as commercial sensitivities may have affected the discussion.   Therefore superintendent pharmacist views and experiences were sought in semi-structured interviews.

The opportunity to participate in this part of the study was offered to all community pharmacists and superintendent pharmacists who participated in the earlier study investigating the views of pharmacists regarding the NMS prior to the services implementation (Chapter 4). The number of participants recruited was limited by a low recruitment rate in the earlier part of my study therefore additional participants were recruited through personal contacts.

The questions used in the focus groups and interviews were developed with reference to literature including the provisional service specification and the results of the pre-implementation study (Chapter 4). The topic guides and interview schedules have been included in Appendices 4 and 5. The topic guide for pharmacists covered the introduction of the NMS, training, patients eligible for the service, conducting and recording the service and the payment structure. The interview schedule content for superintendent pharmacists was similar to the topic guide, covering the preparation for implementing the NMS, implementation of the service, the effect the NMS has had, and the payment structure.

The community pharmacist focus groups and interviews were conducted in February and March 2012 with a total of 11 participants. Two focus groups were conducted with three and six participants respectively. An additional two participants were interviewed separately as they were unable to attend the focus group sessions. The average length of focus group sessions was 65 minutes and the interviews averaged 28 minutes.

Interviews with six superintendent pharmacists were carried out between February and April 2012. The participants were interviewed individually at their place of work or by telephone according to participant preference. The interviews lasted on average 45 minutes.

The interviews and focus groups were audio-recorded with permission and transcribed verbatim. The transcripts were analysed thematically using the method detailed in Chapter 4, and checked by my supervisor as previously. The data management software NVivo 9 was used to facilitate the analysis.

5.3   Results

Eleven community pharmacists took part in the study and represented a range of ages (Table 5.1). The majority of participants were female and there were more employee pharmacists than locums. The participants represented community pharmacies from across the sector including independents, small chain pharmacies, large multiples and supermarket pharmacies.

Six superintendent pharmacists also took part in this study. Three superintendent pharmacists represented independent (1-5 pharmacies) or small chain pharmacies (6 or more pharmacies not including the 10 largest pharmacy chains in England), and three represented larger chains (the 10 largest pharmacy chains in England).[1] Demographics have not been reported to prevent identification of participants.

Table 5.1: Demographics of the community pharmacist participants (n=11)

	Gender		Age					Employee/Locum	
	Male	**Female**	**22-25**	**26-30**	**31-40**	**41-50**	**51+**	**Locum**	**Employee**
Focus group 1	2	1	-	1	-	1	1	1	2
Focus group 2	2	4	2	1	1	2	-	3	3
Interviews	-	2	-	1	-	1	-	-	2
Total number of participants	4	7	2	3	1	4	1	4	7

This study aimed to explore participants' views and experiences of the NMS implementation, in order to identify any facilitators and barriers that may have affected the service's introduction. This study did not use grounded theory therefore data saturation was not required, although some data saturation was observed. Analysis of the focus group and interview data produced three main themes; facilitators to NMS implementation, barriers to NMS implementation, and the long term impact of the NMS.

5.3.1 Facilitators to NMS implementation

Participants reported that a key facilitator to the provision of the NMS was positive pharmacist attitude towards the service. They reported that there was an initial enthusiasm to provide the service which helped the early implementation of the NMS. Participants suggested that the NMS gives pharmacists an opportunity to use their clinical knowledge to benefit patients in a tangible way, and this increased participant job satisfaction. There was a suggestion that because the NMS focuses on one item it is more manageable than an MUR, which reviews all the patient's medicines, and participants felt confident providing advice and support in this way. Another possible contributor to positive pharmacist attitudes was the financial benefit gained from providing the service which was seen as *'based on what pharmacists do anyway'* (SP5).

The participants in this study reported there was pressure to provide the NMS. A reduction in remuneration for dispensing was reported to create commercial pressure to provide services and participants described the strategic importance of the NMS as an incentive to provide the service. Community pharmacist participants also reported that they had received pressure from management to provide the service and the combination of these pressures had facilitated the implementation of the NMS.

Certain pharmacy characteristics were seen as facilitating the provision of the service. Firstly, having adequate consultation space within a pharmacy was seen as important. Participants described a growing demand on the consultation room in their pharmacies and multiple consultation rooms per pharmacy was seen as desirable;

> *'One of pharmacies, we had to build an extra consultation room because the pharmacist couldn't get in to do MUR's'* SP1

The IT system used within a pharmacy also holds the potential to facilitate NMS provision. Participants using a Patient Medical Record (PMR) system with an integrated NMS module that identifies eligible patients and prints consent forms found NMS provision easier than those who used a PMR system without that facility. Another pharmacy characteristic that participants reported as affecting NMS provision was the pharmacy's opening hours. Participants who worked in pharmacies with opening hours that allowed them to conduct the intervention and follow-up stages of the service in evenings or weekends reported a greater success with contacting patients. Lastly, a pharmacy's location was reported as affecting the numbers of NMS eligible patients seen, with pharmacies in close proximity to GP practices being reported as having more opportunities to provide the service.

A characteristic of the NMS service that was seen as facilitating the implementation of the service was the option for conducting the intervention and follow-up stages of the NMS by telephone. Participants reported that most of their NMS interventions and follow-ups were conducted in this way. The option for telephone consultations was seen as popular with patients as it does not require a visit to the pharmacy and it was also seen as benefitting pharmacy as it allows pharmacists to manage their workload by carrying out the telephone consultations at the quietest time of the day in the pharmacy.

> *'In some ways I prefer to do it face-to-face, but a combination*
> *of logistics and patient preference drives most of them towards*
> *a phone call.'* P19 (Female, independent, 41-50yrs)

It was reported that staff engaged with the NMS and were involved in identifying patients, facilitating the provision of the service in their pharmacy by reducing the burden on pharmacists. Participants suggested that a key factor affecting staff attitudes towards the NMS was the training they received before the implementation of the service, with a lack of training being associated with a lack of staff engagement with the service.

> *'I think if the staff have been informed at the beginning before*
> *the launch and you can see the benefits, then they're more*
> *likely to be on-board and supportive on those, but if they really*
> *haven't got a clue, then they won't be bothered.'* P18 (Female,
> large multiple, 31-40yrs)

Participants compared the implementation of the NMS with the introduction of MURs, suggesting that uptake of NMS had been quicker than the uptake of

MURs. Participants suggested that the experience of providing MURs had facilitated the NMS implementation as pharmacists were already familiar with providing advanced services, seeing it as a key part of their role as a pharmacist. Participants also reported that they did not require any further training to provide NMS consultations as the skills had already been learned in order to provide MUR consultations.

5.3.2 Barriers to NMS implementation

The pharmacist participants suggested that the timing of the NMS launch may have hindered the services uptake as it coincided with the start of flu vaccination season and the run up to Christmas, traditionally a busy time for pharmacies. However participants did acknowledge that there would be disadvantages to launching a service at any time during the year.

Both pharmacist and superintendent pharmacist participants described a lack of service details as they prepared for the introduction of the NMS. It was suggested that this made the implementation of the service harder and could have affected the rate of uptake. In particular participants reported a lack of information about PharmaBase (software for recording the NMS) and a lack of clarity around the availability of PMR modules for the service.

> '*We went live* [with PharmaBase] *without very much of a trial period at all so effectively beta testing was done in situ as we were operating and inevitably there are always going to be some teething issues.*' SP4

Some pharmacist participants described more problems engaging patients with the service than the other participants, with one pharmacist reporting that up to half of all patients she had invited to take part in the NMS had declined, a much higher figure than the other participants described. This could suggest that a pharmacist's ability to communicate the purpose and requirements of a service affects the likelihood of patient engagement. Participants also reported a lack of GP engagement with the NMS, despite having spoken to practices prior to the launch of the service. This may be another example of pharmacist communication skills acting as a barrier to service provision.

The NMS was described as affecting pharmacists' workload in several ways. It was suggested that introducing a new service put additional strain on pharmacies by increasing the amount of time pharmacists are not available

for dispensing and increasing the demand on pharmacies consultation rooms. Participants suggested that there was a need to reduce the dispensing burden on pharmacists if clinical services are going to be successful. Some participants reported concerns about the increased workload on pharmacists potentially affecting the quality and safety of care provided;

> '*At some point in time, because of the pressures being placed upon pharmacists, because of the new services…we are going to have an accident with somebody. Somebody will die because a pharmacist has been doing a* [service] *and something else has dropped through.'* SP6

In addition to NMS provision adding to the general workload of pharmacists, participants reported that the recording required for the service was in itself a burden for pharmacists. Participants reported having to record the consultations on paper before transferring the information onto PMRs at a later point in time. Participants using PharmaBase had a further step as the information also had to be transcribed onto that system. Therefore whilst participants reported that the time spent conducting the NMS consultations was not that burdensome, the time spent on recording them was significant.

> '*It's a bit like with the police and crime and reporting crime. You deal with the crime and then you have to fill out a twenty-five page report, and that's how it feels.'* P9 (Female, large multiple, age 41-50 yrs)

Participants questioned the restrictions on eligible patients stating that some patients missed out because the eligibility criteria are too restrictive. In particular participants were concerned that a lot of new asthma medication is prescribed for children who cannot consent to the service and the current service specification does not allow parents or carers to provide consent. Participants also suggested that opening the service to other conditions would allow more patients to benefit. In particular patients newly prescribed anti-depressants were seen as a group of patients for whom the NMS could make a real difference. Other groups that pharmacists were keen to provide support for included pain, rheumatoid arthritis, and high risk medicines.

The complexity of the service structure seemed to be causing problems with the provision of the NMS. Participants described the consent form as a barrier, questioning the need for some of the statements. Participants noted that patients do not have to provide written consent for consultations with other health care professionals and questioned the need for written consent for pharmacy consultations. Participants were also critical of the suggested consultation questions and reported that they often create their own consultation structure to make it seem more naturalistic:

> 'I sit down and look at [the questions], read through them as a refresher, then structure it the way I would speak because I don't follow that sort of line when I speak to patients' P3 (Male, small chain, age 51+ yrs)

A key barrier to NMS implementation identified by the participants was the payment structure. The complexity of the payment structure meant that the pharmacist participants were confused about how many NMS they had been paid for and how many they needed to conduct to meet the thresholds. The tiered levels according to dispensed items was specifically described as a problem as pharmacies experience fluctuating monthly prescription numbers therefore participants felt that it was difficult to predict whether they had met the threshold levels for payment. This uncertainty as to whether a pharmacy would receive payment for an NMS conducted led to some pharmacist participants opting to provide an MUR instead of an NMS as they were guaranteed payment for MURs.

> 'There have been a couple of occasions where I've had the option to do a prescription intervention [MUR] or an NMS and if I do the prescription intervention…it's a guaranteed £28. With an NMS it's a possible £25 if you're lucky' P10 (Male, Locum pharmacist, age 26-30)

A second barrier associated with the payment structure was the assumption that 0.5% of all prescription items dispensed in a pharmacy would be eligible for the NMS. Participants reported that the rate of opportunities seemed lower in practice and that opportunities varied. Participants suggested that pharmacies located inside or next to GP practices would have more opportunities to provide the NMS than pharmacies located on the high street. They suggested that this may be due to a combination of better GP-pharmacist relationships and more newly prescribed items being dispensed.

One superintendent pharmacist participant expressed concern that the difference in opportunity rates could lead to the NMS only being offered in healthcentre pharmacies. In addition participants were concerned that pharmacies that dispensed a high level of Misuse of Drugs Act (MDA) prescriptions or prescriptions for care home residents would be disadvantaged. The participants reported that most eligible patients were recruited to the service and that the low numbers of NMS opportunities was not down to eligible patients not being identified.

Participants expressed a concern that the problems associated with the payment structure could impact on pharmacists' enthusiasm for the service, leading them to become demotivated. It was suggested that unless the payment structure was addressed soon, pharmacists would cease to provide the NMS.

> '*My concern is that pharmacists themselves will become*
> *demotivated... They are not seeing a reward for the provision*
> *of the service…they see their employer isn't being paid*
> *therefore they themselves are not being recognised for the*
> *service they are providing and as a consequence there is*
> *potential for demotivation if we don't sort it out soon.'* SP4

Participants suggested that this barrier to NMS implementation could be removed by changing the payment structure to per item of service remuneration. Participants reported that they would be content with a lower amount of remuneration per service if payment was received for every NMS provided. It was suggested that by changing the structure to payment per item would make the provision of the NMS more appealing to pharmacists and thereby facilitate the implementation.

5.3.3 Long term impact of NMS

Participants described the long term impact of the NMS as centred on the pharmacist-patient relationship. It was suggested that by participating in clinical services such as the NMS increases patient awareness of the professionalism of pharmacists and what they can offer:

> '*It has changed some people's perceptions of what the*
> *pharmacist is capable of and is there for'* P10 (Male, Locum
> pharmacist, age 26-30)

Participants also described the NMS as building trust between pharmacists and patients which facilitates discussion of other health related subjects, such as smoking cessation:

> '*I think it's really bringing them closer to the pharmacist and the team clinically which is great, so for instance…it's not going to be so odd talking to people about stopping smoking because they know we're concerned about their health.*' SP1

Whilst most participants were enthusiastic about the positive impact the NMS was having of the pharmacist-patient relationship, one participant expressed concern that introducing clinical services could undermine the informal nature of the relationship, which was seen as an advantage for the profession over other health care providers.

5.4   Discussion

This chapter explores the views and experiences of community pharmacists and superintendent pharmacists of the implementation and provision of the NMS. The study identified barriers, facilitators and the long term impact of the NMS implementation. Identified barriers included the complexity of the service structure, including the restrictions on eligible patients and the payment structure, the effect of the NMS on pharmacists' workload, pharmacists' communication skills and the lack of details available to pharmacists prior to the launch of the service. The facilitators identified by participants included positive pharmacist attitudes towards the NMS, certain pharmacy characteristics, the pressure to provide the service, pharmacy staff views and involvement with the service, and the experience of providing MURs. The long term impact of the NMS described by participants focused on the effect of NMS provision on building pharmacist-patient relationships.

A key facilitator to NMS implementation identified by this study was the positive attitude towards the service held by pharmacists. This was identified as a potential facilitator in an earlier study (Chapter 4) and supports the idea that the attitude towards a service and confidence of a pharmacist to provide it can affect the implementation of the service.[109-111]   There were several factors reported by participants as contributing to this positive attitude including the perceived benefit to patients and the increased job satisfaction associated with using clinical knowledge. Research from MURs showed that pharmacists were motivated to provide MURs because it gave them the opportunity to use their clinical knowledge to support patients in their

medicine taking, supporting the idea that pharmacists are keen to offer services that use their knowledge to benefit patients.[7]

As predicted by my earlier study, the largest barrier to the NMS implementation described in this study was payment structure (Chapter 4). The participants suggested that changing the payment structure to a payment per item of service would remove this barrier. In May 2012 a new payment structure was introduced ensuring that pharmacies would be remunerated for every NMS completed.[90] The results from this study suggest that this would facilitate the implementation of the NMS by making the provision of the service more attractive to pharmacists.

Participants in this study expressed concern that the introduction of the NMS had increased their workload and this had the potential to affect safety in the pharmacy. A review of the literature in 2011 found that dispensing volume has increased as well as the number of pharmacies providing non-essential services, suggesting the pharmacists' workload has grown and the addition of the NMS would have further increased their workload. However, the review did not find robust evidence that that the increased workload had affected patient safety but did report that high dispensing volume was associated with a decrease in the number of interventions made, suggesting that there is potential for dispensing workload to affect patient safety.[104] There is no consensus regarding the point at which the dispensing volume begins to affect patient safety, in the UK it has been suggested that 500 prescriptions per pharmacist per 9-hour day is too much, whilst in Australia the threshold for the safe dispensing of prescriptions was identified as 150 prescriptions per pharmacist in a 9-hour day.[105,106] What is agreed is that it is the number of prescriptions per pharmacist that is important rather than per pharmacy, suggesting that to ensure patient safety, pharmacist staffing levels should be examined.

The participants in this study identified that certain characteristics of a pharmacy's PMR system had the ability to facilitate the provision of the NMS by reducing the workload associated with conducting the service. There appears to be very little literature regarding how PMR systems can facilitate the provision of pharmacy services, as this appears to be an important facilitator to NMS implementation, perhaps further research in this area would be beneficial.

It was suggested that the combination of commercial and managerial pressure to provide the NMS, in addition to the political significance of the NMS had facilitated the implementation of the service. Anecdotal evidence regarding MURs suggested that the managerial pressure on pharmacists to provide services had was associated with MURs of questionable quality and value being carried out.[96,119] Therefore whilst the pressure to provide the NMS may have facilitated the implementation of the service, it may also have adversely affected the quality of the services completed.

The largest barrier to NMS implementation identified both pre- and post-implementation was the payment structure. Concerns were raised that the opportunity rate to provide the NMS in practice is much lower than the theoretical value of 0.5% of prescription items used to determine the remuneration for providing the service. Therefore the next chapter will detail a study conducted in order to determine the actual NMS opportunity rate seen in pharmacies.

Chapter 6: What Proportion of Prescription Items Dispensed in Community Pharmacies are Eligible for the New Medicine Service?

6.1 Introduction

The findings of earlier studies described in Chapters 3, 4 and 5 suggest that the actual opportunity rate to provide the NMS is less than the theoretical assumption that 0.5% of prescription items are eligible for the service. Therefore this chapter reports the findings of a study conducted examining the actual proportion of prescription items dispensed that were eligible to receive the NMS.

6.2 Methods

This study was carried out in pharmacies in Nottingham belonging to a large chain to minimise inter-pharmacy variation. At least one thousand consecutive prescription items were sampled from each pharmacy (a total of 8005 items) as for most pharmacies this represents several days prescriptions and enabled several pharmacies in different locations to be sampled to provide a broader picture. This provided a balance between collecting large numbers of prescription items and being more representative of an individual pharmacy, and collecting from a wide range of pharmacy location types to be more representative of the pharmacy sector. The sample size software nQuery Advisor version 6[128] was used to conduct a sample size calculation based on the primary outcome to estimate a proportion with 95% confidence intervals to a power of 90%. This showed that 7852 prescription items were needed in total to detect a 0.5% difference (a 0.0025% change in prescription items eligible for the NMS), allowing for clustering effects, therefore data from at least 7852 prescription items would be collected.

The 17 pharmacies belonging to a large multiple in Nottingham were grouped into three distances from GP practices: less than 100 metres, 100-500 metres and over 500 metres and the three groups were sampled to reflect as closely as possible the distribution of all pharmacies in Nottingham. These distances were chosen in order to distinguish between pharmacies co-located or next to GP practices, and pharmacies further away from GP practices. The distances were calculated by entering the pharmacy postcode into the "Find GP Services" page of the NHS choices website (www.nhs.uk). Pharmacies were excluded from the study if they dispensed less than 1000 prescription items per week (so that data collected in each pharmacy would be sufficient), if the pharmacy's staffing levels required more than one person to receive and hand

out prescriptions, meaning that more than one researcher would be needed to collect the data, or if the pharmacy primarily catered to an atypical demographic and were therefore unrepresentative meaning that the results from the pharmacy would be unlikely to reflect the average demographics seen by pharmacies. One pharmacy was excluded from the study because they dispensed less than 1000 items per week. Two pharmacies were excluded from the study because they required more than one person to receive and hand out prescriptions. One pharmacy was excluded due to its atypical demographic. This pharmacy was located within a university health centre and mainly caters to young people who are less likely to require medicines for hypertension, COPD, type 2 diabetes or need anti-platelet agents or anticoagulants as these are conditions mainly affecting older people.   Therefore this pharmacy could be expected to have a lower opportunity rate for the NMS than other pharmacies. Eight pharmacies were sampled from the remaining 12 possible pharmacies reflect the distribution of pharmacies in Nottingham according to distance from GP surgery. After gaining approval from the head office of the large chain and area managers, pharmacies were contacted directly by myself to be invited to participate in the study.

In each pharmacy the data were collected by me taking in and handing out prescriptions to patients. Prescriptions were included in the study if they were a NHS prescription, regardless of who collected the prescription, what type of NHS prescription it was, or whether the prescription was dispensed as part of a care home service. Prescriptions were only excluded from the study if they were private (non-NHS) prescriptions. A prescription item was eligible to receive the NMS if it was newly prescribed for hypertension, type 2 diabetes, asthma/COPD or was an anti-platelet or anti-coagulant agent, and the medicine was included in the list of medicines eligible for the NMS as specified in the service specification.[10] In order to determine whether a medicine was new, the PMR was checked and each patient was asked if they had been prescribed the medicine before. A prescription item meeting these criteria for the NMS was recorded in the study as eligible to receive the service regardless of who collected the prescription or whether it was part of a care home service. Therefore the study recorded the number of prescription items dispensed that were eligible to receive the NMS as well as actual NMS opportunities.

For each NHS prescription the researcher recorded the number of items on the prescription, whether the patient or a representative collected the prescription, if the prescription was delivered, whether the prescription was a MDA form or part of a care home service. Where an item was eligible for the NMS, the therapeutic class it fell into was recorded along with whether or not the NMS was offered and whether it was declined (and a brief reason why if provided by the patient).   This study also recorded instances where items which were eligible for the NMS did not translate into an opportunity for the pharmacy to provide the service, for example where the patient was a child unable to consent to the service, or the patient was a care home resident. Data relating to private prescriptions were not recorded as only NHS prescriptions are eligible for the NMS.   The data were collected between January and May 2013.

The data collected were inputted into the statistical software SPSS and frequency counts with percentages determined. Proportions were calculated for each distance group of pharmacies and for the total number of opportunities to provide the NMS. In order to determine whether there was a significant difference between the study results and the estimate that 0.5% of prescription items are eligible for the NMS, The difference between the two proportions was calculated and the standard error of the difference determined.   The standard error was then used to calculate the 95% confidence interval of the difference between the proportions, with the difference deemed as significant if 0 did not lie within the confidence interval, as 0 represents no significant difference.   The difference between the proportion of NMS opportunities seen in pharmacies less than 100 metres from a GP practice and the proportion in pharmacies located further away was calculated in the same way and the significance of the result tested.[116]

6.3 Results

In total 8005 items were recorded in 8 pharmacies in Nottingham (a minimum of 1000 items in each pharmacy) and of these 6080 items (76%) were NHS prescription items that were not MDA items or for care home residents (Table 6.1). Of the 8005 items recorded, 1965 (25%) were delivered to the patient or care home, and the remaining 6040 (75%) were collected from the pharmacies.   Of the prescription items collected in the pharmacies, 28% (n=1720) were collected by patient representatives.

Table 6.1: The types of prescription items included in the data collection

Types of NHS prescription	Number of items recorded (%)
Care home service	1665 (21%)
MDA	260 (3%)
Other	6080 (76%)
Total	8005

In this study 20 prescription items, 0.25% (95% CIs 0.14%-0.36%), were eligible for the NMS. This differs significantly from the assumption that 0.5% of prescription items are eligible for the NMS as 0 (representing no difference) lies outside the CI. There were 17 opportunities (0.21%, 95% CIs 0.10%-0.32%) to provide the NMS (Table 6.2) as not all the eligible items translated into opportunities to offer the NMS.   Three items were prescribed for the treatment of asthma in children who could not consent to the service (Table 6.3).   The NMS was offered to 16 of the 17 patients that represented opportunities to provide the service. The one opportunity where the service was not offered was where a patient's representative collected the dispensed prescription.   The service was declined by 2 of the 16 patients offered the NMS, both of whom had been prescribed an anti-coagulant. Both patients stated the reason for declining the service was that they were receiving a lot of support from other health care professionals and felt that the support offered by the NMS was not needed.

Table 6.2: The frequency and percentage of NMS opportunities and NMS eligible items by distance from nearest GP practice (n=8005).

Distance of pharmacy from nearest GP practice	Number of items collected	Eligible items		NMS opportunities	
		Number	Percentage with 95% CIs	Number	Percentage with 95% CIs
<100m	2002	7	0.35 (0.09-0.61)	6	0.3 (0.06-0.54)
100-500m	5004	11	0.22 (0.09-0.35)	9	0.18 (0.05-0.31)
>500m	999	2	0.2 -	2	0.2 -
Total	8005	20	0.25 (0.14-0.36)	17	0.23 (0.10-0.32)

Table 6.3: The number of NMS eligible items and opportunities to provide the service by condition from 8005 prescription items dispensed.

	Asthma/ COPD	Hypertension	Type II diabetes	Antiplatelet/ Anticoagulant
Number of NMS eligible items	9	5	1	5
Number of NMS opportunities	6	5	1	5

There was no significant difference between the proportion of NMS eligible items at pharmacies located less that 100 metres from a GP practice compared with those further away (more than 100 metres from a GP practice) (difference= 0.13%, 95% CIs -0.14% to 0.42%).

6.4 Discussion

This study found that 0.25% of prescription items dispensed in community pharmacies are eligible for the NMS which is significantly different from the Department of Health's theoretical assumption that 0.5% of prescription items would be eligible. It is possible that in calculating the 0.5% estimate the

effect of some factors affecting the number of eligible items, such as prescriptions for care home residents, were underestimated, possibly explaining the difference between the observed number of eligible prescription items and the theoretical estimate.

Pharmacists were able to earn up to £55m in the first year of the service based on pharmacists performing the NMS for 0.5% of their prescription items each month. In order to be remunerated for the NMS conducted, pharmacies claim payment each month for completed NMS in the same way that payment is claimed for NHS prescriptions dispensed. The results from this study would suggest that pharmacists were not able to access the full potential funding as the number of opportunities to carry out the NMS is less than 0.5% of their prescription items. NMS funding is outside the total agreed funding for pharmacy contractors, and if it is not earned then contractors are no longer able to access it and is not guaranteed to be made available for other public health initiatives. In April 2012 the PSNC communicated that theoretical assumption may not reflect the rate of NMS opportunities for all pharmacies and has stated that it will be reconsidered in the future.[90] This study suggests that the actual rate of NMS opportunities is less than the theoretical rate which means that it would be possible to widen the scope of the NMS by including other conditions eligible for the service to increase the number of opportunities a pharmacist has to conduct the NMS and consequently the number of patients who could benefit, without exceeding the funding limit.

Studies examining the provision of other UK pharmacy services have found that adequate funding is important to the success of a service.[7,110,111] This is not unique to the UK; research conducted in Finland has also found that pharmacies must be adequately reimbursed for providing a service if the service is going to be successful long term.[112] This study suggests that the assumptions used to calculate the funding envelope for the NMS are flawed as the actually opportunity rate to provide the service is less than the theoretical rate that underpins the potential funding available. This highlights the importance of evidence based methodologies to calculate funding allocation.

The results of this study suggest that a pharmacy's opportunity rate to provide the NMS is less than the number of eligible items dispensed. In this study the reason for this was that eligible items were prescribed to patients who were not able to take part in the service because their age prevented them from being able to consent. The service to patients with asthma and is

likely to be affected by this more than the other groups as children are less likely to have hypertension, type 2 diabetes or require anti-platelet agents or anti-coagulants, than asthma.[8,85-87,94,122,123]

Of the 17 opportunities to offer the NMS in this study, there was just one occasion where the NMS was not offered to the patient, suggesting that the pharmacists engaged with the service take most available opportunities to provide the service. This contrasts with the early implementation of Medicine Use Reviews (MURs), where a national evaluation found that pharmacies offering MURs provided just 13.7% of the maximum number of MURs that could have been claimed for, despite this service being available for patients with any long term therapy.[8] The study carried out before the implementation of the NMS suggested that pharmacist engagement and NMS uptake would be greater than it was for MURs because when MURs were introduced it was seen as a change in direction for pharmacy requiring a cultural shift, whereas the NMS was seen as a natural extension of the role of community pharmacists (Chapter 4).

In this study there were 16 occasions when the NMS was offered to patients and 2 occasions where the patient declined the service. The stated reason for this was the same in both instances, that the patient felt that they were receiving enough support from other health care professionals. There is evidence to suggest that the reason given by patients in a pharmacy for declining a service may not be the sole or entire reason the patient did not want the service[133], however both patients had been prescribed anti-coagulant agents and were attending anti-coagulant clinics so it is possible that the declines in this study indicate that some patients taking anti-coagulants are content with the existing support provided by other health care professionals.

The most common condition receiving the NMS was asthma/COPD, followed by hypertension and anti-platelet agents/anti-coagulants with type 2 diabetes being the least common condition. National data published by the PSNC show that the most common NMS condition receiving the service is hypertension (54.4%), followed by asthma and COPD (26.4%), then type 2 diabetes (11.3%) with anti-platelet agent/anti-coagulant being the least common new medicines receiving the NMS (7.9%).[92] The likely reason for the difference between the study data and the national data is the small numbers of NMS recorded in this study. If the sample size had been greater it is likely that the proportions of conditions would reflect the national data. Another possible

reason for the difference between the study data and national data is that all the pharmacies sampled were in the same geographical location (Nottingham) and the demographics could potentially be different to demographics nationally. There is also some sensitivity to seasons with asthma and COPD with cold weather causing exacerbations. This could have affected the results of this study as data were collected in winter and spring, whereas the national data represents all four seasons.

In this study 28% of prescription items were collected by patient representatives, or proxies. Whilst the proportion of prescriptions collected by patient representatives nationally is unknown, it is widely reported that around a third of requests for health information and non-prescription medicines in pharmacies are made by proxies.[134-136] The significance of this finding is that proxies are unable to provide consent for patient to receive the NMS and represent a barrier to NMS engagement.

The results of this study did not find a statistical difference between the proportions of NMS eligible prescription items dispensed in pharmacies co-located with GP practices and pharmacies further away. However, the study was not powered to test this so it is possible that with a larger sample size a difference may be detected.

Chapter 7: Analysis of NMS Service Provision

7.1 Introduction

This chapter presents the results of a study investigating the uptake and impact of the NMS by analysing data recorded in PharmaBase service records for one large multiple pharmacy chain. PharmaBase was a national recording system available to all pharmacies in England with a NMS module that allowed pharmacies to record NMS registrations and consultations (an updated version of the recording system called PharmOutcomes is now available). The records in PharmaBase comprised 43% of all NMS consultations claimed for during the first year of operation.[92] The records were made using tick boxes or selecting predefined options to questions. Using this database was not compulsory although the large multiple encouraged its use.

7.2 Methods

The data from NMS consultations from October 2011 to September 2012 (September was a partial month) as recorded using PharmaBase, were obtained from one large, national, multiple chain pharmacy. The data had all patient identifiable details removed before the records were received. The data were provided in three parts; registrations, interventions and follow-ups, which were merged in SPSS.

The dataset included the following variables:

Demographic information:

- Registration identifier, unique for each new NMS patient registration
- Patient medicine identifier, unique for each new medicine included in the NMS
- Pharmacy identifier, unique for each pharmacy providing the NMS
- NMS status (options: completed; completed not claimable)
- Patient age
- Patient gender
- Method of entry into the service (options: pharmacy recruitment; GP referral; practice nurse referral)
- PCT
- Medicine
- Pharmacy name
- Pharmacy address

- Condition (options: antiplatelet/anticoagulants; asthma/COPD; hypertension; type 2 diabetes)
- Dosage
- Registration date (day, month and year)

For both intervention and follow-up consultations:
- Date of consultation (day, month and year)
- Withdrawal Reason (options: patient could not be contacted; patient has withdrawn consent of information sharing; patient has withdrawn consent to receive the service; prescriber has stopped new medicine; remove erroneous patient registration)
- Consultation method (options: face to face in the pharmacy; telephone)
- Matters identified with patient (options for all: Y; blank):
  - Using medicine as prescribed
  - Need for more information about the medicine
  - Side effects
  - Negative feelings about the medicine
  - Uncertainty on whether the medicine is working
  - Concern about remembering to take the medicine
  - Not using medicine as prescribed
  - Not having started the medicine
  - Prescriber has stopped the new medicine
  - Not using the medicine in line with the directions of the prescriber
  - Missing a dose in the past 7 days
  - Difficulty using the medicine due to its form
- Outcomes of the discussion with the patient (options for all: Y; blank):
  - Information provided:
    - How to manage or minimise side effects
    - Interactions with other medicines
    - Why am I using the medicine/what is it for
    - How to use the medicine
    - Correct dose of the medicine
    - Effect of the medicine on the body/how it works
    - Why should I take the medicine
    - Timing of the dose
    - Interpretation of side effect information
  - Agreed patient actions:
    - Carry on using medicine as prescribed
    - Use medicine as agreed during the intervention

- o Submit yellow card report to MHRA
- Actions taken by the pharmacist:
  - o Reminder strategies to support use of medicine
  - o Change to timing of doses to support adherence
  - o Referral
  - o Yellow card report submitted to MHRA
  - o Reminder chart/MAR chart provided
- Healthy living advice provided
  - o Diet and nutrition
  - o Smoking cessation
  - o Physical activity
  - o Alcohol consumption
  - o Weight loss
  - o Sexual health

7.2.1 Cleaning the data

Data were cleaned using Microsoft Excel prior to analysis. The age data were examined for outliers and 631 cases were found to have an age of 999years. The ages for these cases were treated as missing data and not included in calculating the median age of NMS patients. The medicines were expanded, placing the drug name (or brand name) in one column, before converting all brand names to generic drug names. The records for the healthy living advice given during consultations were also expanded and converted to six columns, one for each of the different types of healthy living advice offered during NMS consultations.

There were some potential limitations in the data; the dates for the NMS registrations were not usable (the data did not include the date, just the time of registration), however the registration dates were also included in the intervention and follow-up records. Therefore when examining uptake by month of the service, the dates were taken from the intervention records. The data also appeared to contain input errors as evident in table 7.1.

Table 7.1: The frequency of possible input errors when recording the dates of the different stages of the NMS

Error	Frequency in records
Registration date = Intervention date	2213
Registration date = Completion date	3
Registration date later than intervention date	116
Registration date later than completion date	5679
Registration date is before Oct 1st 2011	2
Intervention date = Completion date	34

The registration data for the service contained 93,411 cases, and the intervention and follow-up consultation data contained 92,978 cases, a difference of 433. When examining the 433 registration cases that were not included in the intervention and follow-up data I found that they were cases that did not have a registration date recorded. It is possible that these cases were instances where data had been erroneously recorded using PharmaBase and did not represent actual NMS provided. Therefore the 433 cases were excluded from analysis. In addition cases with an intervention withdrawal reason of 'remove erroneous patient registration' were also excluded as they didn't represent valid NMS registrations (4 cases).

7.2.2 Analysis

In order to investigate the uptake of the NMS and understand the problems patients experience and the interventions pharmacists make when providing the service, analysis of the data was conducted using the IBM SPSS statistics 20 software as follows.

7.2.2.1 Demographics

Before examining the uptake of the NMS and exploring what problems patients experience and the interventions pharmacists make during NMS consultations, it was important to describe the data including profiles of the

patients receiving the service, the rate of dropout from the service, the medicines registered for the NMS and the consultation methods used.

In order to understand the profile of patients receiving the NMS the data were analysed by patient rather than by medicine as some patients had more than one medicine registered for the service. To understand the split between genders and conditions, frequency counts with percentages were calculated for patients registered for the NMS. When exploring the average age of patients receiving the service, the median age was calculated rather than the mean as the age data were not normally distributed (determined visually from a histogram with a normal curve plotted).   The interquartile range was determined because it provides insight as to the spread of ages.

The dropout rate (the number of cases where the medicine was registered for the NMS but the patient left the service at either the intervention or follow-up stage) was calculated because if a patient leaves the service without receiving the intervention consultation, the pharmacy cannot claim payment for that service. In addition the dropout rate can provide an indication of whether the service is acceptable for patients, with a high dropout rate possibly indicating that patients do not like the service. The data set included withdrawal reasons for each registered medicine where the patient did not receive a consultation at either the intervention or follow-up stages of the NMS. Therefore in order to calculate the dropout rate, the frequencies of the different reasons for withdrawal from the service were combined and taken away from the number of cases at the previous stage.

Analysis of the medicines registered for the service involved frequency counts being performed for the generic drug data. The results were grouped by condition and also grouped by BNF category in order to understand which group of medicines were most frequently registered for the service for each condition. The frequency per 1000 medicines prescribed for condition was reported rather than the percentage because the high number of different medicines eligible for the service meant that some of the percentages were very small.

In order to understand how the service was conducted, the frequency of each consultation method (telephone or face to face in the pharmacy) was calculated.   The data are also presented as a percentage of medicines registered for the service and as a percentage of medicines for which the consultation method was recorded.

7.2.2.2 Uptake of the NMS

The uptake of the NMS was explored by calculating the cumulative number of pharmacies providing at least one NMS per month from October 2011 to August 2012. The frequency of medicines registered for the service and the frequency of completed NMS were calculated for each month allowing the provision of the service over the first year after implementation to be understood. In addition the mean length of time between registration and completion of the NMS was determined in order to be able to compare it with the time frame set out in the service specification (21-45 days).

When calculating these figures, cases where registration was recorded as having happened before 1st October 2011 or after completion of the service were excluded as they represented errors in the data (Table 7.1). Therefore a total of 5681 cases (6%) were excluded from these calculations.

7.2.2.3 Matters identified with the patient

In order to understand the interventions pharmacists make when providing the service, it was first necessary to understand the problems identified by pharmacists in NMS consultations. This was done by analysing 11 variables listed earlier under 'matters identified with the patient'. These variables were split into concerns and adherence related problems. One variable was not included in analysis (patient 'not using medicine in line with directions') as it was not sufficiently different from the 'not using medicine as prescribed' variable (frequency of cases where the patient was recorded as not using medicine in line with directions = 574, frequency of cases where the patient was recorded as not using medicine in line with directions and not using medicine as prescribed = 561).

The intervention and follow-up consultation data were analysed by medicine rather than by patient as there were cases where patients were registered for the NMS with more than one medicine. In addition, whilst some of the potential problems experienced could be patient specific, there were also problems that could be medicine specific (such as experiencing side effects) so it was decided that it would be appropriate to analyse the consultation data by medicine.

Analysis of this data involved frequency counts with percentages or frequency per 1000 of medicines at intervention and follow-up. In order to determine whether there was a statistical difference between frequencies at intervention and follow-up, the proportions of medicines were tested for significance. The

standard error of the difference between the two proportions (SE) was established before confidence intervals were calculated. Differences were deemed as significant if 0 did not lie within the confidence interval, as 0 represents no significant difference. This method of testing for significance was also used to determine whether there was a significant difference between conditions.

7.2.2.4   Outcomes of the discussion with the patient

To understand the interventions pharmacists make when providing the service, the variables listed above under 'outcomes of the discussion with the patient' were divided into: information provided, agreed patient actions, actions taken by the pharmacist, and healthy living advice. As for the matters identified with the patient, the outcomes of the discussion with the patient were analysed by medicine rather than by patient. Variables classed as 'agreed patient actions' were not analysed as they did not represent interventions made by pharmacists as part of the NMS. For the remaining variable frequency counts and percentages of medicines at intervention and follow-up were calculated. In addition, the frequency and proportion of medicines where the patient was provided with support in the form of advice, provision of information or referral to their prescriber with information was calculated and the frequency and proportion of medicines where the patient did not receive any advice, information or a referral to their prescriber was determined.

7.3 Results

After cleaning the data there were 92,973 cases to be analysed. There were records of NMS being conducted in a total of 1,674 pharmacies (approximately 75% of the English pharmacies in the chain).

7.3.1 Demographics

Of the 92,973 cases, 80,083 (86%) were completed and were claimable, and 14% (12,890) had been completed but were not claimable. The 92,973 cases translated to 88,656 different patients receiving the NMS as some patients were prescribed more than one new medicine at a time.

7.3.1.1 Rates of drop out from the service

Figure 7.1 shows the number of registered medicines that did not go on to receive both NMS consultations. Almost three quarters (72%) of medicines

registered received both the intervention and the follow-up consultations. The proportion of medicines registered that did not lead to the patient receiving the intervention was 14%, and 17% of medicines where the patient had received the intervention did not lead to the patient receiving the follow-up stage.
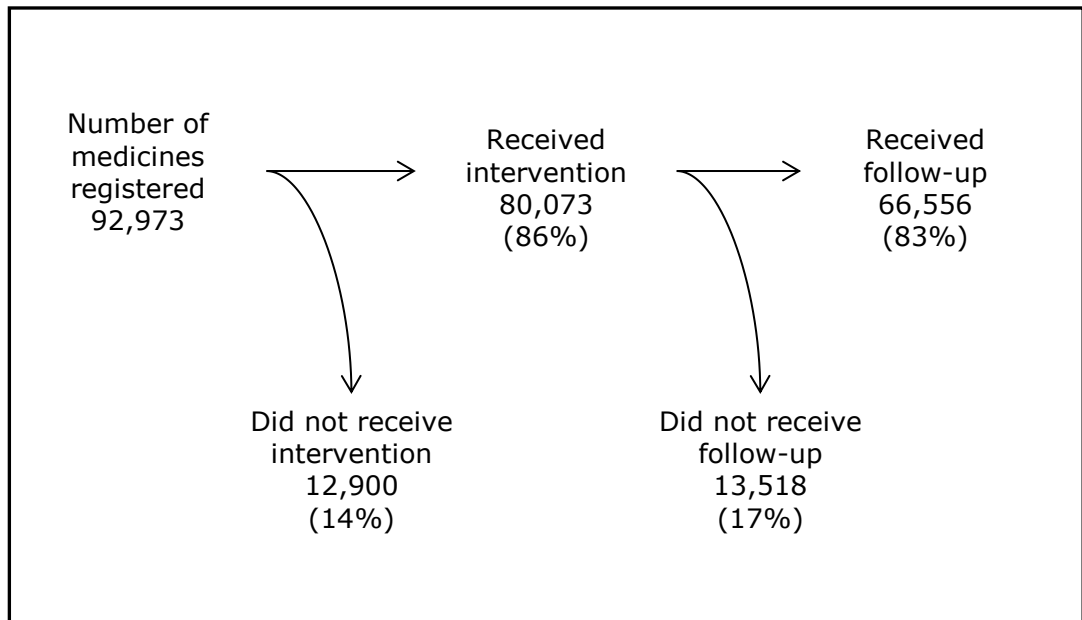
Figure 7.1: Diagram showing the number of medicines that received each stage of the NMS and those that did not.

Medicines prescribed for asthma/COPD were associated with a significantly higher proportion of patients dropping out of the service than patients with other conditions at both intervention and follow-up (95% CI of difference at intervention: 0.0316, 0.0423, at follow-up: 0.0249, 0.0373, Table 7.2). After excluding erroneous patient registrations, there were 5 possible options available to pharmacists when recording reasons for patients leaving the service:

- Prescriber has stopped the new medicine
- Patient has withdrawn consent to receive the service
- Patient has withdrawn consent for information sharing
- Patient could not be contacted
- Other

The most common reason for patients dropping out at either intervention or follow-up stages was that the pharmacy was unable to contact the patient

(n=9,342 (10%) at the intervention stage, n=10,435 (13%) at the follow-up stage). The second most common reason that patients dropped out of the NMS was that the prescriber had stopped the new medicine (n=2,264 (2%) at the intervention stage, n=2,028 (3%) at the follow-up stage).

Table 7.2: Drop out rates at intervention and follow-up stages for each condition (n=92,973)

Condition	Number of registrations	Frequency of drop out at intervention stage (%)		Frequency of drop out at follow-up stage (%)	
Hypertension	52,528	7,023	(13%)	7,486	(16%)
Asthma/COPD	23,755	3,950	(17%)	3,807	(19%)
Type 2 diabetes	9,517	1,146	(12%)	1,268	(15%)
Antiplatelet/anticoagulant	7,173	781	(11%)	957	(15%)

7.3.1.2 NMS initiation

The majority of NMS were initiated by pharmacy staff (99.7%) with just 0.3% of cases entering the service after a referral from a GP or practice nurse. Further analysis of prescriber referrals into the NMS showed that the 192 GP referrals were spread out over 172 pharmacies and 89 different PCTs and that practice nurse referrals fitted the same pattern. This suggests widespread low prescriber engagement with the NMS.

7.3.1.3 Profiles of patients receiving the NMS

Of the 88,656 patients who received the NMS, 55% were female (n=48,548) and 45% were male (n=40,108). The most common condition for which the NMS was provided was hypertension (57%), followed by asthma/COPD (26%), type 2 diabetes (10%) and lastly antiplatelet/anticoagulant therapy (8%). The median age of patients receiving the NMS was 64 years (minimum 0 years, maximum 108 years) with an interquartile range of 52-74 years.

7.3.1.4 Medicines registered for the NMS

Of the four conditions hypertension has the largest number of medicines eligible for the NMS (66 of the 119 medicines listed in the service specification).[85] The most commonly prescribed new medicine for hypertension was amlodipine (26%) followed by ramipril (18%) and losartan (10%) (see Table 7.3). When grouped by BNF category, calcium-channel

blockers were most commonly registered for the NMS followed by angiotensin-converting enzyme inhibitors (Table 7.3)

Table 7.3: The frequency of the most common hypertension medicines registered for the NMS by BNF catagory (n=52,528)

BNF category / Drug name	Frequency	Frequency per 1000 Medicines Prescribed for Condition
Thiazides and related diuretics	**6325**	**120**
Bendroflumethiazide	3106	59
Indapamide	3086	59
Chlortalidone	116	2
Other	17	<1
Beta-adrenoceptor blocking drugs	**6092**	**116**
Bisoprolol	4137	79
Atenolol	1011	19
Propranolol	560	11
Other	384	7
Vasodilator antihypertensive drugs	**48**	**1**
Centrally acting antihypertensive drugs	**180**	**3**
Moxonidine	114	2
Other	66	1
Alpha-adrenoceptor blocking drugs	**1928**	**37**
Doxazosin	1891	36
Other	37	1
Angiotensin-converting enzyme inhibitors	**13971**	**266**
Ramipril	9578	182
Lisinopril	3171	60
Perindopril	925	18
Other	297	6
Angiotensin-II receptor antagonist	**7161**	**136**
Losartan	5167	98
Candesartan	1442	27
Irbesartan	232	4
Other	320	6
Renin inhibitors	**9**	**<1**
Aliskiren	9	<1
Calcium-channel blockers	**16814**	**320**
Amlodipine	13487	257
Felodipine	1264	24
Lercanidipine	739	14
Other	1324	25

The second largest group of medicines eligible for the NMS belonged to the asthma/COPD condition group. The most commonly prescribed medicine for asthma/COPD was salbutamol (35%) followed by beclometasone (21%) and tiotropium (10%). When the medicines are grouped by BNF category bronchodilators are most commonly prescribed, followed by corticosteroids and other medicines (see Table 7.5). This reflects the treatment steps for asthma and COPD outlined in the guidance for asthma treatment published by the British Thoracic Society and Scottish Intercollegiate Guidelines Network.[129]

Table 7.4: Frequency of common asthma/COPD medicines registered for the NMS by BNF chapter (n=23,749).

BNF Category	Drug Name	Frequency	Frequency per 1000 Medicines Prescribed for Condition
Bronchodilators		**12,548**	**528**
	Salbutamol	8,313	350
	Tiotropium	2,468	104
	Salmeterol	757	32
	Other	1,010	43
Corticosteroids		**10,474**	**441**
	Beclometasone	5,016	211
	Fluticasone/Salmeterol	2,630	111
	Budesonide/Formoterol	1,561	66
	Other	1,267	53
Cromoglycate and related therapy and leukotriene receptor antagonists and phophodiesterase type 4 inhibitors		**727**	**31**
	Montelukast	702	30
	Zafirlukast	17	1
	Other	8	<1

Type 2 diabetes had the third largest group of medicines eligible for the NMS. Metformin was the most frequently prescribed medicine (49%), with gliclazide (19%) and sitagliptin (14%) coming second and third respectively (Table 7.5). When grouped by BNF category Biguanides were the most commonly registered medicines for type 2 diabetes. Insulins were the least commonly registered medicines as expected due to them being further down the treatment pathway for type 2 diabetes than oral antidiabetic medicines (as recommended by the National Institute for Health and Care Excellence (NICE)).[133]

Table 7.5: The frequency of the most common type 2 diabetes medicines registered for the NMS by BNF category (n=9,510).

BNF category	Drug name	Frequency	Frequency per 1000 Medicines Prescribed for Condition
Insulins		**385**	**40**
	Lantus	76	8
	Humulin	75	8
	NovoMix	63	7
	Other	171	18
Sulphonylureas		**2,058**	**216**
	Gliclazide	1,828	192
	Glimepiride	186	20
	Glipizide	20	2
	Other	24	3
Biguanides		**4,653**	**489**
	Metformin	4,653	489
Other antidiabetic drugs		**2,414**	**254**
	Sitagliptin	1,374	144
	Pioglitazone	323	34
	Saxagliptin	273	29
	Other	444	47

The smallest group of medicines eligible for the NMS are anti-platelets and anti-coagulants. Aspirin was the most commonly prescribed medicine for the antiplatelet/anticoagulant category (35%). Warfarin was the next most frequent medicine (31%) with clopidogrel third (30%). When grouped by BNF category antiplatelet drugs were much more commonly registered for the NMS than oral anticoagulant drugs (Table 7.6).

Table 7.6: The frequency of the most common antiplatelet/anticoagulant medicines registered for the NMS by BNF category (n=7,186).

BNF category Drug name	Frequency	Frequency per 1000 medicines prescribed for condition
Antiplatelet drugs	**4864**	**676.87**
Aspirin	2500	347.90
Clopidogrel	2143	298.22
Dipyridamole	161	22.40
Other	60	8.35
Oral anticoagulants	**2322**	**323.13**
Warfarin	2195	305.46
Dabigatran	81	11.27
Rivaroxaban	29	4.04
Other	17	2.37

A complete table of all medicines registered for the NMS is included in appendix 6.

7.3.1.5 Consultation Methods

A majority of records (48,721) did not include the consultation method (Table 7.7) as recording the method was not mandatory for the full sample period.[92] Where this data was recorded, it could be seen that more consultations were conducted by telephone (72% of intervention consultations and 75% of follow-up consultations) than in face-to-face consultations in the pharmacy (28% of intervention consultations and 25% of follow-up consultations) (Table 7.7). These data can give an indication that telephone consultations may be the consultation method most commonly used, supported by the intervention and follow-up data being very similar, but care must be taken when applying the results as so many records did not include these data.

Table 7.7: The frequency of method of consultation being recorded (n=80,074).

Consultation Method	Intervention		Follow-up	
	Frequency	Percentage of interventions (%)	Frequency	Percentage of follow-ups (%)
Not recorded	48,721	61	40,972	62
Face-to-face in the pharmacy	8,628	11	6,299	9
Telephone	22,725	28	19,285	29

7.3.2 Uptake of the NMS

The cumulative number of pharmacies that have provided at least one NMS by month (October 2011 to August 2012) indicates the fast initial uptake of the NMS (Figure 7.2). The number of pharmacies that registered at least one NMS for each month has some fluctuation with lower numbers of pharmacies recording NMS in April and August, which could be due to those months being popular holiday times, however the overall number of pharmacies recording at least one NMS using PharmaBase per month remains generally steady (Figure 7.2).
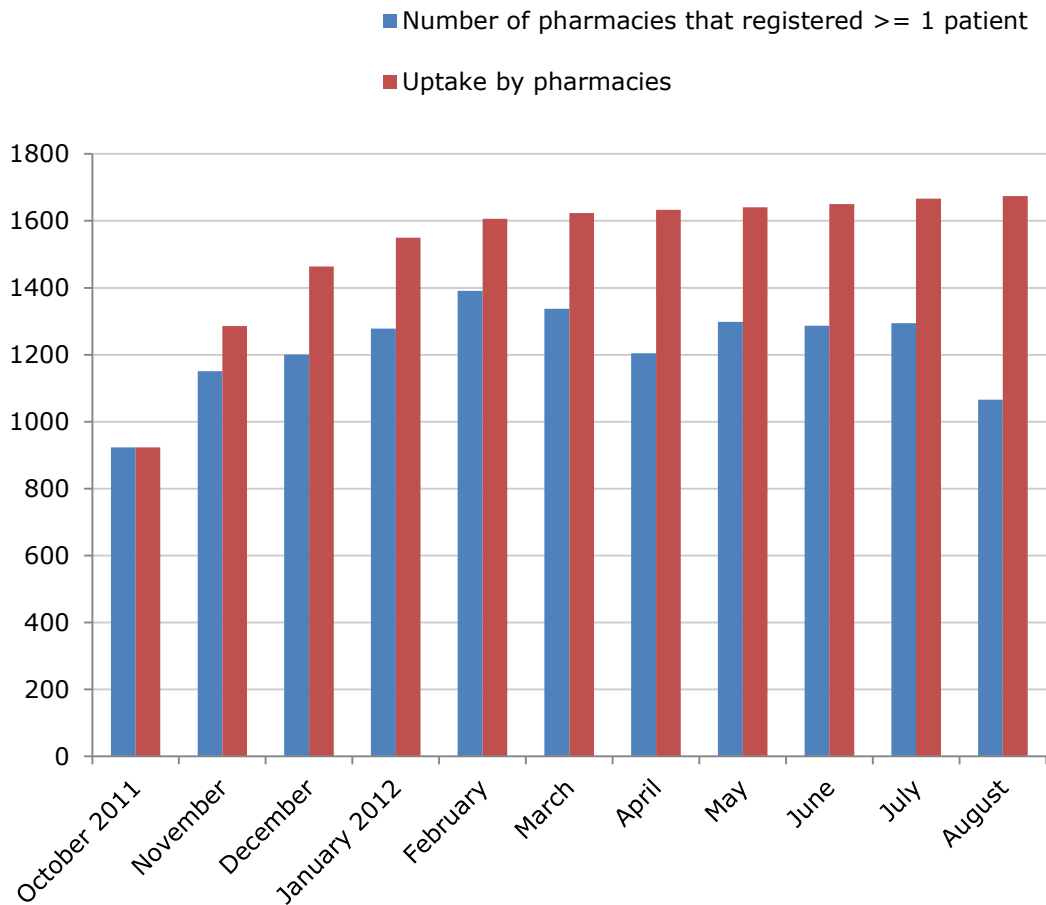
Figure 7.2: The rate of uptake of the NMS by pharmacies

The number of medicines registered for the NMS steadily increased in the first few months of the service, reaching a peak in February 2012 (Figure 7.3) which could be due to the requirement of pharmacies completing 6 NMS before March 1st 2012 to be eligible for a one off implementation payment. Apart from the first month where the number of completed NMS was low due to the NMS taking up to 5 weeks to complete, the frequency of completed services each month stays relatively consistent (Figure 7.3).

Figure 7.3: The frequency of NMS registrations and NMS completions by month.

The mean length of time between registration and completion of the NMS was 27.3 days (95% CI 27.2-27.5 days). The maximum length of time recorded was 339 days. The mean length of time between registration and completion lies within the range set out in the NMS specification of 21-45 days, although 47,946 (52%) cases fell outside this range (less than 21 days=39081 cases, more than 45 days=8865 cases).

7.3.3 Matters identified with the patient

The dataset shows that pharmacists identified a total of 30,462 problems at the intervention stage of the NMS with 10.1% of medicines having at least one problem recorded (medicines receiving intervention=80,074). At the follow-up consultation 13,144 problems were identified with 14.2% of medicines having a problem recorded (medicines receiving follow-up=66,556)

(Table 7.8). The problems identified include concerns raised by patients about their medicines and adherence related problems.

At both NMS stages the most common concern identified was that the patient was unsure whether the medicine was working (Tables 7.8 and 7.9). At intervention the second most common concern raised was that the patient wanted more information about the medicine. This concern was the third most common at follow-up suggesting that patients want information about their medicines when they first start taking them and this need decreases over time.

Table 7.8: Problems identified in NMS intervention consultations (n=80,074).

Type of problem	Problem Identified	Frequency at Intervention	Frequency at intervention per 1000 medicines
Concerns	Need for more information about the medicine	3,162	40
	Negative feelings about the medicine	2,775	35
	Uncertainty on whether the medicine is working	4,232	53
	Concern about remembering to take the medicine	507	6
Adherence issues	Experiencing side effects	12,117	151
	Not using the medicine as prescribed	4,525	57
	Not having started using the medicine	757	10
	Missing a dose in the last 7 days	995	12
	Difficulty using the medicine due to its form	329	4
Other	Prescriber has stopped the medicine	489	6

Table 7.9: Problems identified in NMS follow-up consultations (n=66,556)

Type of problem	Problem Identified	Frequency at Follow-up	Frequency at follow-up per 1000 medicines
Concerns	Need for more information about the medicine	773	12
	Negative feelings about the medicine	1,022	15
	Uncertainty on whether the medicine is working	1,544	23
	Concern about remembering to take the medicine	197	3
Adherence issues	Experiencing side effects	5,305	80
	Not using the medicine as prescribed	2,651	40
	Not having started using the medicine	112	2
	Missing a dose in the last 7 days	443	7
	Difficulty using the medicine due to its form	126	2
Other	Prescriber has stopped the medicine	683	10

Whilst the majority of medicines did not have problems associated with them recorded (90% at intervention and 86% at follow-up), some patients experienced more than one problem per medicine (Table 7.10). The number of cases where no problems with medicines were recorded is greater than the number of cases where the patient was recorded as using their medicine as prescribed at both stages of the NMS.

Table 7.10: **The number of problems identified per medicine at intervention and follow-up (intervention: 80,074 medicines, follow-up: 66,556 medicines).**

Number of problems identified per medicine	Intervention		Follow-up	
	Frequency	Frequency of problems per 1000	Frequency	Frequency of problems per 1000
0	72025	899	57135	858
1	1461	18	7084	106
2	4553	57	1794	27
3	1560	19	418	6
4	357	4	99	1
5	89	1	19	<1
6	22	<1	5	<1
7	6	<1	2	<1
9	1	<1	0	<1

At the intervention stage there were 65015 cases where patients were reported as using their medicines as prescribed (81.2% of medicines at intervention). At the follow-up stage this figure was 48638 cases (73.1% of medicines at follow-up). However this does not mean that patients reported as using their medicines as prescribed did not experience problems; 11,955 concerns were identified at the intervention stage, and 2724 problems identified at the follow-up stage, in patients recorded as taking their medicines as prescribed (Table 7.11).

Table 7.11: Concerns identified for patients reported as taking their medicine as prescribed (intervention: 65,015, follow-up: 48,638).

Concerns Identified	Frequency at Intervention	Frequency per 1000 medicines	Frequency at Follow-up	Frequency per 1000 medicines
Need for more information about the medicine	6,214	78	648	10
Negative feelings about the medicine	1,778	22	674	10
Uncertainty on whether the medicine is working	3,597	45	1,263	19
Concern about remembering to take the medicine	366	5	139	2
Total	11,955		2,724	

7.3.3.1   Side Effects

The most common problem identified during NMS consultations was that the patient was experiencing side effects of the new medicine (n=12,117 (15%) at intervention, n=5,305 (8%) at follow-up) (Table 7.8 and Table 7.9). A higher percentage of medicines for type 2 diabetes or hypertension were associated with side effects being reported than antiplatelets/anticoagulants or medicines for asthma/COPD (diabetes: 19%, hypertension: 19%, asthma/COPD: 7% and antiplatelets/anticoagulants: 10%) (Table 7.12). The proportion of medicines leading to patients experiencing side effects was smaller at the follow-up consultation compared to at the intervention consultation (Table 7.12).

Table 7.12: The frequency of medicines associated with side effects and the proportion of medicines for each condition that were associated with this problem (n=92,974).

Condition	Intervention		Follow-up	
	Frequency	Percentage of medicines within condition (%)	Frequency	Percentage of medicines within condition (%)
Antiplatelet/anticoagulant	638	10	302	6
Asthma/COPD	1,423	7	591	4
Type 2 diabetes	1,620	19	686	10
Hypertension	8,436	19	3,726	10
Total	12,117	15	5,305	8

The reduction in the proportion of medicines reported as causing side effects between the intervention and follow-up consultations is significant (95% CI of the difference between proportions: 0.0837,0.0911). This reduction is also significant for each of the four therapeutic areas as determined by the CIs (antiplatelet/anticoagulant: 0.0026, 0.0042, asthma/COPD: 0.0077,0.0101, type 2 diabetes: 0.0006,0.0112, hypertension: 0.0466,0.0521).

7.3.3.2 Patient not using the new medicine as prescribed

At the intervention consultation 4,525 (6%) medicines were reported as not being used by patients as prescribed (Table 7.13). This figure dropped to 2,651 (4%) at the follow-up consultation. The proportion of medicines where patients were affected by this problem were similar for hypertension, type 2 diabetes and antiplatelet/anticoagulant therapy (5.0%, 4.8% and 4.1% at intervention, 3.8%, 2.9% and 2.4% at follow-up respectively). A greater proportion of asthma/COPD patients were reported as not using their new medicines as prescribed compared to the other conditions at both the intervention and follow-up stages (95% CI of difference between proportions at intervention: 0.0285-0.0368, CI of difference at follow-up: 0.0180,0.0256) (Table 7.13).

Table 7.13: The frequency of medicines where the patient is not using the medicine as prescribed and the proportion of medicines in each condition affected by this problem (n=92,974).

Condition	Intervention		Follow-up	
	Frequency	Percentage of patients with condition (%)	Frequency	Percentage of patients with condition (%)
Antiplatelet/anticoagulant	264	4	31	2
Asthma/COPD	1,606	8	878	5
Type 2 Diabetes	401	5	208	3
Hypertension	2,254	5	1,434	4
Total	4,525	6	2,651	4

The reduction in the proportion of patients recorded as not using their medicines as prescribed between the intervention and follow-up consultations is significant as indicated by the 95% CI of the difference between the proportions: 0.0145,0.0189.

7.3.3.3   Patient has not started using the new medicine

Pharmacists reported that patients had not started to take the new medicine at the intervention consultation in less than 1% of cases and this number dropped further at the follow-up stage (Table 7.14). In a significantly greater proportion of asthma/COPD cases, patients were recorded as not having started the new medicine at both the intervention and follow-up consultations compared with the other therapeutic groups (95% CI of difference between proportions at intervention: 0.0019,0.0051, CI of difference at follow-up: 0.0011,0.0030).

Table 7.14: The frequency of medicines where the patient had not started taking it at the time of the consultation, and the proportion of medicines in each condition that were associated with patients experiencing this problem (n=92,974).

Condition	Intervention		Follow-up	
	Frequency	Percentage of patients with condition (%)	Frequency	Percentage of patients with condition (%)
Antiplatelet/anticoagulant	45	0.7	8	0.2
Asthma/COPD	277	1.4	52	0.3
Type 2 Diabetes	64	0.8	5	0.1
Hypertension	371	0.8	47	0.1
Total	757	0.9	112	0.2

Although the numbers of patients who had not started the new medicine at either consultation were small, the reduction in the proportion of patients reported as not having started using the new medicines between the intervention and follow-up stages is statistically significant as indicated by the 95% CI of the difference between proportions: 0.0070,0.0085.

7.3.3.4 Patient has missed a dose in the last 7 days

The number of patients recorded as having missed a dose in the 7 days prior to the consultation was low with just 1.2% of medicines at intervention leading to patients being recorded as having missed a dose (Table 7.15). At the follow-up consultation this figure was lower, with 0.7% of medicines leading to pharmacists reporting patients as having missed a dose.

Table 7.15: The frequency of a dose being missed in the 7 days prior to the consultation, and the proportion of medicines in each condition leading to patients experiencing this problem (n=92,974).

Condition	Intervention		Follow-up	
	Frequency	Percentage of patients with condition (%)	Frequency	Percentage of patients with condition (%)
Antiplatelet/anticoagulant	61	1.0	34	0.6
Asthma/COPD	338	1.7	138	0.9
Type 2 Diabetes	82	1.0	44	0.6
Hypertension	514	1.1	227	0.6
Total	995	1.2	443	0.7

The difference between the proportion of cases where the patient has missed a dose in the last 7 days at intervention and follow-up is statistically significant (95% CI of the difference between the proportion of cases at intervention and follow-up: 0.0048,0.0068). The proportion of medicines where patients had missed a dose in the 7 days prior to the follow-up consultation was found to be statistically less than the proportion at intervention for each condition (95% CI of the difference in proportions: hypertension: 0.0040,0.0066, asthma/COPD: 0.0061,0.0107, type 2 diabetes: 0.0008,0.0064, and antiplatelets/anticoagulants: 0.0001,0.0065).

7.3.3.5 Patient having difficulty due to form

The number of medicines that lead to pharmacists recording that patients were having problems with their new medicine due to the form of the medicine was low just 0.41% of medicines at intervention being reported as causing patients difficulty (Table 7.16). At the follow-up consultation this value was 0.19% of medicines. Despite the low numbers, the difference in the number of patients experiencing difficulty due to form at intervention and follow-up was found to be significant (95% CI of the difference between the proportion of medicines at intervention and follow-up: 0.0017,0.0028).

Table 7.16: **The frequency of medicines leading to patients experiencing difficulty due to the medicines form, and the proportion of each condition affected by this problem (n=92,973).**

Condition	Intervention		Follow-up	
	Frequency	Percentage of patients with condition (%)	Frequency	Percentage of patients with condition (%)
Antiplatelet/anticoagulant	15	0.2	11	0.2
Asthma/COPD	260	1.3	93	0.6
Type 2 Diabetes	14	0.2	10	0.1
Hypertension	40	0.1	12	<0.1
Total	329	0.4	126	0.2

When analysed by condition, asthma/COPD medicines lead to significantly more patients experiencing difficult due to form than medicines used for the other conditions (95% CI of the difference in proportion of asthma/COPD medicines compared to the other conditions at intervention: 0.0104, 0.0136, at follow-up: 0.0035, 0.0059).

7.3.4 Outcomes of the discussion with the patient

67% of intervention records showed the pharmacist providing support to patients in the form of advice, provision of information or referral to their prescriber. The data showed that support was not provided in either consultation in 25% of records.

More advice was given and referrals made in intervention consultations compared with follow-up consultations (Table 7.17). This was expected as in follow-up consultations patients have already had the opportunity to ask questions and receive advice in the intervention consultation. The most frequently given type of advice given was information regarding the purpose of the new medicine (at intervention n=20,983 (26%), at follow-up n=7,469 (11%)), with information about how to take it also being commonly provided (at intervention n=18,215 (23%), at follow-up n=6,406 (10%)) (Table 7.17).

Table 7.17: Information provided to patients during NMS consultations (n=92,974)

Information provided	Intervention		Follow-up	
	Frequency	Percentage of Interventions (%)	Frequency	Percentage of Follow-ups (%)
How to manage or minimise side effects	10,106	13	4,567	7
Interactions with other medicines	6,292	8	2,934	4
Why am I using the medicine? What is it for?	20,983	26	7,469	11
How to use the medicine	18,215	23	6,406	10
Correct dose of the medicine	16,465	21	7,135	11
Effect of the medicine on the body, how it works	15,799	20	5,749	9
Why should I take the medicine?	14,676	18	5,807	9
Timing of the dose	17,835	22	7,010	11
Interpretation of side effect information	12,407	15	5,294	8

At intervention a greater proportion of patients taking antiplatelet/anticoagulants were provided with information regarding interactions with other medicines than patients with the other 3 conditions (antiplatelet/anticoagulant=15%, asthma/COPD=4%, type 2 diabetes=6%, hypertension=7%, 95% confidence interval of the difference between proportions: 0.0811, 0.0980). This may reflect the high number of medicines

that can affect international normalised ratio (INR) levels (a measure of blood coagulation used in patients taking anticoagulants).

A significantly higher proportion of patients with asthma/COPD were provided with information regarding how to use the medicine than patients prescribed medicines for other conditions (asthma/COPD=27%, antiplatelet/anticoagulant=20%, type 2 diabetes=20%, hypertension=16%, 95% CI of difference between proportions: 0.0890, 0.1013). This may reflect the need for asthma/COPD patients to receive inhaler technique advice, which patients with the other conditions do not require.

In addition a significantly lower proportion of patients with asthma/COPD were provided with information regarding the interpretation of side effect information (asthma/COPD=9%, antiplatelet/anticoagulant=15%, type 2 diabetes=15%, hypertension=15%, 95% CI of difference between proportions: 0.0525, 0.0615). This fits with the finding that the proportion of asthma/COPD patients affected by side effects was less than the other conditions (Table 7.12).

The records show intervention consultations triggered referrals to prescribers in 4.7% of cases (Table 7.18). This figure was lower in follow-up consultations (3.6%), perhaps due to problems developing quickly after starting to take the medicine, therefore the problems may have been spotted and addressed in intervention consultations. The number of yellow card reports being submitted to the MHRA was low (0.06% of intervention cases and 0.05% of follow-up cases) relative to the high numbers of side effects reported. Guidance provided by the MHRA to health care professionals asks that all adverse drug reactions be reported for black triangle medicines (subject to additional monitoring), all adverse drug reactions in children, and all serious adverse drug reactions.[131] The relatively low numbers of yellow card reports could indicate that pharmacists are following the MHRA guidance as most of the medicines included in the NMS have well established side effect profiles which do not need reporting.

Table 7.18. Actions taken by pharmacists (n=92,974).

Actions taken by pharmacist	Intervention		Follow-up	
	Frequency	Percentage of Interventions (%)	Frequency	Percentage of Follow-ups (%)
Reminder strategies to support use of medicine	9385	12	5857	9
Change to timing of doses to support adherence	2204	3	825	1
Referral	3760	5	2402	4
Yellow card report submitted to MHRA	52	<1	33	<1
Reminder chart/MAR chart provided	53	<1	0	<1

Pharmacists also had the opportunity to provide Healthy Living Advice (HLA) to patients in intervention and follow-up consultations (Table 7.19). The records show that the most common HLA provided in NMS consultations was advice regarding diet and nutrition (n=18,417 (23%) at intervention; n=11,075 (17%) at follow-up), followed by physical activity (n=13,030 (16%) at intervention; n=7,860 (12%) at follow-up). Sexual health advice was the least common type of HLA provided in NMS consultations, which could be explained by the conditions eligible for the service having little effect on sexual health. At intervention pharmacists provided HLA in 28% of cases and 21% of cases received HLA at the follow-up consultation.

Table 7.19. Healthy living advice provided to patients during NMS consultations (n=92,974).

Health Living Advice Provided	Intervention		Follow-up	
	Frequency	Percentage of Interventions (%)	Frequency	Percentage of Follow-ups (%)
Diet and nutrition	18,417	23	11,075	17
Smoking	7,013	9	3,461	5
Physical activity	13,030	16	7,860	12
Alcohol	5,449	7	2,575	4
Weight loss	4,119	5	2,453	4
Sexual health	168	<1	117	<1

Earlier we saw that some patients who were using their medicines as prescribed still experienced problems. I also found that pharmacists still provided information to patients who were not reported as experiencing problems with 44% of cases at intervention (n=31269) and 22% of cases at follow-up receiving at least on piece of advice. Advice regarding the purpose of the medicine was the most frequent type of advice provided (at intervention n=14,834 (21%); at follow-up n=6,030 (7%)) (Table 7.20).

Table 7.20: The frequencies of information provided and actions taken by pharmacists where the patient is not reported to be experiencing problems (at intervention n=71,770, at follow-up n=83555).

Information provided and action taken by pharmacists	Intervention		Follow-up	
	Frequency	Frequency per 1000 medicines	Frequency	Frequency per 1000 medicines
How to manage or minimise side effects	5,102	71	2,851	34
Interactions with other medicines	4,656	65	2,510	30
Why am I using the medicine? What is it for?	14,834	207	6,030	72
How to use the medicine	13,196	184	5,270	63
Correct dose of the medicine	12,148	169	602	7
Effect of the medicine on the body, how it works	10,449	146	4,421	53
Why should I take the medicine?	9,921	138	4,518	54
Timing of the dose	12,916	180	5,794	69
Interpretation of side effect information	6,882	96	3,394	41
Reminder strategies to support use of medicine	6,734	94	4,956	59
Change to timing of doses to support adherence	1,017	14	521	6
Referral	401	6	473	6
Yellow card report submitted to MHRA	8	<1	7	<1
Reminder chart/MAR chart provided	41	1	13	<1

The relatively high numbers of cases where the patient was recorded as not experiencing problems and information was provided may indicate that either patients still want information about their medicines despite not experiencing problems, or pharmacists still see value in providing information to patients who are not experiencing problems. In 6% of cases at both intervention and follow-up pharmacists referred patients to their prescribers, and at both consultations there were cases where it was reported that the pharmacist had submitted a yellow card report to the MHRA (at intervention n=8, at follow-up n=7) (Table 7.20). This suggests that in some cases the pharmacist identified problems requiring a referral or a yellow card report but did not record the problem using PharmaBase. It is possible that the patients were experiencing problems not covered by the options available on PharmaBase, or that pharmacists omitted the problems when recording the consultations on PharmaBase.

7.4   Discussion

This study found that the dropout rate of medicines registered for the NMS was less than 20% at both intervention and follow-up. The results show low levels of GP and practice nurse engagement with the service as more than 99% of NMS were initiated by pharmacies. Where reported, the most commonly recorded consultation method was by telephone at both consultations. When examining the uptake and provision of the NMS, it was found that the initial uptake of the service happened rapidly with the frequency of completed NMS per month quickly becoming consistent. At intervention at least one problem was recorded for 10% of medicines (14% at follow-up) with the most common problem reported being the patient experiencing side effects. In the majority of cases it was reported that the patient received support from the pharmacist in the form of advice, provision of information, or referral to their prescriber. Pharmacists provided healthy living advice in 28% of cases at intervention and 21% of cases at follow-up. It was also found that pharmacists provided support to patients who were not recorded as experiencing problems which could indicate omissions in recording the consultation.

When comparing the results of this study to an evaluation of the complete national PharmaBase (now called PharmOutcomes) NMS data the results are similar.[92] This study found a very similar split in gender (female: 54.8%, male: 45.2%) to that of the national PharmaBase evaluation (female: 53.1%,

male: 46.9%). The percentage of NMS recruited by the pharmacy rather than by GPs or practice nurses were also very similar (this study: 99.7%, national data: 99.6%), and both studies found that where the consultation method was recorded approximately 70% of consultations were conducted by telephone. The split of cases between the four conditions were also very similar between the two studies (this study: hypertension=56%, asthma/COPD=26%, type 2 diabetes=10%, antiplatelet/anticoagulant=8%; PharmaBase evaluation: hypertension=54%, asthma/COPD=26%, type 2 diabetes=11, antiplatelet/anticoagulant=8%). This suggests that the data in this study is representative of the data collected nationally despite being collected from just one pharmacy chain.

The results of this study found that the uptake of the NMS by pharmacies happened rapidly in the first few months of the service before reaching a steady number of NMS completed each month. The study also found that after the initial few months the number of pharmacies recording at least one NMS per month remained relatively steady.   This is supported by national NHS Prescription Services data which shows that the uptake of the service happened very quickly before reaching a steady number of NMS conducted and number of pharmacies claiming for at least one completed NMS per month.[92]

The rapid uptake of the NMS is in contrast with the more gradual uptake of MURs in 2005. The national evaluation of the 2005 pharmacy contract reported that in the first year (2005-6) just 38% of pharmacies delivered the MUR service[7] whereas this study found that approximately 75% of the pharmacies in the chain provided the NMS between October 2011 and August 2012 as recorded using PharmaBase. The actual percentage of pharmacies in the chain providing the NMS may be higher than this figure as using PharmaBase was not compulsory (although encouraged) therefore some pharmacies may have been providing the service but not using PharmaBase to record them. However one must be cautious when comparing these two figures as there is evidence to suggest that pharmacy chains have greater uptake of services compared to the national pharmacy sector[5,7] and therefore the results from this study are likely to be higher than the national rate of uptake of the NMS.

This study found that three quarters of pharmacies within the sampled chain had used PharmaBase to record NMS consultations. Whilst the proportion of pharmacies in England that used PharmaBase to record NMS consultations

has not been published, the national evaluation reported that NMS recorded using PharmaBase represented 43% of all NMS claimed for by pharmacies. This could suggest that uptake of PharmaBase by the large multiple sampled in this study was greater than the national uptake. It is likely that the greater proportion of pharmacies using PharmaBase in this study is due to management within the company encouraging its use.

The results of this study found that 15% of patients were experiencing side effects from their medicine at intervention and 7% of patients reported experiencing them at follow-up. These figures seem to be much lower than expected as other studies have found that between 33-61% of patients experience side effects.[16-18] This could reflect omissions in the information recorded on PharmaBase by pharmacists or the lower incidence of side effects found could be due to patients not reporting them during the NMS consultations, or the side effects may not have appeared within the NMS timeframe (although this is less likely).

This study found very low rates of instances where a patient had missed a dose in the 7 days prior to the consultation (<2% of patients) and the number of medicines that were not being taken as prescribed (<5% of medicines) which are indicators of non-adherence. There has been much research conducted examining the levels of non-adherence for long term conditions and it is widely accepted that the proportion of medicines prescribed for long term conditions not being taken as prescribed is much higher than the results of this study would suggest (30-60% of medicines).[12,22] In addition the study conducted by Clifford that the NMS is based on reported that 10 days after the intervention 30% of patients were non-adherent and 4 weeks after the intervention 25% of patients were still non-adherent.[80,81] This difference may be in part due to patients being less willing to report non-adherence to their regular pharmacists during the NMS consultations than study participants were to pharmacists they did not know in the Clifford study.

There are several possible reasons for the lower than expected level of non-adherence found by this study. One reason is that the data is reliant on the patient reporting the problems they have experienced to the pharmacist during the NMS consultation. They may be unwilling to admit to having missing doses of their new medicine to the pharmacist and there is much evidence that self-reported measures over-estimate adherence.[33] Despite there being validated self-reported adherence measures available, the interview schedule for the NMS consultations was not designed to measure

adherence, but instead to highlight any problems the patient may be having with their new medicine. This means that the data recorded by pharmacists can be used to give an indication of the number of patients who experience problems taking their new medicines, but cannot be used to calculate adherence rates. The study conducted by Clifford used a validated adherence measure to calculate rates of non-adherence which may explain why the PharmaBase data appears to be so different.[41]

A greater proportion of patients with asthma/COPD experienced difficultly taking their medicine due to its form than patients with other conditions (at intervention: asthma/COPD=1.3%, antiplatelet/anticoagulant=0.2%, type 2 diabetes=0.2%, hypertension=0.1%). I would suggest that this may be due to the high proportion of asthma/COPD medicines included in the NMS that are in inhaler form. Inhalers require patients to develop good inhaler technique skills in a way that oral forms of medicine do not. This is supported by the significantly higher proportion of patients with asthma/COPD who were provided with information regarding how to use their medicines compared to other conditions (asthma/COPD=27%, antiplatelet/anticoagulant=20%, type 2 diabetes=20%, hypertension=16%).

This study indicates that for patients receiving the NMS there is a significant reduction in problems reported at the follow-up stage of the service compared with the intervention stage. It is not possible to definitively say if this reduction was a result of patients receiving the NMS as there are other factors that may have contributed to the reduction. However it is possible that the information provided and actions taken by pharmacists during the service played a part in the reduction of adherence related issues.

This study found that although the frequency of advice provided in follow-up consultations was less than at intervention consultations, pharmacists still provided information regarding how to use it in 1 in every ten follow-up consultations. This could be interpreted as 10% of patients still being unclear about how to take their medicine after the first two stages of the NMS; however the results show that just 1% of patients were recorded as needing more information about their medicine at follow-up. Therefore, in this study, the advice provided by pharmacists in NMS consultations does not necessarily indicate patient demand for information.

The results show that pharmacists did not only provide support to patients who were reported as experiencing problems, but also provided advice and

support to patients who were not reported as experiencing problems with their medicines. It may be that patients still want information about their medicines despite not experiencing problems, or pharmacists still see value in providing information to patients who are not experiencing problems. It would suggest that whilst the stated aims of the service are to improve adherence and reduce waste, one role of the NMS may be the provision of reassurance to patients who have concerns about their medical conditions and the new medicines prescribed to them. The idea that part of the role of a pharmacist is to provide reassurance to patients is not a new one; there is evidence from studies examining other pharmacy services that patients see pharmacists as a source of reassurance about their medicines, especially where they do not want to consult their GP fearing a negative reaction to their concerns.[118,119]

Chapter 8: Thesis Discussion and Conclusions

8.1 Introduction to thesis discussion

This chapter will discuss the findings of the five studies conducted in order to understand the uptake of the NMS and the barriers and facilitators to the service's implementation. The implications of these findings for policy, practice and research will be explored and the strengths and limitations of each study described.

8.2 Thesis discussion

8.2.1 Uptake

The study investigating the views and opinions of community pharmacists and superintendent pharmacists prior to the implementation of the NMS found that participants expected the uptake of the new service to be quicker than the uptake of MURs had been. In the post-implementation study, both pharmacists and superintendent pharmacists reported that the uptake of the NMS had been as fast as expected. Likewise, the stakeholder interviews described the uptake of the NMS as good and faster than the uptake of MURs had been. The analysis of PharmaBase records supports this, showing rapid uptake of the NMS in the first few months of the service. In addition the data from the evaluation of national PharmaBase records also showed fast uptake of the service.[92]

A study by Bradley et al found that uptake of MURs was greater in multiple pharmacies (chains with 6 or more pharmacies) compared to independent pharmacies[6]. This trend has been confirmed by other studies[8] and several reasons suggested. The MUR service was introduced at the same time as major contractual changes for community pharmacy and this may have disproportionally affected independent pharmacies as they do not have company support for implementing changes[8]. In addition it has been suggested that company pressure in the form of targets facilitated provision of MURs in volumes[6,8] although this has been linked to MURs of questionable quality[119]. The findings from the studies with community pharmacists and superintendent pharmacists suggest that the uptake of the NMS may be greater in multiple pharmacies as the NMS was introduced at the same time as other contractual changes and companies are likely to encourage NMS provision by setting targets as they did with MURs. It is less likely that the NMS will experience the same problems with quality as MURs as the eligibility

144

criteria are much narrower (meaning there are far fewer opportunities to provide the NMS), and the consultations more focussed.

8.2.2 Facilitators to NMS implementation

The studies conducted identified many facilitators to NMS uptake and implementation. A key facilitator identified by both pharmacists and stakeholders was the experience of MUR implementation and provision. Stakeholders reported that they had aimed to avoid some of the barriers that had affected MUR implementation and uptake when they were developing the NMS. A key barrier they wanted to avoid was the accreditation process. As mentioned earlier in the thesis, the accreditation process for MURs took time and therefore hindered the uptake of the service.[6] By making the accreditation requirements for NMS simpler stakeholders hoped to avoid it inhibiting the uptake of the service. Pharmacists and superintendent pharmacists agreed that the self-accreditation process for the NMS had facilitated implementation and had allowed them to become accredited to provide the service from 1st October 2011, facilitating the uptake of the NMS.

Another barrier experienced during the implementation of MURs that stakeholders wanted to avoid was a lack of pharmacist confidence to provide the service.[6] They consciously chose conditions eligible for the NMS that they believed pharmacists would be confident about delivering, as well as conditions that would provide the best opportunity for evaluation of the service. This seems to have been successful as the pharmacists that participated in the pre- and post-implementation studies reported feeling confident that they could counsel patients with the eligible conditions. This confidence in providing the NMS may not stem from the conditions chosen but rather the purpose of the service. Pharmacists and superintendent pharmacists reported that counselling patients about new medicines was already part of the role of a pharmacist therefore offering the NMS was less of a departure from the existing role of a pharmacist than the introduction of MURs had been in 2005.

The confidence that the service was very much a formalisation of what pharmacists were already doing appears to have translated into positive pharmacist views of the service which was identified as a facilitator to NMS implementation. This supports the findings of other studies investigating the factors affecting service implementation that proposed that positive attitudes held by health care professionals towards a service can facilitate the introduction and uptake of the service.[109-111]

There was concern expressed by stakeholders that pharmacists had been under high levels of workload pressure before the introduction of the NMS and that pharmacists would see the new service as additional workload that they could do without, negatively affecting the uptake of the service. In addition, the pharmacists who participated in the pre-implementation study were concerned that they would be put under inappropriate pressure by management to provide the NMS, however, in the post-implementation study participants reported that the commercial and managerial pressure to provide the NMS had in fact facilitated the service's implementation.

Participants in the post-implementation study reported that the location of a pharmacy affected how many opportunities there were to provide the NMS, with pharmacies co-located with GP practices seeing a higher proportion of prescription items eligible for the service than high street pharmacies. This was supported by the findings of the stakeholder interviews and the results of MUR research which found that pharmacies co-located with GP practices conducted more MURs than pharmacies further away.[7] This finding does not match the findings from the study investigating the proportion of prescription items that are eligible to receive the NMS which did not find a significant difference in the proportion of NMS eligible items between pharmacies at different locations (<100m: 0.35%, 100-500m: 0.22%, >500m: 0.2%). However, it is important to note that the study was not powered to detect a difference in proportions for different locations, and a larger study powered to test whether location is associated with the number of eligible items may be able to detect a difference.

Another characteristic of the NMS identified as facilitating the provision of the service is the option to conduct the intervention and follow-up consultations by telephone. The results from the stakeholder interviews showed that people involved in the development of the NMS were keen that the majority of NMS consultations should be conducted face-to-face in the pharmacy, however prior to implementation community pharmacists and superintendent pharmacists predicted that patients would prefer telephone consultations as it would be more convenient for them. Post-implementation community pharmacists and superintendent pharmacists reported that most consultations are conducted by telephone, and this was supported by the data from service records which showed that where recorded more consultations were conducted by telephone than face to face in the pharmacy. Community pharmacists and superintendent pharmacists suggested that patients prefer

telephone consultations and that they are easier to fit in with dispensing workload within the pharmacy than face to face consultations. The ability to conduct telephone consultations may also improve access to the NMS for patients unable to visit their pharmacy in person.

Whist there are several advantages to conducting consultations by telephone, it is unclear whether they are as effective at meeting patients' needs as face-to-face consultations. For example, an important part of supporting patients with asthma or COPD is ensuring adequate inhaler technique, however it is not possible to check this during a telephone consultation. Therefore, whilst telephone consultations may be suitable for some patients, they may not meet the needs of other patients, and pharmacists should consider this when arranging the method of conducting NMS consultations. It may also be helpful for patients if pharmacists were to use telephone consultations to identify patients who would benefit from a face-to-face consultation (such as house-bound patients with COPD) and offer additional domiciliary visits or consultations in the pharmacy. However, the study on which the NMS is based conducted consultations by telephone, so whilst there is evidence that telephone consultations are effective at improving adherence; it is unknown whether face-to-face consultations are as effective.

8.2.3 Barriers to NMS implementation

The studies reported in this thesis have identified several barriers affecting the implementation of the NMS. The barrier that caused the greatest amount of concern was the payment structure. There is evidence from other pharmacy services that adequate remuneration is an important factor in the success or failure of service implementation.[6,115,116] The results from the pre-implementation study showed that the payment structure for the NMS had been identified as a potential barrier to the service's implementation before its introduction. The post-implementation study and the stakeholder interviews confirmed that the initial payment structure was not fit for purpose and a new payment structure was introduced in May 2012. Whilst some aspects for the structure changed, the new structure retained the theoretical assumption that 0.5% of all prescription items would be eligible for the NMS. The pharmacists, superintendent pharmacists and stakeholders suggested that this assumption was not accurate and that the actual opportunity rate was lower. This assumption was tested in the study investigating the proportion of prescriptions that are eligible for the service and found that the actual opportunity rate for prescription items eligible for the NMS was less than half

the theoretical value (actual opportunity rate=0.23% of prescription items, theoretical opportunity rate=0.5%). The implication of this is that pharmacies are unable to access the full funding available for the NMS. Therefore there is the potential to change the opportunity rate included in the payment structure to further facilitate NMS provision. Another option would be for additional conditions to be included in those eligible for the NMS, increasing the opportunity rate for NMS provision. Neither of these of these options would lead to overspend – something the Department of Health wishes to avoid (Chapter 3).

Before the introduction of the NMS pharmacy remuneration for advanced services had been on a per item basis, however the initial payment structure for the NMS was very different, with remuneration being linked to dispensing volume and thresholds to be met in order to trigger payments. There are several factors that may have led to this change; firstly, stakeholders reported that the Department of Health would like pharmacy to move away from simplistic per item of service payments and introduce remuneration for bundles of care, similar to general practice remuneration for services (Chapter 3). Secondly, there were concerns around the per item of service payments for MURs, including that pharmacists may have been selecting patients with fewer medicines for the service and avoiding potentially complex MURs in order to maximise profit (Chapter 3). The initial NMS payment structure was developed to encourage pharmacists to take every opportunity to provide the service in order to avoid this pitfall (Chapter3).

The recording requirements for the NMS were also identified as a barrier to service implementation. The pre-implementation study highlighted that pharmacists were uncertain as to the recording requirements prior to the introduction of the service which had the potential to hinder the uptake of the NMS. The post-implementation study and the stakeholder interviews also identified the recording requirements as a barrier to NMS provision. Participants reported that inputting data onto PharmaBase during consultations was not possible meaning that pharmacists had to record the data twice, doubling their NMS recording workload. In addition, because PharmaBase records were not clinical records and were not integrated into the PMR systems used in pharmacies, pharmacists reported that they were having to make clinical records of NMS consultations on their PMR systems as well which further increased the workload associated with the service.

Another barrier pharmacists and superintendent pharmacists reported was that there had been early teething issues with PharmaBase. Analysis of service records identified errors in the input of the data which potentially supports the idea that pharmacists had problems with recording NMS consultations on the database. Stakeholders reported that there was a lack of PMR supplier engagement during the development and prelaunch phase of the service. It is possible that a greater level of PMR supplier involvement could have reduced the impact of recording requirements on pharmacist workload. Stakeholders also reported that the database had had low uptake which could potentially be explained by the extra work that recording NMS consultations on PharmaBase created.

Pharmacist participants were critical of the suggested NMS consultation questions and reported that they often create their own consultation structure to make it seem more naturalistic (Chapter 4). However it was found that the wording of the consultations had been specifically chosen to make the service as similar as possible to the intervention research that the NMS was based on and involved a validated question to assess adherence (Chapter 3). The implication of this is that if the pharmacist does not use the adherence question as written, they may not gain a valid indication of patients' adherence to new medicines. However it could be argued that fidelity to the question framework used in the RCT is not important provided that the concepts are covered during the consultations. A precise measure of adherence is not necessary outside research so long as the questions asked by the pharmacist uncover problems patients may be experiencing with their new medicines and the service is able to meet its aim to improve adherence.

Another widely reported barrier to NMS implementation was the lack of GP support and engagement. Studies examining the implementation and provision of MURs and other pharmacy services had also identified lack of GP support and engagement as a barrier, suggesting that this is not a problem unique to the NMS or indeed English pharmacy services.[5-7,98-102] This barrier was identified as a potential problem prior to the introduction of the service, and the post-implementation study and stakeholder interviews confirmed that a lack of GP engagement and support for the service had affected the implementation of the NMS. This finding was supported by the analysis of PharmaBase records which found a very low rate of GP referrals into the service.

It would be desirable if there was wider communication between GPs and pharmacists generally for the benefit of patients, however the commercial environment in which pharmacists work is likely to be a barrier to this. In addition, each pharmacy dispenses prescriptions from a number of GP practices and patients from one practice will use many different pharmacies. Therefore it might be more beneficial if engagement with pharmacies happened at the CCG level rather than the individual practice level.

Professional pharmacy service provision in Australia may also offer some insights into how to improve GP engagement specifically with the NMS. It has been found that collaboration between GPs and pharmacists is minimal for all Australian professional pharmacy services except home medicine reviews.[101] A proposed reason for the increased GP engagement with home medicine reviews is that the service structure allows GPs to be remunerated for engaging with the service in addition to pharmacists receiving payment for conducting the consultations, and this allows the service to be sustainable.[100] An examination of the interactions between GPs and pharmacists relating to home medicine reviews found that the interactions were mainly administrative and suggested that additional remuneration for case discussions after the review would further improve GP engagement with the service.[100] Another factor cited as a possible reason for GP engagement with home medicine reviews is that the contribution of each professional to patient care is clearly set out in the service protocols.[100] These examples from Australia would suggest that GP engagement with the NMS in England may be improved if GPs received remuneration for referring patients into the service, and potentially for communicating with pharmacists regarding patients referred back to their prescriber. In addition, it may help if the NMS service protocol clearly describes the roles of GPs and pharmacists in the provision of the service.

8.3 Implications for policy, practice and research

8.3.1 Implications for policy

The results from the studies conducted as part of this project suggest that if pharmacy stakeholders had been engaged earlier in the development of the NMS, some barriers to service implementation and provision may have been avoided. The interviews with policy makers suggested that they had seen the electronic recording of NMS consultations as important as it would facilitate analysis of service data. However other studies suggested that the national database used to record the service had not had good uptake and that

pharmacists had experienced problems associated with that method of recording consultations, affecting the quality of data recorded (Chapters 5 and 7).

It is possible that had policy makers involved community pharmacists and PMR suppliers in the development process, some of these problems could have been avoided leading to better quality service data that could be used to evaluate the service. In future I would suggest that policy makers engage with pharmacy stakeholders during the development of new services to identify potential problems with the practical provision of new services and ensure they are addressed before the introduction of the services, and therefore avoid them acting as a barrier to service implementation. I would also recommend that when policy makers are developing the recording requirements for a service that they consider its impact on pharmacists' workload. In addition, with analysis of electronic service records seen by policy makers as an important way of assessing the success of a service, it would be beneficial if a method of extracting clinical service data from PMR systems was developed as this would mean that pharmacists would only need to record consultation data once on the PMR system, reducing workload, and policy makers would have access to clinical service records for analysis.

Both prior to and during NMS implementation, the payment structure was identified as a key barrier with the assumption underpinning the structure (that 0.5% of prescription items are eligible for the NMS) being found to be inaccurate (actual opportunity rate: 0.23% of prescription items). I would suggest that this should be addressed if the service is going to continue to be funded in the future. One option would be to change the payment structure to include the actual opportunity rate, allowing pharmacists to access the full funding available for the service. Alternatively, it would be possible for policy makers to expand the conditions included in the service (and therefore the number of opportunities to provide the NMS) without exceeding the funding allocated for the service.

Furthermore it would have been possible to gather information regarding the actual rate of opportunities to potentially provide the NMS during the service development process, reducing the likelihood of the payment structure hindering service implementation. Given the evidence that adequate remuneration is important to the success of a service, I would strongly recommend that policy makers base the payment structures for future services on robust evidence in order to prevent the structure negatively

affecting the implementation of new service. For example, using GP prescribing data to calculate the theoretical opportunity rate for the NMS would be more likely to provide accurate numbers of new medicines prescribed than using pharmacy PMRs.

One criticism levelled at stakeholders involved in the development and launch of the NMS by pharmacists and superintendent pharmacists was that the period between the announcement of the new service and its launch was very short and that some important details were not made available until very close to the start date for the service. It was suggested that this could have led to pharmacies not being prepared to provide the service immediately, affecting the uptake of the NMS. I would suggest that where possible policy makers should provide information in a timely manner and provide a timetable for the publication of service details so that pharmacies can plan their preparation for any new service accordingly.

The studies described in this thesis found a widespread lack of GP engagement with the service. Given that this is not a problem unique to the NMS but one experienced globally with pharmacy services, I believe that it is not enough to rely on individual pharmacists to engage GPs. I would suggest that policy makers need to encourage GPs to support pharmacy services by providing incentives to GPs, perhaps in the form of quality and outcomes framework (QOF) targets. I would also suggest that providing a formal route of communication between GPs and pharmacists would be helpful, perhaps by allowing pharmacists use NMSmail (an email service available to NHS staff).

8.3.2 Implications for practice

Participants from the stakeholder interviews and the pre- and post-implementation studies emphasised the growing importance of clinical services to pharmacy as a profession. This means that good pharmacist consultation skills are also becoming more important and some stakeholders and superintendent pharmacists reported that community pharmacists could benefit from further communication skills training. A study examining MUR consultations suggested that patient centred consultation training could improve the quality of MUR consultations, which could potentially improve the quality of other pharmacy consultations such as the NMS.[113] Health Education England (HEE) published practice standards for consultation skills in pharmacy practice in March 2014 and in partnership with pharmacy stakeholders has set up a website providing training and assessment tool for improving pharmacists' consultation skills (www.consultationskillsforpharmacy.com).[137]

Therefore I would recommend that pharmacists should use these tools to evaluate their consultations skills and where appropriate, undergo further training in patient centred consultation skills.

The growing importance of clinical services to the pharmacy business model also means that pharmacies should consider changing their characteristics in order to facilitate the provision of services. In the post-implementation study, participants suggested that being able to conduct consultations in the evenings and at weekends benefited NMS provision. Participants also reported a growing demand on consultation rooms. Therefore I would suggest that if pharmacies are to expand the number of clinical services they offer they should consider matching their opening hours to patient need, and building further consultation rooms to increase capacity for service provision where a pharmacy employs more than one pharmacist.

Participants in the pre- and post-implementation studies suggested that pharmacy support staff had the ability to facilitate service provision by engaging with the service and reducing pharmacists' workload, freeing them up to conduct consultations. Participants reported that support staff were more likely to engage with a new service if they had received training about it. Therefore I would recommend that pharmacy employers provide their non-pharmacist staff with protected training time in order to learn about new services, and ensure that there are adequate staffing levels for pharmacists to conduct consultations effectively.

Research has identified poor GP engagement with pharmacy services globally and the studies reported in this thesis found a widespread lack of GP engagement with the NMS.[5-7,198-102] Participants reported that GP engagement was better where good GP-pharmacist relationships already existed. Therefore I believe that pharmacists should pro-actively develop their relationships with local GP practices in order to improve GP engagement with all pharmacy services, not just the NMS. Establishing good local relationships will also help facilitate the implementation of future services.

8.3.3 Implications for research

Conducting this project has highlighted the lack of published information available regarding the development and negotiation of new pharmacy services due to the closed nature of service negotiations. This seems to have led to frustration that the evidence desired by policy makers is not always available. I believe that it is important that academic researchers should

work alongside policy makers, providing the information they need to make informed decisions regarding new services. The stakeholder interviews in this project provide some insight into what information policy makers need during service development and negotiations, however I believe that further research is necessary.

Policy makers participating in the stakeholder interviews stressed the importance of basing new services on robust evidence. In particular, they identified cost effectiveness information regarding interventions as being an important factor as to whether the intervention would be developing into a pharmacy service. Therefore I would recommend that economic evaluations should be incorporated into evaluations of interventions as a matter of course in order for policy makers to have robust evidence to base their decisions on.

There has been discussion in this thesis about whether pharmacists have the necessary consultations skills to provide NMS effectively by telephone. Community pharmacists reported that they already have the skills, which were developed through MUR provision; however stakeholders and some superintendent pharmacists suggested that the skills needed to provide MUR consultations may be different to the skills needed for NMS telephone consultations. I believe that this is an area that should be studied as this is the first pharmacy service that can be conducted by telephone and may open the way for more telephone based services to be introduced.

This project has also highlighted the ability of information technology (IT) to facilitate or hinder service provision. Whist there appears to be very little literature about how PMR systems can facilitate the provision of pharmacy services, an international study found that IT solutions are important to the provision of professional services and that a lack of IT solutions could threaten pharmacy's role in patient centred care.[117] As the presence of a NMS module in PMR systems appears to be an important facilitator to NMS implementation, perhaps further research in this area would be beneficial.

8.4 Strengths and limitations

8.4.1 Stakeholder Interviews
The number of participants in this study is low which could affect the generalisability of the results. However there was a limited pool from which to recruit participants due to the closed nature of the negotiations and limited

number of stakeholders involved with NMS implementation. Therefore a strength of this study is that participants were recruited from both parties engaged in the negotiations for the NMS as well as from each area of stakeholder involvement to ensure that the results gained would be as valid and reliable as possible.

8.4.2 Pre-implementation interviews and focus groups

The participants in this study agreed to take part by responding to invitations. They could reasonably be expected to have a greater awareness and interest in the service than the general pharmacist population as pharmacists with a low awareness or interest in the service might have been less likely to respond to the invitation to participate.

A strength of this study is that both community pharmacists and superintendent pharmacists participated, providing insight into the introduction of the NMS as experienced on the ground by pharmacists and also from the perspective of pharmacy employers. In addition participants were recruited from across the pharmacy sector giving a wide range of views and experiences of the pharmacy profession regarding the NMS. However the number of community pharmacists that participated in this study was limited by a low response rate and the short time between the announcement of the services and implementation (5 months). Likewise, the number of superintendent pharmacists that participated was also low, but represented around 23% of the UK pharmacy market.

One of the focus groups was conducted with community pharmacists recruited at a training day provided by their employer that included some training on the NMS. Due to the training received, awareness and understanding of the service were higher than in other focus groups but the views and experiences expressed were similar to those expressed in the other focus groups.

The participants were asked to comment on aspects of the service before the NMS had been implemented. The disadvantage of doing this was that the participants were less familiar with the service than they would have been had they been providing the NMS, however it was necessary to elicit their views at that stage in order to compare the findings with their experiences of conducting the NMS which were collected 4 to 6 months after the service had been implemented.

8.4.3 Post-implementation interviews and focus groups

Pharmacists and superintendent pharmacists who had previously taken part in a study exploring their views of the NMS prior to its implementation were invited to take part in this study. They could reasonably be expected to have a greater awareness and interest in the service than the general pharmacist population as they had already participated in one study regarding the NMS. The number of community pharmacists who participated in this study was limited by the number of pharmacists who had participated in the earlier study which had experienced a low response rate to invitations to participate. Due to some pharmacists not responding, additional participants were recruited through personal contacts.   Likewise, the number of superintendent pharmacists that participated was also low, although all superintendent pharmacists who participated in the pre-implementation study agreed to participate in the post-implementation study.   The superintendent pharmacists who participated represented around 23% of the UK pharmacy market.   A strength of the study is that participants were recruited from across the community pharmacy sector; however whilst a range of views were expressed, the exploratory nature of the study means that not all opinions about the service were expressed in the study. In addition both community pharmacists and superintendent pharmacists participated, providing different perspective of the introduction of the NMS.

8.4.4 Eligibility study

One limitation of this study is that just 8 pharmacies in Nottingham were sampled (out of a total of 97) so it is possible that the study pharmacies would not reflect pharmacies locally. However a strength of this study is that it endeavoured to reflect the distribution of all pharmacies in Nottingham when sampling pharmacies.   It was not possible to exactly match the distribution of pharmacies in Nottingham however, as there were just 2 pharmacies available in the <100m group that matched the inclusion criteria.

Another limitation of the study is that all the pharmacies sampled were located in Nottingham and belonged to the same large chain, so it is possible that the pharmacies did not represent community pharmacy nationally. In addition the study collected 1000 items per pharmacy over a maximum of 6 days so there is a possibility that the 1000 items collected from each pharmacy did not represent a typical week's prescription items for that pharmacy. However the pharmacies were selected to include a range of types

and locations across the Nottingham area and data collection was spread over five months in an attempt to minimise these effects.

In this study pharmacies were excluded if they dispensed less than 1000 items per week or if the pharmacy's staffing levels required more than one member of staff to take in and hand out prescriptions as this could have introduced potential selection bias. These demographic exclusions may reduce full generalizability and is a limitation of the study.

The pharmacies in this study were sampled over 5 months which could be a limitation as number and type of prescription items can vary over time, meaning that the data collected from an individual pharmacy may not reflect its long term dispensing patterns. However, by sampling pharmacies over 5 months the effect of seasonal prescribing patterns on the whole sample was reduced.

8.4.5 Analysis of PharmaBase records

This study examined national service data for one pharmacy chain as recorded using PharmaBase. Whilst using national data avoids geographical variation and provides a better picture of the national experience of NMS, using data from one pharmacy chain may mean that the results do not reflect data from across that pharmacy sector, particularly independent pharmacies.

The study was affected by the limitations of the PharmaBase data. There was evidence of input errors in the data, especially regarding the dates of registration, intervention and follow-up, and there was some evidence that in some cases the records were not complete. It is likely that these problems occurred partly due to limitation of the PharmBase system as a method of recording service data. PharmaBase was not designed to be a clinical record for the NMS and its use was not compulsory. Therefore using the PharmaBase system required pharmacists to record the service in at least two places; on the PMR as a clinical record, and on PharmaBase. It is likely that this increased the number of errors and omissions in the PharmaBase data.

Another limitation of the PharmaBase data, related to it not being a clinical record, is that the records were made using tick boxes or selecting predefined options to questions. Therefore the options for pharmacist to select were limited and may have led to some data not being recorded. For example the potential problems patients could be recorded as experiencing were limited

therefore there may have been additional problems identified during the NMS consultations that were not recorded using PharmaBase.

8.4.6 Reflections on my involvement in the qualitative studies

My background is that I am a UK qualified community pharmacist and have experience providing advanced services. Personally I am an advocate for community pharmacy services, believing that pharmacists are an under-utilised resource for the NHS and have the potential and clinical knowledge to make a greater contribution to patient care than is possible at present. My experience of being a community pharmacist and personal view of pharmacy services had the potential to introduce bias into the studies, as I may have been looking for results that reflect favourably on community pharmacy. All participants in the qualitative studies were made aware that I am a pharmacist as some participants already knew. In an effort to reduce the bias I could have introduced, the interview schedules and focus group topic guides used open questions and did not include leading questions (Appendices 1-3). In addition, my supervisors facilitated the focus groups while I made notes (all three supervisors of this project also have experience of practising as community pharmacists, although not during the lifetime of this project). When analysing the data a conscious effort was made to be objective and to derive themes directly from the data, and the coding was validated by a supervisor to reduce the likelihood of me introducing bias into the results. Whilst efforts were made to reduce the impact of my supervisors and my views on the findings of these studies, it is possible that further assessment of the plausibility of the results could have been gained by asking participants to review the interpretation of the data. However, this was not possible due to concerns regarding confidentiality and the funding body's concerns regarding commercial sensitivities.

8.5 Thesis conclusions

The NMS was developed from an intervention determined to be a cost effective way of improving adherence. When developing the service it was important to policy makers that it should be based on evidence, evaluated, and stay within a funding envelop without risk of overspend. The implementation of the NMS went well with rapid uptake of the service by pharmacies. There have been several facilitators of NMS implementation identified which include positive pharmacist attitudes towards the service, the service being a formalisation of current practice, the accreditation procedure, pressure to provide the NMS, the experience gained from providing MURs,

and certain pharmacy characteristics such as location, and characteristics of the service including the option for telephone consultations, as well as other pharmacy staff involvement. The barriers identified as affecting NMS implementation include a lack of GP engagement, the restrictions on eligible patients, pharmacist communication skills, increased pharmacist workload, and the payment structure. The problems associated with the payment structure stemmed mainly from the actual opportunity rate to provide the NMS being nearly half of the theoretical rate. Whilst the changes to the payment structure have reduced the importance of the opportunity rate, it is still based on the theoretical opportunity rate of 0.5% of prescription items and should be reviewed. During the consultations pharmacists provided information about the new medicine in two thirds of cases and provided healthy living advice in over a fifth of cases. Information and advice was not just provided to patients experiencing problems, pharmacists also counselled patients who were not reported to have any problems with their medicines. There was a significant decrease in recorded adherence related problems between the intervention and follow-up consultations that may indicate that the service has the potential to improve adherence.

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Appendix 1: Stakeholder Interview Schedule

Development and preparation

What was your role in the development of the NMS?

Could you describe to me how the service came about? What were the driving forces behind its development?

What did your organisation do to prepare for the introduction of the NMS?

Implementation of the NMS

How has the roll out of NMS gone?

   – What has gone well and what has gone less well?

What has the uptake of NMS been like?

   -   PharmaBase and non-PharmaBase

What feedback do you have regarding the numbers of eligible patients encountered?

How does the roll out of NMS compare to the implementation of MURs in 2005?

Payment structure

What are your views about the payment structure for the NMS?

Has the current payment structure affected the success of the NMS roll out? If so How?

Do you know what proportion of completed NMS' are reimbursed?

The Effect of NMS introduction

How has the introduction of the NMS affected you and your organisation?

Do you think the NMS has affected the role of the pharmacist, and the relationships between patients, GPs and pharmacists? How?

Has the introduction of the NMS affected other pharmacy activities/services? How?

Appendix 2: Pre-Implementation Focus Group Topic Guide

When and how did you first hear about the NMS?

What do you understand the NMS as being?

Will your pharmacy be offering this service from October 1st?

How do you think the NMS will affect the role of the pharmacist? What does the new service mean for pharmacists?

Training and Self-assessment

What training have you received/will you receive?

What (if any) training have your staff received/ will your staff receive?

Is there anything further that the management of your pharmacy could do to support you in preparation for the roll out of the NMS?

What do you think of the self-assessment requirement? How does it compare to the MUR accreditation?

Eligible conditions

Do you think the conditions chosen are appropriate for the service? Why?

Will the service provided vary between patients with different conditions? Why?

Do you foresee any problems with offering one service for several conditions?

If you had to choose two more conditions or medicine groups to include, what would they be?

Initiation

How will you identify eligible patients?

Are there any problems you foresee with the identification of patients?

How could these problems be addressed?

The service specification suggests that patients may be referred to the service by prescribers in both primary and secondary care. Do you see this happening? How? Why?

Intervention and follow-up

The second two parts of the service can be conducted either in face-to-face consultations, or by telephone. What would your preference be? Why?

The service requires pharmacists to refer patients back to their prescriber if there are problems that cannot be dealt with by them. How do you see this happening?

What do you think about the questions in the interview schedule?

Service paperwork

What do you think about the paperwork for the NMS?

How do you think pharmacists will fill it in?

Appendix 3: Pre-Implementation Superintendent Pharmacist Interview Schedule

Contractual Changes

When and how did you first hear about the NMS?

What will the NMS mean for you, your business and your patients?

How do you think the NMS will affect the role of the pharmacist, and the relationships between patients, GPs and pharmacists?

The last big contractual changes happened in 2005 with the introduction of MURs. How is the situation now with the introduction of the NMS compare to then?

How did the roll out of MURs in your pharmacies go? What went well? What could have gone better? What did you learn from that and how will you put that into practise for the roll out of NMS?

Payment Structure

What are your views about the payment structure for the NMS?

The payment for the NMS is very different from the payment for MURs, how do you think this will affect the roll out of the new service?

How do you think the payment structure will work in practise? For example, at what point during the service will payment be claimed for a patient receiving the NMS?

Preparation for the Roll Out

How has/is your company preparing for the roll out of the NMS?

What training have your pharmacists received/will your pharmacists receive?

Are the other members of pharmacy staff receiving training? How will they be involved in providing the service?

How did you develop the training? What resources did you use?

How are you supporting pharmacists in the self-assessment procedure?

Appendix 4: Post-Implementation Focus Group Topic Guide

Introduction:

Is your pharmacy offering the NMS?

The introduction of the service:

- Have you had any feedback from patients about the service? What have patients told you about the service? (Any anecdotes?)
- How has the implementation gone from your perspective? Have there been things that were easier than expected? Have there been things that were harder than expected?
- What feedback have the staff given you about the service and its implementation?

Has the introduction of the NMS affected your role in the pharmacy?

Do you think offering the NMS has affected any other services or activities you do?

Training:

Do you feel the training you received before the introduction of the service was adequate? Did it prepare you to provide the NMS?

Eligible Patients:

How many eligible patients does your pharmacy see in an average week? (patients who can be signed up i.e. not patient reps)

What is the most common condition in patients who receive the NMS?

Do you have a preference for any particular condition/medicine?

Carrying out the service:

How does your pharmacy identify patients?

Have you had any patients referred into the service from primary or secondary care?

When carrying out the intervention and follow-up, do you do more face-to-face or telephone conversations?

Have you experienced any difficulty with following up patients? How common is it?

Do you use the questions provided?

In your experience, how many patients have experienced problems?

Recording the service:

How do you record the consultations? Do you use a paper-based system or an IT program?

What do you like and dislike about the system you use?

Payment structure:

Do you know what band your pharmacy is reaching? (e.g. 20%)

Do you know how many complete NMS you are reimbursed for compared to the number you have carried out? (Do you know what percentage you are doing but not being paid for?)

What do you think about the payment structure?

It was developed to incentivise pharmacies; do you think it achieves this?

Appendix 5: Post-Implementation Superintendent Pharmacist Interview Schedule

Development and preparation

So when we last met we spoke about the build-up and preparation for the NMS. Briefly, how did your pharmacies prepare for the NMS?

Implementation of the NMS

How has the roll out of NMS gone?

  – What has gone well and what has gone less well?

  - What system do you use to record NMS? Why did you decide to use that system?

What has the uptake of NMS in your pharmacies been like?

What feedback do you have regarding the numbers of eligible patients encountered in your pharmacies?

How does the roll out of NMS compare to the implementation of MURs in 2005?

Payment structure

What are your views about the payment structure for the NMS?

Has the current payment structure affected the success of the NMS roll out? If so How?

Do you know what proportion of NMS' completed in your pharmacies are reimbursed?

The Effect of NMS introduction

How has the introduction of the NMS affected your business?

How has the introduction of the NMS affected your patients? Do you have any stories to illustrate that?

Do you think the NMS has affected the role of the pharmacist, and the relationships between patients, GPs and pharmacists? How?

Has the introduction of the NMS affected other pharmacy activities/services? How?

Appendix 6: A Table of the Complete List of all Medicines Registered for the NMS from the Analysis of PharmaBase Data.

Medicines	Frequency	Percent
Acarbose	20	0.02
Acebutolol	3	0.00
Acenocoumarol	12	0.01
Adipine	9	0.01
Aliskiren	9	0.01
Aminophylline	50	0.05
Amlodipine	13487	14.51
Amlodipine/Valsartan	12	0.01
Apidra	3	0.00
Aspirin	2500	2.69
Atenolol	1011	1.09
Atenolol/Nifedipine	1	0.00
Bambuterol	1	0.00
Beclometasone	5016	5.40
Beclometasone/Formoterol	815	0.88
Bendroflumethiazide	3106	3.34
Bisoprolol	4137	4.45
Budesonide	233	0.25
Budesonide/Formoterol	1561	1.68
Candesartan	1442	1.55
Captopril	2	0.00
Carvedilol	74	0.08
Celiprolol	3	0.00
Chlortalidone	116	0.12
Ciclesonide	24	0.03
Clonidine	29	0.03
Clopidogrel	2143	2.30
Co-tenidone	14	0.02
Cyclopenthiazide	1	0.00
Dabigatran	81	0.09
Diltiazem	605	0.65
Dipyridamole	161	0.17
Dipyridamole/Aspirin	17	0.02
Doxazosin	1891	2.03
Enalapril	214	0.23
Enalapril/Hydrochlorothiazide	3	0.00
Eprosartan	2	0.00
Exenatide	78	0.08
Felodipine	1264	1.36
Felodipine/Ramipril	4	0.00

Medicines	Frequency	Percent
Fluticasone	177	0.19
Fluticasone/Salmeterol	2630	2.83
Formoterol	105	0.11
Fosinopril	4	0.00
Glibenclamide	9	0.01
Gliclazide	1828	1.97
Glimepiride	186	0.20
Glipizide	20	0.02
HumaJect	2	0.00
Humalog	19	0.02
Humulin	75	0.08
Hydralazine	27	0.03
Indacaterol	57	0.06
Indapamide	3086	3.32
Indoramin	6	0.01
Insulatard	21	0.02
Insulin	18	0.02
Insuman	9	0.01
Ipratropium	373	0.40
Ipratropium/Salbutamol	4	0.00
Irbesartan	232	0.25
Irbesartan/Hydrochlorothiazide	14	0.02
Isradipine	1	0.00
Labetalol	77	0.08
Lacidipine	118	0.13
Lantus	76	0.08
Lercanidipine	739	0.79
Levemir	44	0.05
Linagliptin	85	0.09
Liraglutide	129	0.14
Lisinopril	3171	3.41
Lisinopril/Hydrochlorothiazide	56	0.06
Losartan	5167	5.56
Losartan/Hydrochlorothiazide	105	0.11
Metformin	4653	5.00
Metformin/Sitagliptin	34	0.04
Methyldopa	37	0.04
Metolazone	11	0.01
Metoprolol	87	0.09
Minoxidil	7	0.01
Mometasone	18	0.02
Montelukast	702	0.76
Moxonidine	114	0.12
Nadolol	2	0.00

Medicines	Frequency	Percent
Nateglinide	2	0.00
Nebivolol	117	0.13
Nedocromil	1	0.00
Nicardipine	2	0.00
Nifedipine	447	0.48
NovoMix	63	0.07
NovoRapid	55	0.06
Olmesartan	62	0.07
Olmesartan/Amlodipine	4	0.00
Olmesartan/Hydrochlorothiazide	5	0.01
Oxprenolol	2	0.00
Perindopril	925	0.99
Perindopril/Indapamide	10	0.01
Phenindione	1	0.00
Phenoxybenzamine	1	0.00
Pindolol	2	0.00
Pioglitazone	323	0.35
Pioglitazone/Metformin	9	0.01
Prasugrel	37	0.04
Prazosin	9	0.01
Propranolol	560	0.60
Quinapril	3	0.00
Ramipril	9578	10.30
Repaglinide	22	0.02
Rivaroxaban	29	0.03
Roflumilast	3	0.00
Salbutamol	8313	8.94
Salmeterol	757	0.81
Saxagliptin	273	0.29
Sildenafil	7	0.01
Sinthrome	4	0.00
Sitagliptin	1374	1.48
Sitagliptin/Metformin	16	0.02
Sitaxentan	2	0.00
Sodium cromoglicate	4	0.00
Tadalafil	5	0.01
Telmisartan	23	0.02
Telmisartan/Hydrochlorothiazide	2	0.00
Terazosin	21	0.02
Terbutaline	335	0.36
Theophyllin	46	0.05
Theophylline	39	0.04
Ticagrelor	6	0.01
Timolol	2	0.00

Medicines	Frequency	Percent
Tiotropium	2468	2.65
Tolbutamide	15	0.02
Trandolapril	1	0.00
Valsartan	96	0.10
Valsartan/Hydrochlorothiazide	7	0.01
Verapamil	131	0.14
Vildagliptin	30	0.03
Vildagliptin/Metformin	19	0.02
Warfarin	2195	2.36
Xipamide	5	0.01
Zafirlukast	17	0.02